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Terms of Reference

COMMONWEALTH OF AUSTRALIA

Australian Law Reform Commission Act 1996

National Health and Medical Research Act 1992

PROTECTION OF HUMAN GENETIC INFORMATION

1. We, DARYL WILLIAMS, Attorney-General of Australia, and MICHAEL WOOLDRIDGE, Minister for Health and Aged Care, having regard to—

- the rapid advances in human genetic technology; and
- the scientific and medical applications of human genetic information which are, or could be, of benefit to the Australian community; and
- ethical concerns in relation to the collection, storage and use of human genetic samples and information; and
- the potential for inappropriate use or application of human genetic samples and information; and
- evidence of, and the potential for, use of human genetic information by a number of sectors including employment; health, including medical research, pharmaceuticals and health administration; insurance and superannuation; intellectual property; and law enforcement; and
- emerging issues about the control of, ownership of, and intellectual property rights in relation to human genetic samples and information;

refer to the Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council for inquiry and report pursuant to subsection 20 (1) of the *Australian Law Reform Commission Act 1996* and paragraph 35 (3) (c) of the *National Health and Medical Research Act 1992* respectively, matters relating to —

- (a) whether, and to what extent, a regulatory framework is required—
 - (i) to protect the privacy of human genetic samples and information; and
 - (ii) to provide protection from inappropriate discriminatory use of human genetic samples and information; and
 - (iii) to reflect the balance of ethical considerations relevant to the collection and uses of human genetic samples and information in Australia; and
- (b) any related matter.

2. In performing their functions in relation to this reference, the Commission and the Australian Health Ethics Committee shall—

- (a) conduct this inquiry jointly; and
- (b) identify and consult with relevant stakeholders, including the Privacy Commissioner and the Human Rights and Equal Opportunity Commission, and ensure widespread public consultation; and
- (c) have regard to the following matters —
 - (i) the rapid advances in human genetic technology including progress of research towards the mapping of the human genome; and
 - (iv) the scientific and medical applications of human genetic information which are, or could be, of benefit to the Australian community; and
 - (v) evidence of, and the potential for, the inappropriate use or application of human genetic information; and
 - (vi) the range of Australian ethical opinion as to which, if any, uses and applications of human genetic information are ethically acceptable; and
 - (vii) the global dimensions of issues relating to research, regulation and the protection of interests; and
 - (viii) any relevant existing or proposed international law and obligations; and

- (ix) any relevant constitutional issues; and
- (x) any relevant existing or proposed Commonwealth legislation; and
- (xi) the implications of the recent decision by Australian health ministers to develop a national health information network; and
- (xii) developments in other jurisdictions, including legislative and other regulatory action; and
- (xiii) relevant research and discussion of human genetic information privacy and discrimination issues.

3. The Commission and the Australian Health Ethics Committee are to report to the Attorney-General and the Minister for Health and Aged Care by 30 June 2002.*

Dated 5 February 2001

Daryl Williams
ATTORNEY-GENERAL

Michael Wooldridge
MINISTER FOR HEALTH AND AGED CARE

* In his letter of 25 January 2002, the Attorney-General stated that he and the Minister for Health and Ageing, the Hon Kay Patterson agreed to extend the deadline for the final report under this reference to 31 March 2003.

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The Division of the ALRC constituted under the *Australian Law Reform Commission Act 1996* (Cth) for the purposes of this reference comprises the following:

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Australian Bone Marrow Donor Registry Inc	G013
Australian Centre for Intellectual Property in Agriculture	G081
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Australian Federation of Right to Life Association	G082
Australian Huntington's Disease Association (NSW) Inc	G054
Australian Huntington's Disease Association (Tas) Inc	G098
Australian Medical Association	G091
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Australian Nursing Federation	G080
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Committee of Deans of Australian Medical Schools	G077
Commonwealth Attorney-General's Department	G158
Commonwealth Department of Health and Ageing	G150
Confidential	G022CON
Confidential	G023CON

Confidential	G025CON
Confidential	G030CON
Confidential	G034CON
Confidential	G040CON
Confidential	G043CON
Confidential	G046CON
Confidential	G051CON
Confidential	G058CON
Confidential	G063CON
Confidential	G066CON
Confidential	G074CON
Confidential	G075CON
Confidential	G103CON
Confidential	G126CON
Confidential	G132CON
Confidential	G133CON
Confidential	G134CON
Confidential	G137CON
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Abbreviations

AACB	Australasian Association of Clinical Biochemists
AAL	Automatic Acceptance Limit
AAMRI	Association of Australian Medical Research Institutes
ABA	Australian Broadcasting Authority
ABI	Association of British Insurers
ACCC	Australian Consumer and Competition Commission
ACGT	Advisory Committee on Genetic Testing
ACIAR	Australian Centre for International Agricultural Research
ACT	Australian Capital Territory
ACTU	Australian Council of Trade Unions
ADF	Australian Defence Force
AFP	Australian Federal Police
AGSA	Association of Genetic Support of Australasia
AHDA	Australian Huntington's Disease Association
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
AIMS	Australian Institute of Medical Scientists
AIS	Androgen Insensitivity Syndrome
ALRC	Australian Law Reform Commission
AMA	Australian Medical Association
AMC	Australian Medical Council
ANZFA	Australia New Zealand Food Authority
ARC	Australian Research Council
ART	Artificial Reproductive Technology
ARTG	Australian Register of Therapeutic Goods
ASCLD	American Society of Crime Laboratories Directors
ASGC	Australasian Society of Genetic Counsellors
ASIC	Australian Securities and Investments Commission
ASM	Australian Society of Microbiology
ATSIC	Aboriginal and Torres Strait Islander Commission
ATSIC Act	<i>Aboriginal and Torres Strait Islander Commission Act 1989 (Cth)</i>
BMCC	Biotechnology Ministerial Coordinating Committee
BSA	<i>Broadcasting Services Act 1992 (Cth)</i>
CASA	Civil Aviation Safety Authority Australia
CBAC	Canadian Biotechnology Advisory Committee
CCA	Court of Criminal Appeal (NSW)
CCRC	Criminal Cases Review Commission (UK)
CD	Compact disc

CDAMS	Committee of Deans of Australian Medical Schools
CD-ROM	Compact disc — read only memory
CEDA	Committee for the Economic Development of Australia
CF	Cystic Fibrosis
CJD	Creutzfeldt-Jakob Disease
COAG	Council of Australian Governments
CODIS	Combined DNA Index System
CRC	Cooperative Research Centre
<i>Crimes Act</i>	<i>Crimes Act 1914</i> (Cth)
CSAA	<i>Child Support (Assessment) Act 1989</i> (Cth)
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DDA	<i>Disability Discrimination Act 1992</i> (Cth)
DDLS	Disability Discrimination Legal Service
DHA	Department of Health and Ageing
DHHS	Department of Health and Human Services
DI	disability income
DIMIA	Department of Immigration and Multicultural and Indigenous Affairs
DIY	Do-It-Yourself
DMD	Duchenne Muscular Dystrophy
DNA	Deoxyribonucleic acid
DP	Discussion Paper
DPP	Director of Public Prosecutions
EEOC	Equal Employment Opportunity Commission (USA)
EINSHAC	Einstein Institute for Science, Health and the Courts
ELSI	Ethical, legal and social implications
<i>Evidence Act</i>	<i>Evidence Act 1995</i> (Cth)
FAP	Familial Adenomatous Polyposis
FICS	Financial Industry Complaints Service
FL Regulations	<i>Family Law Regulations 1984</i> (Cth)
FLA	<i>Family Law Act 1975</i> (Cth)
FSANZ	Food Standards Australia New Zealand
FSRA	<i>Financial Services Reform Act 2001</i> (Cth)
FSS	Forensic Science Service
GAIC	Genetics and Insurance Committee (UK)
Gene CRC	Cooperative Research Centre for Discovery of Genes for Common Human Diseases
GM	Genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
GP	General Practitioner
GPA	Genetic Privacy Act
GTA	<i>Gene Technology Act 2000</i> (Cth)

GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTRAP	Gene and Related Therapies Research Advisory Panel
GTTAC	Gene Technology Technical Advisory Committee
HD	Huntington's disease
HGAC	Human Genetics Advisory Committee (UK)
HGC	Human Genetics Commission (UK)
HGCA	Human Genetics Commission of Australia
HGP	Human Genome Project
HGSA	Human Genetics Society of Australasia
HIV	Human Immunodeficiency Virus
HREC	Human Research Ethics Committee
HREOC	Human Rights and Equal Opportunity Commission
HREOC Act	<i>Human Rights and Equal Opportunity Commission Act 1984</i> (Cth)
HUGO	Human Genome Organisation
IAAust	Institute of Actuaries of Australia
IBC	Institutional Biosafety Committees
ICA	<i>Insurance Contracts Act 1984</i> (Cth)
IEC	International Electrotechnical Commission
IFSA	Investment and Financial Services Association
IGA	<i>Interactive Gambling Act 2001</i> (Cth)
IGCAHRD	Inter-Governmental Committee on AIDS, Hepatitis and Related Diseases
ILAC	International Laboratory Accreditation Cooperation
IP	Issues Paper
IPP	Information Privacy Principle
ISO	International Standard Organisation
ISP	Internet Service Provider
IVD	In-vitro diagnostic
LACNSW	Legal Aid Commission of NSW
LAWASIA	Law Association for Asia and the Pacific
LIA	<i>Life Insurance Act 1995</i> (Cth)
LIAC	Legal Information Access Centre
LISA	Life Investment and Superannuation Association
LR	likelihood ratio
LSHLG	Life Sciences High Level Group
MBS	Medical Benefits Scheme
MCCOC	Model Criminal Code Officers Committee
MOHLTC	Ministry of Health and Long-Term Care (Canada)
MOC	Medical Officer of the Commonwealth
MSAC	Medical Services Advisory Committee
NATA	National Association of Testing Authorities, Australia
NBAC	National Bioethics Advisory Commission (US)

NCEHR	National Council on Ethics in Human Research
NCIDD	National Criminal Investigation DNA Database
NGO	Non-Government Organisation
NHMRC	National Health and Medical Research Council
NHMRC Act	<i>National Health and Medical Research Council Act 1992</i> (Cth)
NHS	National Health Service
NIFS	National Institute of Forensic Science
NIH	National Institutes of Health (US)
NLRD	Notifiable Low Risk Dealing
NOHSC	National Occupational Health and Safety Commission
NPAAC	National Pathology Accreditation Advisory Council
NPP	National Privacy Principle
National Statement	NHMRC's <i>National Statement on Ethical Conduct in Research Involving Humans</i>
NSW ADB	Anti-Discrimination Board of New South Wales
NT	Northern Territory
NTA	<i>Native Title Act 1993</i> (Cth)
OECD	Organization for Economic Cooperation and Development
OFPC	Office of the Federal Privacy Commissioner
OGTR	Office of Gene Technology Regulator
OTA	Office of Technology Assessment (USA)
PACE	<i>Police and Criminal Evidence Act 1984</i> (UK)
PCR	Polymerase Chain Reaction
PID	Public Interest Determination
PIN	Personal Identification Number
PKU	Phenylketonuria
PMCI	Peter McCallum Cancer Institute
<i>Privacy Act</i>	<i>Privacy Act 1988</i> (Cth)
QCGS	Queensland Clinical Genetic Service
QIMR	Queensland Institute of Medical Research
RACGP	Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia
RDA	<i>Racial Discrimination Act 1975</i> (Cth)
REB	Research Ethics Board
REC	Research Ethics Committee
RGA	Reinsurance Group of America
RNA	Ribonucleic Acid
SA	South Australia
SACGT	Secretary's Advisory Committee on Genetic Testing
SCAG	Standing Committee of Attorneys-General
SDA	<i>Sex Discrimination Act 1984</i> (Cth)
SIDS	Sudden Infant Death Syndrome
SIFS	State Institute of Forensic Sciences

SNPs	Single nucleotide polymorphisms
STRs	Short tandem repeats
TB	Tuberculosis
TGA	Therapeutic Goods Administration
TOR	Terms of Reference
TPD	Total and permanent disablement insurance
UNESCO	United Nations Educational Scientific and Cultural Organisation
UNSW	University of New South Wales
UTS	University of Technology, Sydney
Vic	Victoria
WA	Western Australia
WHO	World Health Organisation
WRA	<i>Workplace Relations Act 1996</i> (Cth)

Executive Summary

Part A: Introduction

The terms of reference for this joint inquiry ('the Inquiry') direct the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) to consider, with respect to human genetic samples and information, how best to:

- protect privacy;
- protect against unfair discrimination; and
- ensure the highest ethical standards in research and practice.

The terms of reference note that this exercise is to be undertaken in such a way as to balance the benefits and potential benefits of scientific and medical applications of the new genetic science and technology with the ethical, legal and social implications of these emerging applications. The final report and recommendations will be presented to the Commonwealth Attorney-General and the Minister for Health and Ageing by 31 March 2003.

The specific drivers for the establishment of the Inquiry in February 2001 were concerns about privacy and discrimination, especially in the contexts of insurance and employment, and about ethical and other oversight of medical and scientific research, clinical practice, and the collection and use of genetic databases. These matters have been central to the process so far, although a number of further issues have been added after being identified or emphasised through submissions, consultations and research.

In November 2001, the Inquiry published an Issues Paper on the Protection of Human Genetic Information (ALRC Issues Paper 26, or 'IP 26'). The primary role of IP 26 was to provide sufficient background material to promote informed community discussion and debate about these new and important issues. To this end, IP 26 also posed a large number of questions to highlight the matters under consideration and to provide a focus for comment and submissions.

From the beginning, the Inquiry has recognised the need for public engagement and widespread consultation, involving the general community as well as experts and interest groups. Between the release of IP 26 and the publication of this Discussion Paper (ALRC Discussion Paper 66, or 'DP 66'), the Inquiry conducted

15 public forums around Australia, held well over 100 meetings with interested parties, and received 168 written submissions.

DP 66 takes on board the further and deeper research that the Inquiry has undertaken, as well as the benefits of the many meetings and submissions. Critically, this document replaces the many questions asked in IP 26 with a series of specific reform proposals (as well as some new, more targeted, questions), to which the community is invited to respond. It is very important to note that these proposals do *not* represent the final views or recommendations of the Inquiry, and are subject to revision — the final report and recommendations inevitably will be influenced by subsequent submissions, consultations and research.

In an earlier era, the centrepiece of any significant law reform effort often was the recommendation of a major new piece of legislation. However, in a more complex environment in which authority is much more diffused, modern law reform efforts are likely to involve a mix of strategies and approaches, including legislation and regulations; official standards and codes of practice (such as those promulgated by the National Health and Medical Research Council and the Privacy Commissioner); industry codes and best practice standards; education and training programs; better coordination of governmental and intergovernmental programs; and so on. Thus, the proposals contained in DP 66 are addressed to a range of parties and not merely to the Commonwealth Government.

All of the literature, and our consultations and submissions, emphasise the rapid development of genetic science and technology. The pace of change certainly will not slow in the foreseeable future. Our improving knowledge of genetics, combined with technical innovations (including the harnessing of information technology), will make human genetic information easier, quicker and cheaper to obtain, and increase the range of potential applications for its use. In such circumstances, there also may be increasing pressures on governments, employers, insurers and others to uncover and utilise genetic information about individuals with whom they interact.

The major challenge for the Inquiry is to find a sensible path that meets twin goals: to foster innovations in genetic research and practice that serve humanitarian ends and to provide sufficient reassurance to the community that such innovations will be subject to proper ethical scrutiny and legal control.

Careful consideration of the legal and policy issues thrown up by the use of genetic samples and information requires a wide range of interests to be balanced. Although relatively easy to articulate in the abstract, achieving the proper balance is difficult in practice, since various interests will compete and clash across the spectrum of activity. For example, employers may wish to discover and use genetic information since they must fulfil common law and statutory duties to provide a

healthy and safe work environment for their employees. Employers also have direct economic incentives to reduce insurance premiums and sick leave, and to guard against future lawsuits by employees whose genetic predisposition to an illness may have been triggered by environmental factors present in the workplace. At the same time, employees have a strong interest in preserving their privacy and being protected against unfair discrimination based on their genetic status.

The current methods of regulation and conflict resolution involve a patchwork of federal, state and territory laws; official guidelines; personal and professional ethics; institutional restraints; peer review and pressure; oversight by public funding authorities and professional associations; supervision by public regulatory and complaints-handling authorities; private interest; and market pressures.

The Inquiry believes its brief is to scrutinise the existing regimes, and then tailor them — if necessary and to the extent possible — to the particular needs and demands of genetic testing and information. Where appropriate, the Inquiry has proposed new forms of regulation to address any existing gaps. Successfully fulfilling this brief not only involves providing adequate protections against the *unlawful* use of genetic information, but also putting into place measures and strategies aimed at ensuring that where such information may be used lawfully, it is used properly, fairly and intelligently.

It may be the case that scientific and technological advances will be so rapid that some of the bases for our policy-making may be dated in a relatively short span of years. Chapter 2 seeks to address the ways in which the Inquiry's suggested reforms may have longevity in the context of rapid scientific change. One such mechanism is through the establishment of appropriate institutions that are charged with the responsibility of advising government on developments in human genetics, as they arise.

In Chapter 3, the Inquiry proposes the establishment of an independent, standing advisory body — the Human Genetics Commission of Australia (HGCA) — following the lead of the United Kingdom, the United States and Canada in this regard. The principal role of the HGCA would be to provide on-going, high-level technical advice to Australian governments about existing and emerging issues in human genetics, and the ethical, legal and social implications arising from these developments. The HGCA should have balanced and broad-based membership, with technical expertise and community representation.

The HGCA also would play a leadership role at the national level in promoting harmonisation of laws and practices; promoting public engagement and community and professional education; and developing policy statements and national guidelines in this area, in association with other governmental agencies or the relevant industries and organisations. For example, the Inquiry proposes that the

HGCA be assigned specific responsibility for approving specific genetic (and related) tests for use by the insurance industry for risk-rating purposes, or perhaps for use by employers where there are compelling occupational health and safety reasons to do so.

Part B: Genetic testing and genetic information

Part B presents important background information relating to genetic testing and genetic information. Chapter 4 describes the different categories of genetic testing, and considers who seeks genetic testing and for what purposes.

Genetic testing can be divided into two broad categories — health-related testing and identification testing. Medical genetic testing includes diagnostic testing; predictive or presymptomatic testing; carrier testing; population screening; pre-implantation and prenatal testing; and testing for medical and scientific research. Identification testing or forensic testing is performed on the non-coding or ‘junk’ portion of DNA, and is used in criminal investigations (to link a suspect to a crime scene, or to exclude them); to identify deceased or missing persons; and to determine parentage or other kinship relationships.

Chapter 5 focuses on regulating access to genetic testing. Access to genetic testing for health purposes is affected by a number of factors. These include the availability of particular genetic tests in Australia, the cost of testing (including coverage by Medicare and private health insurance), and the specified ‘request pathways’ — that is, the steps by which genetic testing services may be obtained from laboratories.

To date, medical practitioners have been the primary ‘gatekeepers’ of genetic testing and the information derived from it, at least for clinical purposes. Increasingly, however, there are other paths by which genetic testing may be accessed. These include direct access to testing services provided by laboratories and over-the-counter or home use genetic testing kits, including for parentage testing. The Inquiry proposes that these forms of ‘do-it-yourself’ genetic testing should be regulated by the Therapeutic Goods Administration, with advice from the HGCA.

Given the emphasis throughout DP 66 on the need for informed consent to genetic testing and the availability of appropriate pre-test and post-test counselling and support, Chapter 5 proposes that laboratory accreditation requirements be developed to ensure that laboratories conduct genetic testing only on bodily samples collected with the appropriate consent of the individual to whom the sample relates, or as approved by a Human Research Ethics Committee (HREC) in some research situations.

Serious privacy and ethical concerns arise from non-consensual testing. A great deal of sensitive, personal information can be derived from genetic testing of a bodily sample, with important health, legal, and social implications for individuals, families and others. It is very easy for another party, such as an employer, private investigator or ‘celebrity trophy hunter’ to obtain a bodily sample (for example, small amounts of saliva, hair, blood, mucus or skin). As noted above, access to genetic testing is now readily and increasingly available.

Existing law provides very limited protection against non-consensual testing. The Inquiry has come to the tentative view that there should be additional legal protection against the unauthorised testing of genetic samples and, to this end, has proposed a new criminal offence. This offence would apply where any individual or corporation, without lawful authority, submits a sample for genetic testing, or conducts genetic testing on a sample, knowing (or recklessly indifferent to the fact) that the individual from whom the sample was taken did not consent to such testing. The UK Human Genetics Commission recently made a similar recommendation.

By definition, this offence would *not* apply to *authorised* non-consensual testing, such as where a law enforcement officer acts with statutory authority under forensic procedure laws, or where an HREC approves testing of a sample for research purposes under the relevant provisions of the National Statement.

Chapter 6 examines the nature of genetic information and some of the facts (and myths) about the implications that may be drawn from information about a person’s genetic status. One of the central matters for the Inquiry is whether to accept arguments in favour of ‘genetic exceptionalism’ — that is, the idea that genetic information is so fundamentally different from, and more powerful than, all other forms of personal health information that it requires different or higher levels of legal protection.

Arguments in favour of genetic exceptionalism tend to focus on the fact that human genetic information: (1) potentially contains large amounts of predictive information about health and well-being; (2) transcends the individual and has implications for family members; and (3) creates possibilities for unfair genetic discrimination, because the information may be misunderstood or misapplied, and because there is a history of genetics being used to stigmatise and victimise.

On the other hand, genetic ‘inclusivists’ argue that genetic information is neither distinctive nor unique in its ability to predict an individual’s health, but indicates only a rough range of probabilities. Information about lifestyle (smoker or non-smoker, skydiver or race car driver, miner or office worker) and non-genetic test results (for example, for hepatitis or HIV/AIDS) also provide important clues to present and future health, may be personally sensitive, and may have implications for family members.

The international experience appears to be that early attempts to regulate human genetic information reflected the exceptionalist approach; however, the recent trend has been to seek the middle ground. In this we agree. The Inquiry believes that an exceptionalist approach would divorce genetic information from the principles, processes and institutions that have been developed over time to provide ethical oversight of research, ensure best practice in clinical medicine, protect personal privacy, and prohibit unlawful discrimination.

However, the Inquiry does accept that there are some special features and issues attaching to genetic information, such that it is necessary to engage in a thorough inspection of existing principles, practices and safeguards, and of the legal, ethical and regulatory landscape, to ensure that all of these are adequate to the task.

Finally, Chapter 6 discusses the dangers of ‘genetic essentialism’ — a reductionist view of human beings as essentially consisting of their genes, with human worth describable in the language of genetics. The challenge for our society is to maintain its moral and ethical compass, supporting those aspects of genetic science that reduce pain and suffering and increase quality of life, while firmly resisting the use of this knowledge to diminish personal freedom and personal responsibility, or create new opportunities for unfair discrimination.

Part C: Regulatory Framework

Part C sets the scene for the detailed proposals in DP 66 by examining the existing regulatory framework in respect of privacy, discrimination and ethics; the general principles underlying each of these areas; and how each framework applies to the collection, use and protection of human genetic samples and information. While the discussion of privacy in Chapter 7 and discrimination in Chapter 8 is based largely around legal regulation, the discussion in Chapter 9 deals with the way ethics influences the various contexts in which human genetic samples and information are used.

Chapter 7 describes the existing privacy regime for the protection of personal information in Australia and the extent to which it offers protection for human genetic samples and information. This regime is principally founded on the *Privacy Act 1988* (Cth); the Information Privacy Principles (IPPs), which apply to the Commonwealth and ACT public sectors; and the National Privacy Principles (NPPs), which apply to the private sector. The chapter also examines other laws regulating the handling of personal and health information at the federal, state and territory levels. The Inquiry considers that strong efforts are needed to harmonise the various information and health privacy regimes.

While genetic samples hold a great deal of personal information that may be revealed by DNA testing and analysis, the samples themselves do not receive protection under the *Privacy Act*. Although this may represent something of a shift in the current focus of the *Privacy Act* on ‘information’ and ‘records’, the Inquiry proposes that the Act be extended to cover identifiable human genetic samples.

Chapter 8 describes the legal framework for preventing discrimination in Australia at the federal, state and territory levels, and includes a discussion of current developments in the international arena. The Inquiry considers the desirability of ‘stand alone’ legislation to address discrimination on the ground of genetic status, but concludes that working within the existing legal framework is more likely to promote certainty and consistency, and build upon existing understanding and practice.

The Inquiry proposes amending the existing definition of ‘disability’ in the *Disability Discrimination Act 1992* (Cth) expressly to cover unlawful discrimination based upon a person’s genetic status (or another’s perception of that status). In order to emphasise that genetic status does not necessarily equate with disability, the Inquiry also asks whether the name of the Act should be changed to the *Disability and Genetic Discrimination Act 1992*.

Chapter 9 discusses conventional approaches to ethics in the field of bioethics, and considers some alternatives. Submissions to the Inquiry generally did not support the establishment of a fixed set of moral standards to regulate the use of genetic information, but emphasised the need to cultivate a robust and inclusive culture of ethical discussion and debate. The Inquiry supports this approach and has attempted to reflect these principles throughout DP 66, including in relation to the structure and functions of the proposed HGCA (see Chapter 3). However, the Inquiry believes that attention to the ‘ethics of discussion’ supplements rather than supplants the fundamental ethical principles of autonomy, beneficence, non-maleficence, and justice set out in the ‘Georgetown mantra’.

Part D: Medical and other human research

Part D examines ethical, privacy and related issues concerning the use of genetic samples and information in the conduct of human genetic research. The adequacy or otherwise of the existing regulatory framework has been the subject of much comment in the course of this Inquiry to date. Chapter 10 summarises the present regulatory framework for the ethical conduct of research centred on the NHMRC’s National Statement and on review of research proposals by HRECs.

Human genetic research generates knowledge with the potential to improve dramatically the diagnosis, prevention and treatment of serious health and medical problems. Research also can reveal information about an individual’s susceptibility

to disease and hence about the individual's future health. The Inquiry aims to develop proposals that will enable human genetic research to be fostered while providing sufficient reassurance to the community that such research is subject to proper ethical scrutiny and legal control. Any reform proposals need to balance the interests of researchers — who need access to genetic samples and information from many sources — and the needs of individuals and their families — whose rights to autonomy and privacy must be respected.

The requirements for research institutions or HRECs to be registered with the NHMRC, or to follow the processes set down in the National Statement, are currently incomplete. In particular, there is no obligation upon wholly private research bodies to adhere to the provisions of the National Statement. The Inquiry considers that, in view of the increasing commercialisation of human genetic research, the mechanisms by which compliance with the National Statement is enforced need to be strengthened. Chapter 11 proposes that the *National Health and Medical Research Council Act 1992* (Cth) be amended to prohibit the conduct of human genetic research other than in compliance with the National Statement.

The concept of consent is fundamental to the legal and ethical regulation of medical and other human research and to the protection of privacy. The National Statement generally requires consent to the use of human tissue samples, genetic material and genetic information in medical research, other than in limited and defined circumstances. Submissions received by the Inquiry have raised concerns about various aspects of consent. In particular, it was questioned whether privacy is adequately protected by the current provisions which permit an HREC to waive consent requirements (in specified circumstances) when granting ethical approval for research proposals. A related issue is the extent to which researchers are able to obtain meaningful consent from research participants for the use of their genetic samples or information in relation to unspecified future research. Chapter 12 makes a number of proposals, and asks further questions, with the aim of enhancing the reporting of HREC waivers of consent and providing more guidance on consent requirements, through changes to the National Statement.

Based on extensive consultations with researchers and volunteers, the Inquiry believes that it may be useful for AHEC to augment the National Statement with model research protocols for human genetic research, as well as to provide guidance on the drafting of consent forms for use in human genetic research. The intention is to promote international best practice in the conduct of human genetic research, provide further guidance to researchers and HRECs, and achieve greater consistency across the nation. The possible content of these model or template documents is discussed in detail in Chapter 13. The Inquiry suggests that particular attention needs to be paid to transparent disclosure to research participants of the potential commercialisation of research outcomes and of any conflicts of interest.

Chapter 14 considers ways in which HREC oversight may be strengthened, including through more rigorous reporting requirements under the National Statement; on-going monitoring of approved research by HRECs; the review or accreditation of HRECs; and the ‘skilling-up’ of HRECs through changes to membership or providing additional training and resources to members.

Part E: Human Genetic Databases

Part E deals with the collection and storage of genetic samples. This encompasses the creation of human genetic databases specifically for use in research, as well as collections formed for other purposes that subsequently are found to have research uses. Some of the issues in this Part touch on the discussion in Chapter 7 concerning the Inquiry’s proposal to extend the *Privacy Act* to cover genetic samples — since collections of this kind illustrate the overlap between genetic samples and genetic information.

Chapter 15 discusses the creation and use of human genetic research databases. Databases of this kind are used to study genetic links to disease, often by relating genetic samples to information about the medical history, family pedigree and environment of the individuals from whom they were taken. This allows researchers to examine the interaction of these factors on genetic mutations and disease.

Chapter 15 examines the privacy and consent issues that arise in relation to such research databases. These problems are distinct because of the links the databases make between genetic samples and information. Protection of genetic samples and information held on research databases may be problematic under the present legal framework because different aspects of the handling of samples and information are covered by different legal regimes — in particular, information and health privacy legislation and the Human Tissue Acts.

Chapter 15 also outlines the patchwork of legal and ethical regulation that applies to human genetic research databases, and highlights the need for harmonisation. The Inquiry considers the licensing or registration of human genetic research databases. The use of a ‘gene trustee’ system to address issues of privacy and consent to the research use of samples and information is also discussed.

Chapter 16 discusses the collection, storage, use and disclosure of, and access to, genetic samples and information held in tissue collections maintained by hospitals and pathology laboratories. Samples and information held in these collections have usually been obtained in the course of clinical medical treatment, and include pathology samples and neonatal Guthrie test cards.

These collections differ from human genetic research databases because they are not originally created for use in research. However, access to these collections may be sought because of their immense value as a research tool. Samples and information held in collections also have potential uses in parentage and kinship testing, forensic and police investigations and as evidence in court proceedings. These secondary uses raise important issues of consent and privacy.

Following a review of the regulatory frameworks governing the collection, storage, use and disclosure of, and access to these samples and information, the Inquiry concludes that there is a clear need for nationally consistent policies and practices in relation to human tissue collections, including Guthrie cards.

In Chapter 17, the Inquiry considers other legal mechanisms for regulating the collection, storage, disclosure and use of, and access to genetic samples through the law of property or the extension of the state and territory Human Tissue Acts. Human bodies and body parts, including genetic samples, are subject to very limited property rights. These rights are confined generally to the possession of genetic samples after they have been preserved. The chapter outlines the common law on which these limited rights are based and provides an overview of the current state of the law.

The Inquiry considers whether privacy interests in genetic information might be protected more effectively by recognising increased property rights over genetic samples. However, the Inquiry's view at this time is that there should be no change to the current position whereby hospitals and pathology laboratories have a right to possession of preserved samples but full property rights in genetic samples are not recognised.

Each Australian State and Territory has enacted human tissue legislation that regulates the donation of human tissues and organs for transplantation and research. In IP 26, the Inquiry asked whether amending the various Acts to cover the collection, storage, use and access to genetic samples would be an effective means of protecting privacy interests. Chapter 17 considers the benefits and disadvantages of amending these Acts and concludes that privacy would be better protected through amendments to privacy legislation, as proposed in Chapter 7.

Part F: Health services

Part F focuses on systemic issues of privacy and ethical practice related to the provision of medical and allied health services by doctors, genetic counsellors and other health professionals.

Historically, confidentiality has been a cornerstone of the doctor-patient relationship. However, genetic information about an individual may have important health implications for that person's genetic relatives. Chapter 18 focuses on questions about how individual patients and their doctors (and other health professionals, including genetic counsellors) should collect and deal with genetic information about genetic relatives, derived in the course of diagnosis, treatment or counselling.

The Inquiry considers that there may be exceptional circumstances in which health professionals should be permitted to disclose personal genetic information to blood relatives without the consent of their patient. Consequently, the Inquiry proposes amending the *Privacy Act* to authorise such disclosures in circumstances where the genetic risk is not necessarily 'imminent' (which is the current language of the Act), but failure to disclose could place the genetic relative at significant risk of serious illness or death.

The collection and disclosure of family genetic information, and rights of access to such information, are central to the operation of genetic registers and to the conduct of genetic counselling. The primary purpose of genetic registers is to provide an effective means of identifying and contacting members of families who are at significantly increased risk of developing an inherited disorder or of passing on a disorder to their children. The information on a genetic register generally will comprise genetic information about many genetically related people and also may contain tissue samples. Chapter 19 deals with general questions about the operation of genetic registers and, in particular, whether the existing privacy protection framework is adequate.

Medical practitioners have already received an authorisation from the federal Privacy Commissioner to collect family medical history information for clinical purposes without breaching the *Privacy Act*. The Inquiry proposes that organisations operating family cancer registers and other similar public health-oriented genetic registers also should continue to be able to collect family medical history information without breaching privacy legislation.

When individuals receive genetic test information it may have profound medical and psychological implications for them and their families. These implications will depend on the nature and context of genetic testing — the genetic condition being tested for and the reasons for testing. The results and implications often will be complex and difficult to comprehend, and it is therefore important that individuals are provided with sufficient information and, where appropriate, provided with genetic counselling and on-going support.

Chapter 20 discusses the nature and importance of genetic counselling, the need for genetic counselling services, and issues related to the further development of genetic counselling as a recognised allied health profession. This chapter also examines the need for enhanced education and training of medical students and practitioners in clinical genetics, genetic counselling and related ethical issues. The Inquiry proposes that all Australian governments cooperate in developing strategies to increase significantly the availability of genetic counselling services.

The Inquiry also proposes that the HGCA develop genetic testing and counselling practice guidelines to identify categories of ‘sensitive’ genetic tests that require special treatment in relation to restrictions on request pathways, or ensuring access to adequate pre-test and post-test counselling.

Population screening involves genetic testing of large groups of people to detect genetic conditions or the incidence of certain genetic mutations that run within populations. In Chapter 21, the Inquiry notes the concerns that sometimes arise in this area with respect to the privacy of test results; consent to be screened (especially where this involves children); the provision of genetic counselling; the cost to the health care system of large-scale screening; the effect on persons who wish to assert their ‘right not to know’; and the implications of testing for subsequent applications for mutually rated insurance. This chapter also examines issues in relation to the research use of genetic samples and information that are collected as part of population screening programs.

This is another area in which the Inquiry believes there is a need to develop nationally consistent policies and practices. The Inquiry proposes such an effort in relation to the implementation and conduct of population screening programs, with particular attention to issues of approval for initiation, consent, privacy protection, and the provision of pre-test and post-test counselling and support.

Part G: Insurance

Many submissions raised concerns about the use of genetic information in insurance, and expressed fears about the creation of a ‘genetic underclass’ of people who may be unable to obtain insurance coverage and related benefits.

Other concerns included the impact on individual and public health outcomes where people may feel deterred from undergoing recommended genetic testing for health purposes because of an apprehension that the information may later disadvantage them or their families in obtaining insurance. Insurers, on the other hand, noted the potential threat to the viability of the voluntary insurance market if applicants were no longer under an obligation to make full disclosure of all material information, and insurers were thus denied information needed to assess risk accurately. Other areas of concern raised in submissions related to the scientific reliability and actuarial relevance of genetic information.

The Inquiry has examined alternative models regarding the use of genetic information in underwriting personal insurance, such as those developed in some European countries. The Inquiry's preliminary view is that the evidence does not support a departure at this time from the fundamental principles that have long governed the voluntary mutually rated personal insurance market, namely, equality of information between the applicant and the insurer. Instead, the Inquiry has put forward a range of proposals that target a number of specific concerns. However, the Inquiry also proposes that the HGCA monitor developments overseas with a view to reviewing Australian insurance practices at a later stage.

Chapter 22 describes the framework for insurance in Australia, including the differences between various types of insurance products and, in particular, the difference between mutually rated and community rated insurance. Most concerns raised in submissions related to mutually rated insurance and the use made by insurers of genetic information to determine risk. The chapter describes the insurance cycle and the participants involved in assessing risk and making decisions about whether, and on what terms, to accept the risk.

Chapter 23 focuses on the use of genetic information in the insurance industry. The chapter examines the exchange of information between applicants for insurance and insurers; the type and amount of genetic information currently collected by insurers; and industry policy in this area, including the Genetics Testing Policy developed by the Investment and Financial Services Association (IFSA) — the peak body of life insurers.

Chapter 24 deals with the substance of the concerns raised in submissions. The proposals in this chapter proceed on the basis that parity of information between the applicant and the insurer is necessary in a voluntary mutually rated insurance market. Anti-discrimination legislation throughout Australia recognises that it is necessary for mutually rated insurance to differentiate between individuals on the basis of certain characteristics. The *Disability Discrimination Act 1992* (Cth), for example, includes a specific exception for discrimination in insurance where the discriminatory conduct is based on actuarial or statistical data, or is otherwise reasonable.

In this connection, the Inquiry makes a number of proposals aimed at promoting fair underwriting practices that will maintain public confidence in the use of genetic information by insurers. For example, the Inquiry proposes that the HGCA be assigned the role of approving the use of particular genetic tests in insurance underwriting; that insurers be obliged to provide comprehensive reasons in relation to unfavourable underwriting decisions based on genetic information; and that the review and appeal mechanisms available to applicants who have received an adverse industry decision be expanded and improved.

Chapter 25 examines the privacy protection afforded to genetic information in the insurance context. Insurers are now covered by the private sector provisions of the *Privacy Act 1988* (Cth) and are obliged to comply with the NPPs (or a customised industry code approved by the federal Privacy Commissioner) to the handling of all personal information they collect and hold. Although the insurance industry holds large quantities of sensitive personal information, including health information, submissions reflected a reasonable degree of satisfaction with the industry's practices in relation to information privacy.

One issue examined in Chapter 25 is the collection of family medical history information from applicants without the knowledge or consent of the genetic relatives to whom the information relates. The Inquiry proposes that the industry apply for a public interest determination under the *Privacy Act* to legitimate this practice. A second issue is the impact of various insurance industry practices on the nature and quality of the applicant's consent to provide genetic information in an application for insurance. The Inquiry proposes that insurers review their consent forms to ensure that applicants have sufficient information to give informed consent to the disclosure of their genetic information.

Part H: Employment

Part H deals with the use of genetic testing and information in the employment context. Chapter 26 discusses the types of genetic information that might be relevant in this context, and the legal and ethical issues involved in the use of such information. There is little evidence that Australian employers are currently seeking access to genetic information about job applicants or employees, although there is evidence of this overseas. Other forms of workplace testing (such as drug and alcohol testing) or testing of applicants (such as psychometric tests) which were unknown some years ago are now relatively commonplace. There is little doubt that the pressures to use genetic information will increase as the reliability and availability of genetic tests increases, and as the cost of testing decreases.

Chapter 27 describes the existing regulatory framework governing discrimination in employment and considers its application in relation to employers' requests for, or use of, genetic information. The Inquiry considers that there are sound reasons of public policy for intervening in the use of genetic information by employers. However, rather than supporting a complete prohibition on use, the Inquiry proposes that employers should be able to collect and use genetic information in relation to job applicants or employees only where this is reasonable and relevant within the terms of anti-discrimination and occupational health and safety legislation, and subject to the limitations set out in Chapters 28–30.

Chapter 28 sets out three main concerns regarding the existing anti-discrimination framework. The first concern is the scope of the ‘inherent requirements’ of the job exemption in the *Disability Discrimination Act 1992* (Cth) and other legislation. A number of submissions expressed the view that it would be unfair to use predictive genetic information to assess a person’s ability to perform his or her job requirements in the future, and to deny a person employment on that basis. The Inquiry proposes that this exemption should be clarified to ensure that employers are able to rely only on a person’s *current* ability to perform the inherent requirements of a job.

The second concern relates to the current absence of effective restraints upon the ability of employers to request genetic information from employees. After considering several options for reform, the Inquiry proposes a prohibition on requests for genetic testing and information, except where the employer can demonstrate that the information is reasonably required for a purpose that does not involve discrimination — such as to ensure that a person is able to perform the inherent requirements of the job. This places the onus on the employer to prove that the request for information is reasonable and relevant to the employment context.

The third concern relates to the need for independent oversight of the use of genetic testing and information by employers, to ensure that test results are interpreted accurately and that employers do not use genetic information inappropriately. The Inquiry proposes that the Human Rights and Equal Opportunity Commission (HREOC), in consultation with the proposed HGCA and other relevant stakeholders, develop Disability Standards to deal specifically with the collection and use of genetic information in employment.

Chapter 29 discusses employers’ duties regarding occupational health and safety and considers each of the ways in which genetic screening or monitoring could be used in this context. Briefly, employers might seek to conduct genetic testing to screen for work-related susceptibilities, to monitor workplace-induced conditions, or to screen for the purpose of protecting the safety of third parties.

Many submissions expressed strong concerns about the potential use of genetic screening programs by employers. In particular, a number of groups and individuals expressed anxiety that employers might use such screening to exclude ‘high risk’ individuals from the workplace to avoid facilitating their compliance with occupational health and safety duties — such as by taking all reasonably practicable steps to remove hazardous substances from the workplace. In this way, it was suggested, employers would seek to transfer their responsibility for workplace safety onto their employees.

The Inquiry is sensitive to these concerns but also recognises the potentially beneficial use of genetic information to protect employees against the onset of conditions to which they have a particular susceptibility, or for which they exhibit early signs of development. There is also a need to take steps to protect third parties from unreasonable risks to their health and safety, especially in areas involving inherent dangers, such as the aviation industry.

Accordingly, the Inquiry proposes that employers should be able to collect and use genetic information in limited circumstances where this is directly relevant to the discharge of their obligations to protect and promote the health and safety of their workers and third parties. To this end, the Inquiry also proposes that the National Occupational Health and Safety Commission (NOHSC), in consultation with the proposed HGCA, develop model regulations to govern this aspect of workplace genetic testing.

Chapter 30 identifies the existing privacy protections applying to genetic information obtained from job applicants and workers in the course of their employment, and notes the existence of the ‘employee records’ exemption in the *Privacy Act*. The Inquiry considers that there is no reasonable justification for the lack of protection currently provided for genetic information contained in employee records, and therefore proposes that the definition of ‘employee record’ be amended to exclude genetic information held by an employer in relation to a past or present employee.

Part I: Other contexts

Part I deals with the use of genetic information to determine biological parentage or other forms of kinship relations. This application of genetic information involves the creation of a DNA profile from the non-coding section of the DNA molecule found within a person’s bodily sample. The DNA profile is then compared with the profile of another person to determine their relatedness.

Chapter 31 discusses the use of DNA testing for the purpose of determining parentage or kinship. This may arise in a variety of contexts — most commonly in family law and child support proceedings, but also in relation to succession to estates, identification of missing persons or human remains, genealogical curiosity, and so on.

IP 26 contained a brief discussion of the use of DNA parentage testing in family law proceedings. Subsequently, the Inquiry received a number of submissions and representations from various support groups, laboratories conducting parentage testing, and private individuals — both in support of, and sharply critical of, aspects of the current regulatory framework and industry practice. Concerns focused on access to parentage testing; the provision of what is known as

‘motherless testing’; consent and decision-making in relation to testing (in particular on behalf of children); the provision of associated counselling and support; and the need to protect against fraudulent practices.

The Inquiry recognises the sensitivity of this area, and the need for greater regulation of DNA parentage testing in the public interest. The Inquiry believes that a number of these concerns should be addressed by the proposal that DNA parentage testing be conducted only by NATA-accredited laboratories, and in accordance with NATA accreditation requirements. The Inquiry also proposes that NATA should review its accreditation requirements to ensure that they meet the highest technical and ethical standards, particularly in relation to consent to testing, ensuring the integrity of the samples tested, and the provision of associated counselling.

In relation to consent, the Inquiry proposes that children over the age of 12 years should be permitted to make their own decisions in relation to participating in parentage testing, where they have sufficient maturity to do so. Where a child is under 12 years, or is over that age but lacks sufficient maturity, the Inquiry considers that all those with parental responsibility for the child should be required to consent on behalf of the child for testing to proceed. In those cases in which agreement cannot be reached, the dispute should be resolved by a court, taking into account the interests of all affected parties.

Chapter 32 considers the possible use of DNA parentage and other kinship testing in the context of establishing Aboriginal identity. While cultural identity is a social construct, and normally would be regarded as purely a personal matter, legal issues of Aboriginal and Torres Strait Islander identity already have arisen in a number of contexts.

While recognising the relevance of factors such as self-identification and acceptance by an Aboriginal community, Australian courts generally have required proof of Aboriginal ‘descent’ as a necessary basis for Aboriginal identity. The Inquiry discusses the advantages and disadvantages of this emphasis on descent, and proposes that the Aboriginal and Torres Strait Islander Commission (ATSIC) give formal consideration to the appropriate test or tests to be applied in Australian law for determining Aboriginal or Torres Strait Islander identity. To the extent that any such test might require evidence of descent, the Inquiry proposes that ATSIC should consider the appropriateness or otherwise of using genetic testing and information to establish such descent.

Chapter 33 deals with the current and potential uses of genetic testing and information by immigration authorities. The Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) currently accepts evidence of DNA parentage and other kinship testing as proof of family relationships in the context

of ‘family stream’ visa applications. The chapter also considers potential uses of genetic information in this context, for example, in relation to identification of asylum seekers, or as a component of the health test that is applied to persons who wish to migrate to Australia.

The Inquiry notes that the use of genetic testing in immigration is primarily regulated by internal policy guidelines, rather than legislation or regulations. These guidelines do not provide for counselling in relation to test results, which might disclose misattributed parentage or predictive health status. The Inquiry proposes that DIMIA review its policies and procedures regarding the provision of information to migration applicants about kinship testing. In addition, DIMIA should develop policies, in consultation with the HGCA, on the use of predictive genetic tests and information in relation to the health requirement.

Part J: Law Enforcement and Evidence

Part J deals with the use of genetic testing and information in criminal investigations, and in criminal and civil proceedings. DNA profiling is a major tool for Australian law enforcement authorities. Contrary to the practice of DNA testing in the clinical and research contexts, forensic testing is performed on non-coding or ‘junk’ DNA, with respect to a number of agreed sites on a chromosome, in order to construct a DNA profile for identification purposes. Such profiles are then used in criminal investigations, to exclude or to link a suspect to a crime scene, or to identify a missing person or human remains.

The Inquiry has endeavoured to confine its deliberations in this area to matters with privacy, discrimination or ethical implications, in keeping with its terms of reference. While the Inquiry has identified several other related issues and concerns, these are more appropriate for consideration by the recently established independent review into the operation of Part 1D of the *Crimes Act 1914* (Cth).

Chapter 34 discusses the current and potential uses of DNA profiling in criminal investigations and provides an overview of the regulatory framework for the forensic use of genetic information in Australia and overseas.

Chapter 35 discusses concerns arising from the lack of harmonisation between the forensic procedures legislation of the Commonwealth and each State and Territory. This chapter includes the Inquiry’s primary proposal in relation to Part J: the harmonisation of Australian forensic procedures legislation to promote both greater effectiveness and improved safeguards, particularly in relation to the collection, use, storage, destruction and index matching of forensic samples and the DNA profiles created from such samples.

Chapter 36 discusses specific issues arising from the regulatory framework for forensic procedures, in particular in relation to the operation of a national DNA database system for the storage and matching of DNA profiles, and the inter-jurisdictional sharing of information for criminal investigations. The Inquiry makes a number of proposals for reform — and, while each proposal focuses primarily on Part 1D of the *Crimes Act*, each should be read in light of the primary proposal to achieve harmonisation of forensic procedures legislation.

The Inquiry proposes that compulsory procedures (authorised by a senior officer or a court, depending upon the circumstances) should be the only means by which a forensic procedure may be carried out on a suspect or serious offender. This better reflects the inherently coercive nature of the procedures in these circumstances, and would remove potential arguments that consent given by a suspect or serious offender was not a valid informed consent. To ensure the preservation of crime scene material for the purpose of possible post-conviction review, the Inquiry proposes the permanent retention of forensic material found at crime scenes.

To promote public confidence in the integrity of police practices in this area, the Inquiry also proposes that forensic procedures legislation provide for ongoing independent monitoring of the operation of the national DNA database system as a whole, and in particular in relation to the forensic procedures regimes in each jurisdiction participating in the National Criminal Investigation DNA Database (NCIDD).

Chapter 37 discusses the use of DNA evidence in criminal proceedings. The Inquiry considers that there is a need for better education of those involved in criminal trials, and proposes the development of continuing judicial and legal education programs in relation to DNA evidence. In addition, the Inquiry proposes that a standard jury direction be developed and inserted into the *Evidence Act 1995* (Cth), regarding the need for caution in evaluating DNA evidence and the statistical calculations relating to that evidence.

Chapter 38 discusses a number of forms of post-conviction review that involve the use of DNA evidence or other genetic information. The Inquiry proposes that the Commonwealth establish a body to consider applications for post-conviction reviews based on DNA evidence, where a person convicted of a criminal offence can provide *prima facie* evidence that there is a reasonable possibility that a miscarriage of justice has occurred.

Chapter 39 considers the potential use of genetic evidence in civil proceedings, and the potential use of genetic information in the context of workers' compensation claims and common law actions for work-related injuries. In keeping with the proposal made in respect of the participants in criminal proceedings, the Inquiry also proposes the development of continuing judicial and legal education programs in relation to the use of DNA evidence in civil proceedings.

List of Proposals and Questions

3. A Standing Advisory Body on Human Genetics

Proposal 3-1. A Human Genetics Commission of Australia (HGCA) should be established under federal legislation as an independent, stand-alone, statutory authority with sufficient resources to fulfil its mission.

Proposal 3-2. As a general matter, the role of the HGCA should be to provide:

- on-going, high-level technical advice to Australian governments about existing and emerging issues in human genetics;
- similar high-level advice on the ethical, legal and social implications arising from these developments;
- national leadership in managing the process of change, including engagement of the public on these issues;
- direct expertise and a consultative mechanism for the development of policy statements and national guidelines in this area, where appropriate in association with other governmental agencies or the relevant industries and organisations;
- assistance with the development of community, school, university and professional education about human genetics; and
- a focus for the coordination and integration of various national — and perhaps regional and international — programs and initiatives.

Proposal 3-3. The HGCA also should have specific responsibility for:

- identifying genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment — such as through restricted clinical request pathways or through the assignment of a higher risk classification by the Therapeutic Goods Administration;
- approving specific genetic tests for use by the insurance industry for risk-rating purposes, or by employers for compelling occupational health and safety reasons; and

- performing any similar function or providing expert advice on any other matters relating to human genetics, upon the request of the responsible minister or ministers.

Proposal 3-4. The HGCA structure should involve at least two principal committees: (a) a Technical Committee, and (b) an Ethical, Legal and Social Implications Committee.

Proposal 3-5. Appointments to the HGCA should ensure a balanced and broad-based range of expertise, experiences and perspectives relevant to the use and protection of human genetic information. The appointments process should involve consultation with appropriate communities and stakeholders.

Proposal 3-6. As a general rule, meetings of the HGCA and its committees should be open to the public.

Proposal 3-7. The HGCA should liaise closely with other relevant governmental departments, authorities and entities (such as the NMHRC and its committees, state and territory departments of health, the TGA, the OGTR, and AHMAC) to promote a national approach to the protection of human genetic information.

5. Regulating Access to Genetic Testing

Question 5-1. Should legislation be enacted to require laboratories that conduct genetic testing to be accredited by the National Association of Testing Authorities, Australia (NATA) and to comply with accreditation standards in respect of all genetic testing?

Question 5-2. Should genetic test results be admissible as evidence in court proceedings only where the testing is conducted by (a) an accredited Australian laboratory in accordance with the relevant accreditation standards, or (b) an overseas laboratory that complies with equivalent standards?

Proposal 5-1. The National Pathology Accreditation Advisory Council (NPAAC), in consultation with NATA and the Royal College of Pathologists of Australasia (RCPA), should consider whether accreditation standards should ensure that laboratories conduct genetic testing only on bodily samples collected with the appropriate consent of the individual to whom the sample relates or as approved by a Human Research Ethics Committee (HREC).

Proposal 5–2. The *Therapeutic Goods Act 1989* (Cth) and *Therapeutic Goods Regulations 1990* (Cth) should be amended to enable the Therapeutic Goods Administration (TGA) to regulate home use genetic in vitro diagnostic devices (IVDs) and home use DNA identification test kits, including for parentage testing.

Proposal 5–3. The proposed HGCA should be responsible for developing codes of practice and other advice on home use genetic testing, including advice to the TGA on the regulation of genetic home use IVDs under the *Therapeutic Goods Act 1989* (Cth).

Question 5–3. Should legislation be enacted to prohibit Internet advertising of home use genetic testing unless approved by the TGA?

Proposal 5–4. The Standing Committee of Attorneys-General should initiate the development of a model criminal offence relating to non-consensual genetic testing, for enactment into Commonwealth, state and territory law.

Proposal 5–5. Criminal liability should attach to any individual or corporation that, without lawful authority, submits a sample for genetic testing, or conducts genetic testing on a sample, knowing (or recklessly indifferent to the fact) that the individual from whom the sample has been taken did not consent to such testing.

7. Information and Health Privacy Law

Proposal 7–1. As a matter of high priority, Commonwealth, state and territory governments should pursue the harmonisation of information and health privacy legislation as it relates to human genetic information. This would be achieved most effectively by developing nationally consistent rules for handling all health information.

Proposal 7–2. The *Privacy Act 1988* (Cth) should be amended expressly to: (a) define personal information to include bodily samples from an individual whose identity is apparent or can reasonably be ascertained from the sample; and (b) define a ‘record’ to include a bodily sample.

Question 7–1. Does the *Privacy and Personal Information Protection Act 1998* (NSW) provide an appropriate model for amending the *Privacy Act* to include bodily samples within the definition of personal information?

Question 7–2. What are the implications of Proposal 7–2 for the operation of the existing audit, investigation, complaints handling and enforcement provisions of the *Privacy Act*?

Question 7–3. If the *Privacy Act* were amended to cover genetic samples, what problems, if any, might arise in the relationship between that Act and other laws relating to bodily samples, such as the Human Tissue Acts?

Question 7–4. Should genetic samples obtained in Australia be exported only to jurisdictions whose laws provide protections equivalent to that of the *Privacy Act* and the NHMRC’s National Statement on Ethical Conduct in Research Involving Humans?

Question 7–5. Is NPP 9 of the *Privacy Act* an appropriate model for regulating the export of genetic samples?

Question 7–6. Does the *Privacy Act* adequately deal with issues that may arise in relation to the genetic samples and information of deceased individuals?

Proposal 7–3. The *Privacy Act* should be amended to clarify that ‘health information’ includes genetic information, whether or not the information is collected in relation to the health of, or the provision of a health service to, an individual.

Proposal 7–4. The *Privacy Act* should be amended to ensure that all small business operators that hold genetic information are subject to the provisions of the Act.

8. Anti-Discrimination Law

Proposal 8–1. Discrimination on the ground of genetic status should continue to be dealt with under the framework of existing federal, state and territory anti-discrimination laws, subject to the specific proposals for legislative amendments identified in this Discussion Paper.

Question 8–1. Should the name of the *Disability Discrimination Act 1992* (Cth) (DDA) be amended to the *Disability and Genetic Discrimination Act 1992* (Cth)? Should the objects of the DDA be amended to clarify that discrimination on the basis of genetic status falls within the Act?

Proposal 8–2. Federal anti-discrimination legislation should be amended to:

- define ‘disability’ in the DDA and define ‘impairment’ in the regulations made under the *Human Rights and Equal Opportunity Commission Act 1986* (Cth) (HREOC Act) to clarify the application of the legislation to discrimination based on genetic status;

- define ‘impairment’ in the regulations made under the HREOC Act to clarify the application of the legislation to a disability that may exist in the future;
- insert a definition of ‘disability’ in the *Workplace Relations Act 1996* (Cth) to conform with federal anti-discrimination legislation, as amended by these proposals.

Proposal 8–3. The States and Territories also should consider amending their anti-discrimination legislation to accord with the policies reflected in Proposal 8–2.

Question 8–2. What form of words should be used in federal anti-discrimination laws to ensure that they apply to discrimination based on genetic status?

Question 8–3. Should discrimination on the ground of a medical record be added to the DDA and other relevant legislation as a prohibited basis of discrimination?

Proposal 8–4. The regulations made under the HREOC Act should be amended expressly to include discrimination on the basis of association with a person who has an impairment or disability.

11. Enforcing Compliance with the National Statement

Proposal 11–1. The *National Health and Medical Research Council Act 1992* (Cth) should be amended to prohibit the conduct of any human genetic research, other than in compliance with the NHMRC’s National Statement on Ethical Conduct in Research Involving Humans (the National Statement).

Question 11–1. How should ‘human genetic research’, or a similar term, be defined for the purposes of the NHMRC Act?

Question 11–2. What sanctions should apply to non-compliance with the National Statement and to whom should the sanctions be directed?

12. Human Genetic Research and Consent

Proposal 12–1. HRECs should be required to report annually to AHEC with respect to human genetic research proposals for which waiver of consent has been granted under the National Statement.

Question 12–1. What sort of information should be contained in HREC reports to AHEC on waiver of consent?

Question 12–2. Are any changes needed to: (a) the National Statement; or (b) the s 95 or s 95A Guidelines under the *Privacy Act*, in relation to waiver of consent by HRECs to the collection, use or disclosure of genetic samples or information for research purposes?

Proposal 12–2. The proposed new chapter of the National Statement dealing with human genetic research databases (see Proposal 15–1) should provide guidelines dealing specifically with obtaining consent to unspecified future research.

13. Encouraging Best Practice in Human Genetic Research

Proposal 13–1. AHEC should develop model research protocols for human genetic research to provide guidance to HRECs, researchers, and research participants about best practice in the conduct of human genetic research. These protocols should include guidance on:

- the mechanisms for coding or de-identifying genetic samples and information used in research, and the relative advantages and disadvantages of each approach in different research contexts;
- the use of independent intermediaries to hold codes linking genetic samples or information with the identifiers;
- the discharge of legal and ethical obligations to inform research participants about the health implications of testing of their genetic samples; and
- full disclosure by researchers to research participants of information about actual or anticipated commercial arrangements connected with human genetic research proposals.

Proposal 13–2. AHEC should develop guidelines for preparing consent forms for human genetic research, covering such matters as:

- graduated consent options;
- full disclosure by researchers about actual or anticipated commercial arrangements;
- ownership or property interests in genetic samples or information;
- methods of protecting privacy; and
- withdrawal of consent by participants.

14. Strengthening Review by HRECs

Question 14–1. Are any changes needed to the reporting obligations of HRECs under the National Statement in order to enhance the operation of the current system of ethical review?

Question 14–2. Should HRECs be required to report to AHEC specifically on commercial arrangements relating to human genetic research proposals?

Question 14–3. Are the current minimum monitoring requirements adequate for human genetic research projects? Are there certain categories of human genetic research that require more active scrutiny by HRECs? If so, what changes should be made to the National Statement?

Question 14–4. How else might the role of HRECs in ethical review be strengthened? For example, should HRECs be accredited or should there be changes to their structure, composition or resourcing?

15. Human Genetic Databases for Research

Proposal 15–1. The National Statement should be amended to include a new chapter providing ethical guidance on the operation of human genetic research databases.

Question 15–1. Should human genetic research databases be subject to a licensing or registration scheme? If so:

- would a licensing or registration scheme be preferable?
- how should human genetic research databases be defined for the purposes of licensing or registration?
- what conditions should attach to licensing or registration?
- what form of independent scrutiny of database operations should be involved?

Question 15–2. Should the proposed HGCA have any role in the regulation of human genetic research databases?

Question 15–3. Should the use of a gene trustee or other independent intermediary be a condition of the licensing or registration of human genetic research databases?

Question 15–4. Do we need legislation governing the disclosure, for law enforcement purposes, of genetic samples and information held in human genetic research databases?

16. Human Tissue Collections

Question 16–1. Do we need legislation governing the disclosure, for law enforcement purposes, of the genetic samples or information held on Guthrie cards?

Proposal 16–1. The Australian Health Ministers' Advisory Council, in collaboration with key professional bodies, should develop nationally consistent policies and practices in relation to the collection, storage, use of and access to pathology samples, banked tissue, Guthrie cards and other samples collected and stored as part of a population genetic screening program.

17. Ownership of Human Genetic Samples

Proposal 17–1. The common law right to possession of preserved samples, which is currently enjoyed by hospitals and others, should continue to be upheld, but full property rights in genetic samples should not be granted.

Proposal 17–2. The Human Tissue Acts should not be used as the vehicle for regulating collection, storage, access to, or use of genetic samples, whether for the purposes of human genetic research or otherwise.

18. Health Professionals and Family Genetic Information

Proposal 18–1. NPP 2.1(e)(i) of the *Privacy Act* should be amended so that disclosure of genetic information by a health professional to the genetic relatives of a patient is permitted where failure to disclose would place the health or life of a genetic relative at serious risk.

Proposal 18–2. State and territory governments should consider amending their privacy legislation in accordance with Proposal 18–1.

Proposal 18–3. The NHMRC should develop guidelines for health professionals pursuant to s 7 of the NHMRC Act dealing with disclosure of genetic information to the genetic relatives of their patients. These guidelines should address the circumstances in which disclosure to genetic relatives is ethically justified or required, and the need for patients to be counselled about the disclosure of information in these circumstances.

Proposal 18–4. The guidelines referred to in Proposal 18–3 also should assist health professionals in dealing with requests for access to genetic information by the genetic relatives of their patients.

19. Genetic Registers and Family Genetic Information

Proposal 19–1. An organisation operating a genetic register for public health purposes should seek a Public Interest Determination (PID) under the *Privacy Act* to ensure that it can continue to collect family medical history information without breaching the NPPs.

Proposal 19–2. State and territory governments should consider amending their privacy regulation in accordance with Proposal 19–1.

Question 19–1. Should the proposed PID referred to in Proposal 19–1 also apply to the collection of health information from other health professionals for the purpose of verifying information provided by the registrant?

Question 19–2. Do the requirements for the de-identification of information on genetic registers contained in the NHMRC Guidelines for Genetic Registers cause problems for the effective operation of genetic registers? If so, how should these Guidelines be modified?

Question 19–3. Should the proposed PID referred to in Proposal 19–1 also apply to the use or disclosure of health information recorded on genetic registers?

20. Genetic Counselling and Medical Education

Proposal 20–1. As a matter of priority, Commonwealth, state and territory governments should develop strategies to assess and respond to the need for more genetic counselling services throughout Australia.

Proposal 20–2. Commonwealth, state and territory governments should examine options for the further development of genetic counselling as a recognised health profession, including the possibility of a registration system for certified genetic counsellors.

Proposal 20–3 The proposed HGCA should develop genetic testing and counselling practice guidelines, in consultation with the Human Genetics Society of Australasia, state clinical genetics services, and other interested organisations. These guidelines should identify genetic tests, or categories of genetic tests, that require special treatment in relation to procedures for ordering testing and ensuring access to genetic counselling. (See Proposal 3–3).

Proposal 20–4. The Australian Medical Council and the Committee of Deans of Australian Medical Schools should pursue measures to enhance medical school programs in clinical genetics, genetic counselling and related ethical issues.

Proposal 20–5. The Australian Medical Council and the Committee of Presidents of Medical Colleges should pursue measures to enhance postgraduate training and continuing professional development programs for medical practitioners, whether general practitioners or specialists.

Proposal 20–6. The proposed HGCA should play a role in working with the relevant groups to design and enhance education and training programs aimed at improving genetic health services provided by medical practitioners and other health professionals. (See Proposal 3–2).

21. Population Genetic Screening

Question 21–1. Should tests used in population genetic screening programs be required to meet an agreed standard for reliability, sensitivity and utility? If so, should the proposed HGCA play a role in such regulation?

Proposal 21–1. The Australian Health Ministers' Advisory Council, in collaboration with the proposed HGCA and key professional bodies, should develop nationally consistent policies and practices in relation to the implementation and conduct of population genetic screening programs, covering such matters as informed consent, counselling and testing standards.

24. Genetic Discrimination in Insurance

Proposal 24–1. Although there is no demonstrated justification for departing from the fundamental principle underlying the market in voluntary, mutually rated personal insurance (namely, equality of information between the applicant and the insurer), where the underwriting of such insurance involves the use of human genetic information, the process of underwriting should be subject to the qualifications identified in Proposals 24–3 to 24–9 below.

Proposal 24–2. The proposed HGCA should monitor the experience of the insurance industry in using genetic information in underwriting, both in Australia and overseas, with a view to reviewing Australian insurance practices at a later time.

Question 24–1. Should there be a fundamental change to the way in which genetic information is used to underwrite personal insurance, such as the introduction of a two-tier system; a prohibition on the use of genetic information; or a public subsidy for poorer risks?

Question 24–2. Should an adult applicant for insurance be obliged to disclose the result of a genetic test undertaken while that person was a child?

Proposal 24–3. No predictive genetic test should be used by insurers in underwriting mutually rated insurance unless the test has been approved for that purpose by the proposed HGCA.

Question 24–3. Would Proposal 24–3 be implemented most effectively through an industry code or legislation? If the latter, should this be through amendment to: (a) the insurance exemption in anti-discrimination legislation; (b) the duty of disclosure in the *Insurance Contracts Act 1984* (Cth); or (c) both?

Proposal 24–4. The insurance industry, through its peak bodies and in consultation with the proposed HGCA, should develop and publish policies on the use of family medical history for underwriting mutually rated insurance.

Proposal 24–5. The *Insurance Contracts Act 1984* (Cth) should be amended to clarify the nature of the obligation of an insurer to provide written reasons for an unfavourable underwriting decision. Where such a decision is based on genetic information, the insurer should give reasons that are clear and meaningful and that explain the actuarial or statistical basis for the decision.

Proposal 24–6. The *Disability Discrimination Act 1992* (Cth) and related legislation should be amended to clarify the nature of the information required to be disclosed by an insurer and to ensure that the complainant is entitled to access to the information so disclosed.

Proposal 24–7. The insurance industry, through its peak bodies, should develop a policy regarding the provision of reasons by an insurer to an applicant in response to an unfavourable underwriting decision based on family medical history. The policy should ensure that the reasons given are clear and meaningful and that they explain the actuarial or statistical basis for the decision.

Proposal 24–8. The insurance industry, through its peak bodies, should develop appropriate mechanisms for reviewing underwriting decisions involving the use of genetic information. Such reviews should be:

- conducted in a timely and efficient manner;
- undertaken by a panel of individuals, each of whom is independent of the insurer that made the decision;

- carried out by suitably qualified individuals with a demonstrated understanding of insurance law and anti-discrimination law, underwriting practice, and clinical genetics; and
- binding on the insurer but not on the complainant.

Proposal 24–9. The insurance industry, through its peak bodies, should review its policies and practices in relation to the training and education of industry members and their authorised representatives in relation to the nature, collection and use of genetic information in insurance.

25. Insurance and Genetic Privacy

Proposal 25–1. Insurers should review their consent forms, including medical authority forms, to ensure that they contain sufficient information about the collection and use of genetic information to allow applicants to make an informed decision about whether to provide the information.

Question 25–1. Does the practice of ‘bundling consents’ by insurers undermine the ability of an applicant to make an informed decision about whether to provide genetic information to an insurer? If so, what measures should be taken to address this problem?

Proposal 25–2. Insurers should seek a Public Interest Determination under the *Privacy Act* in relation to the practice of collecting family medical history from applicants for use in underwriting insurance policies in relation to those applicants.

Question 25–2. Is there evidence that genetic information is shared between various arms of insurance organisations? If so, does this practice raise concerns about the protection of the privacy of genetic information? How might these concerns be addressed?

27. Genetic Discrimination in Employment

Proposal 27–1. Employers should be able to collect and use genetic information in relation to their employees only where this is reasonable and relevant within the terms of anti-discrimination and occupational health and safety legislation, and subject to the limitations set out in the proposals in Chapters 28–30.

28. Inherent Requirements of the Job and Related Issues

Proposal 28–1. In assessing whether an applicant or employee is able to perform the inherent requirements of a job, only current ability to perform the inherent requirements should be relevant. The term ‘inherent requirements’ in the DDA, the HREOC Act and the *Workplace Relations Act 1996* (Cth) should be clarified accordingly. The States and Territories also should consider amending their legislation to similar effect.

Proposal 28–2. Peak employer associations should encourage members to produce clearly defined job descriptions that set out the inherent requirements of every position in the workplace.

Proposal 28–3. The DDA should be amended to prohibit an employer from requesting or requiring genetic information from a job applicant or employee unless the employer can demonstrate that the information is necessary for a purpose that does not involve unlawful discrimination, such as ensuring that a person is able to perform the inherent requirements of the job. The States and Territories should consider adopting a similar provision in their anti-discrimination legislation, where one does not already exist.

Proposal 28–4. HREOC should, in consultation with the proposed HGCA and other relevant stakeholders, develop Disability Standards dealing with the collection and use of genetic information in employment. As an interim measure, HREOC should issue guidelines in this area.

29. Occupational Health and Safety

Proposal 29–1. Genetic screening of applicants or employees for susceptibility to work-related conditions should be conducted only where:

- there is strong evidence of a clear connection between the working environment and the development of the condition;
- the condition may seriously endanger the health or safety of the applicant or employee; and
- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

Proposal 29–2. The National Occupational Health and Safety Commission (NOHSC), in consultation with the proposed HGCA, should develop model regulations regarding genetic screening for susceptibility to work-related conditions. The model regulations should:

- specify the genetic tests that have been approved for use;
- provide guidelines for interpreting test results;
- indicate the circumstances in which family medical history may be collected and used;
- make provision for genetic counselling for those undergoing screening;
- provide for the confidentiality of test results; and
- indicate appropriate responses by employers where genetic screening reveals relevant susceptibilities.

Proposal 29–3. Genetic monitoring of employees should be conducted only where:

- there is strong evidence of a clear connection between the working environment and the development of the condition;
- the condition may seriously endanger the health or safety of the employee; and
- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

Proposal 29–4. NOHSC, in consultation with the proposed HGCA, should develop model regulations for the conduct of genetic monitoring of employees exposed to hazardous substances in the workplace.

Proposal 29–5. Genetic information should be collected from an applicant or employee and used for the protection of third party safety only where:

- the applicant or employee's condition poses a real risk of serious danger to the health or safety of third parties; and
- the danger cannot be eliminated or significantly reduced by other reasonable measures taken by the employer to eliminate or reduce the risks.

Proposal 29–6. NOHSC, in consultation with the proposed HGCA, should develop model regulations with respect to the collection and use of genetic information from applicants and employees for the protection of third party safety. (See also Proposal 29–2).

30. Employment and Genetic Privacy

Proposal 30–1. The definition of ‘employee record’ in the *Privacy Act* should be amended to exclude genetic information held by an employer in relation to a current or former employee.

Proposal 30–2. The pending inter-departmental review of the employee records exemption to the *Privacy Act* should consider whether health information generally should be excluded from the ambit of the exemption.

31. DNA Parentage Testing

Proposal 31–1. Legislation should be enacted to ensure that DNA parentage testing in Australia is conducted only by laboratories accredited by the National Association of Testing Authorities, Australia (NATA), and only in accordance with NATA accreditation requirements.

Proposal 31–2. NATA should review its accreditation requirements for DNA parentage testing to ensure that they meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing counselling. (See also Proposals 31–6, 31–9, 31–11 and 31–12).

Proposal 31–3. Part IIA of the *Family Law Regulations 1984* (Cth) should be reviewed to ensure that the legislative requirements for parentage testing meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing counselling. (See also Proposal 31–7).

Proposal 31–4. In accordance with Proposals 5–2 and 5–3, home use parentage test kits should be subject to regulation under the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth).

Question 31–1. What steps, if any, should be taken to regulate Internet advertising of home use DNA parentage test kits and testing services?

Proposal 31–5. The *Family Law Act 1975* (Cth) should be amended to provide that parentage testing reports are admissible in proceedings under the Act only if made in accordance with the provisions of the *Family Law Regulations 1984* (Cth).

Proposal 31–6. NATA should develop accreditation requirements that require laboratories to be satisfied that the sample of each adult donor has been supplied for parentage testing with his or her consent.

Proposal 31–7. The *Family Law Regulations 1984* (Cth) should be amended to require that the prescribed affidavit and declaration submitted to a laboratory in relation to parentage testing include a signed consent form for each adult donor indicating that the sample has been supplied with his or her consent.

Proposal 31–8. Legislation should provide that a child who: (a) has attained 12 years of age; and (b) has sufficient maturity to make a free and informed decision, may decide on his or her own behalf whether to submit a genetic sample for parentage testing. The child's maturity should be assessed by two independent professionals, such as teachers, social workers, counsellors, medical practitioners, or ministers of religion, who have known the child for not less than two years.

Proposal 31–9. NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain the required child consent in accordance with Proposal 31–8.

Proposal 31–10. Legislation should require that, where a child does not have sufficient maturity to make a free and informed decision whether to submit a genetic sample for parentage testing, such testing can be performed only with the written consent of all persons with parental responsibility for the child, or pursuant to other lawful authority. Where one person with parental responsibility withholds consent or cannot reasonably be contacted, a court should be authorised to make a decision on behalf of the child.

Proposal 31–11. NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain the required parental consents in relation to samples of every child who is under the age of 12 years or who, being over that age, lacks sufficient maturity to consent on his or her own behalf.

Proposal 31–12. NATA should develop accreditation requirements that require laboratories performing DNA parentage tests to:

- inform all persons who provide genetic samples of the availability of counselling, both at the time the samples are submitted for testing and at the time the results are made available; and
- forward test results to an independent person who has the skills to counsel the tested individuals and other relevant family members. Such a person should be nominated by each individual who has provided a genetic sample, and might be a qualified counsellor, social worker, minister of religion, medical practitioner, lawyer or court officer.

Question 31–2. How should DNA kinship testing (other than parentage testing) be regulated? Should NATA accreditation standards be extended to cover this form of genetic testing?

32. Genetic Information and Aboriginality

Proposal 32–1. The Aboriginal and Torres Strait Islander Commission (ATSIC) should consider the appropriate test or tests to be applied in determining Aboriginal or Torres Strait Islander identity. To the extent that any such test requires evidence of Aboriginal or Torres Strait Islander descent, ATSIC should consider the appropriateness or otherwise of using genetic testing and genetic information for this purpose.

Question 32–1. Are there circumstances in which genetic information may be relevant to a native title claim made under the *Native Title Act 1993* (Cth)? If so, how should genetic information be regulated to protect privacy and prevent unfair discrimination?

33. Immigration

Proposal 33–1. The Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) should review its policies and procedures on the provision of information to applicants about kinship testing. Relevant officers should be required to advise applicants about the potential implications of kinship testing and the desirability of seeking counselling before or after testing.

Proposal 33–2. DIMIA should review the adequacy of its policies and procedures for dealing with identity fraud in relation to kinship testing.

Question 33–1. Should procedures for conducting genetic kinship testing for the purpose of migration decision making be given more formal status, for example in the *Migration Regulations 1994* (Cth)?

Proposal 33–3. The Department of Health and Ageing, in consultation with DIMIA and with the proposed HGCA, should develop policies on the use of predictive genetic testing and information for the purpose of assessing the health requirements under migration legislation.

35. Harmonisation of Forensic Procedures Legislation

Proposal 35–1. The Commonwealth, States and Territories should work together to achieve harmonisation in Australian forensic procedures legislation, in particular in relation to the collection, use, storage, destruction and index matching of forensic material and the DNA profiles created from such material. Inter-

jurisdictional sharing of forensic material and DNA profiles, whether on a bilateral basis or via the national DNA database system, should be permitted only after such harmonisation has been achieved.

Proposal 35–2. In order to achieve greater transparency, ministerial agreements for the sharing of information and inter-jurisdictional matching protocols should be prescribed in regulations.

36. Criminal Investigations

Proposal 36–1. Except in relation to volunteers, the consent provisions should be removed from forensic procedures legislation so that an order by the appropriate Australian Federal Police officer or judicial officer is required before a forensic procedure can be carried out on a suspect or serious offender.

Proposal 36–2. Notwithstanding Proposal 36–1, forensic procedures legislation should continue to provide that suspects and serious offenders must be given prescribed information about the nature and consequences of the forensic procedure prior to it being carried out.

Proposal 36–3. Forensic procedures legislation should provide that children and incapable persons who are volunteers should be given the prescribed information about the nature, purpose and consequences of a forensic procedure prior to it being carried out. (See also Proposal 36–2).

Proposal 36–4. Forensic procedures legislation should provide that a forensic procedure may be carried out on a child volunteer of 12 years or above only with the consent of a parent or guardian and the child.

Proposal 36–5. Forensic procedures legislation should be amended by:

- specifying that known victims of crime should be treated as volunteers;
- inserting a new index for ‘identified victims’ profiles’ into the DNA database system, with limited index matching rules that exclude comparisons between this index and the crime scene index; and
- providing that specified information should be given to victims regarding the storage of their profiles.

Proposal 36–6. Regulations or police guidelines should be developed in every jurisdiction on the conduct of mass screening programs, both in relation to the approval process for initiation as well as the manner in which such programs are conducted.

Proposal 36–7. Forensic procedures legislation should be amended to delete reference to the DNA profiles of blood relatives of missing persons from the definition of the ‘missing persons index’.

Proposal 36–8. Forensic procedures legislation should provide that samples (including crime scene samples) collected or otherwise obtained for use in the law enforcement context may be subject to genetic testing and analysis only with respect to the non-coding sections of the DNA, and only for the purposes of creating a DNA profile, quality assurance or equipment validation.

Proposal 36–9. Forensic procedures legislation should provide that forensic analysis of genetic samples must be conducted only by laboratories accredited by NATA in the field of forensic science.

Proposal 36–10. Forensic procedures legislation should require the permanent retention of forensic material found at crime scenes to ensure the preservation of crime scene material for post-conviction analysis.

Proposal 36–11. Forensic procedures legislation should provide that forensic material taken from a suspect, and any information obtained from its analysis, must be destroyed as soon as practicable after the person has been eliminated from suspicion, or police investigators have decided not to proceed with a prosecution in relation to that investigation.

Proposal 36–12. Forensic procedures legislation should be amended to prohibit the establishment or maintenance of any DNA database that does not fit within the legislative definition of a DNA database system.

Proposal 36–13. Forensic procedures legislation should be amended to provide for independent, co-ordinated and nationally consistent monitoring of the operation of the entire national DNA database, and in particular the interaction of the forensic procedures regimes operating in each jurisdiction that participates in the national DNA database system.

Proposal 36–14. Forensic procedures legislation should be amended to:

- specify the person responsible for notifying the forensic laboratory, and CrimTrac, of the destruction date of forensic material and any information obtained from it;
- establish a process for persons to obtain confirmation that their forensic material, and any information obtained from it, has been destroyed; and

- provide (in regulations) a standard consent form for use at the time the forensic procedure is carried out to enable a volunteer (or parent or guardian) to specify the retention period for both the forensic material and any information obtained from it.

Question 36–1. Should the definition of ‘destruction’ in Part 1D be changed to provide for physical destruction of forensic material and information obtained from its analysis? Do the practical difficulties in tracing and physically destroying all remnants of a sample, and all records of the profile, justify confining privacy protection to de-identification rather than physical destruction?

37. Criminal Proceedings

Proposal 37–1 The National Judicial College of Australia and the Law Council of Australia (through its constituent professional associations) should ensure the availability of continuing legal education programs for judges and legal practitioners, respectively, in relation to DNA evidence.

Proposal 37–2. A standard jury direction should be inserted into the *Evidence Act 1995* (Cth) for use where DNA evidence has been admitted in criminal proceedings. The direction should outline the warning that trial judge should give the jury regarding the need for caution in evaluating DNA evidence and the statistical calculations relating to that evidence.

Proposal 37–3. The National Institute of Forensic Science should provide ongoing guidance to forensic scientists and legal practitioners regarding reliable methods of DNA analysis, statistical calculation, and presentation of evidence in criminal proceedings.

Proposal 37–4. Forensic procedures legislation should be amended to provide that the prosecution has a duty to provide defendants with reasonable pre-trial notice of all DNA samples collected at a crime scene in order to give defendants an opportunity to have this evidence independently analysed.

38. Post Conviction Use of Genetic Information

Proposal 38–1. The Commonwealth should legislate to establish an independent body to consider applications for post-conviction review based on DNA evidence where the person provides prima facie evidence that there has been a miscarriage of justice.

Proposal 38–2. The Standing Committee of Attorneys-General should consider developing equivalent legislation and processes in the States and Territories.

39. Civil Proceedings

Proposal 39–1. The National Judicial College of Australia and the Law Council of Australia should ensure the availability of continuing legal education programs for judges and legal practitioners, respectively, in relation to the use in civil proceedings of evidence based on genetic information.

Question 39–1. Should employers or insurers have access to an employee’s genetic information to determine the liability, or to assess compensation or damages, in relation to a workers’ compensation claim or a common law claim for work-related injury?

Part A. Introduction

1. Introduction to the Inquiry

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An ALRC–AHEC Joint Inquiry

1.1 In August 2000, the Attorney-General of Australia, the Hon Daryl Williams AM QC MP, and the then Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, announced the establishment of an inquiry into genetic testing and information, to be conducted jointly by the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC).¹ On 5 February 2001, the same Ministers announced that terms of reference had been settled and signed,² signalling the formal start of the joint inquiry (the Inquiry).

1.2 Following representations from the ALRC, AHEC and others, the responsible Ministers approved an extension of time to the final reporting date to 31 March 2003, expressly in order to afford greater opportunities for public participation in the Inquiry’s consultative processes.³

1 Attorney-General and Minister for Health and Aged Care, ‘Gene Technology’, *Joint News Release*, 9 August 2000.
2 Attorney-General and Minister for Health and Aged Care, ‘Genetic Privacy’, *Joint News Release*, 7 February 2001.
3 Daryl Williams AM QC MP, *Correspondence*, 25 January 2002. The original reporting date was 30 June 2002.

1.3 The Government's decision to opt for a joint inquiry reflects the wide array of legal and ethical concerns and contentions surrounding this new field. The ALRC has experience in dealing with legal issues that involve important ethical and social dimensions, and well-tested processes for engaging in effective community consultation.⁴ The Commission has worked on medico-legal issues before, most notably in relation to alcohol, drugs and driving;⁵ human tissue transplants⁶ and informed consent to medical procedures.⁷ However, it was considered that the addition of the specialist expertise of AHEC would be valuable to the success of the Inquiry.

1.4 AHEC is a principal committee of the National Health and Medical Research Council (NHMRC). It advises the NHMRC on ethical issues relating to health, and is also responsible for developing guidelines for conduct of medical research involving humans.⁸ The Minister for Health and Ageing also has asked AHEC to play a role in the promotion of community debate on health ethics issues, monitor the work of human research ethics committees (HRECs), and monitor and advise on international developments in health ethics. AHEC's membership is specified in its establishing legislation, and draws on experts in philosophy, the ethics of medical research, public health and social science research, clinical medical practice and nursing, disability, law, religion and health consumer issues.⁹

1.5 Some of AHEC's recent work includes the *National Statement on Ethical Conduct in Research Involving Humans*,¹⁰ *Guidelines for Genetic Registers and Associated Genetic Material*,¹¹ and an information paper *Ethical Aspects of Human Genetic Testing*.¹² AHEC also has produced a Handbook to assist HRECs in applying the National Statement,¹³ and is currently engaged in the process of reviewing the guidelines governing the use of Assisted Reproductive Technologies (ART) in Australia, as well as participating in the NHMRC working group developing guidelines for xenotransplantation.

4 The functions of the ALRC are set out in *Australian Law Reform Commission Act 1996* (Cth) s 21.

5 Australian Law Reform Commission, *Alcohol, Drugs and Driving*, Report 4 (1976), AGPS, Canberra.

6 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), AGPS, Canberra.

7 Australian Law Reform Commission, *Informed Decision-Making in Medical Procedures*, Report 50 (1989), AGPS, Canberra.

8 The functions of AHEC are set out in the *National Health and Medical Research Council Act 1992* (Cth) s 35.

9 Ibid, s 36.

10 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

11 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra.

12 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra.

13 National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra.

Advisory committees

1.6 It is standard operating procedure for the ALRC to establish a broad-based, expert Advisory Committee to assist with the development of its inquiries. In this particular case, the Advisory Committee established by the ALRC and AHEC includes leaders in the areas of genetic and molecular biological research; medicine; clinical genetics and genetic counselling; community health; indigenous health; health administration and community education; insurance and actuarial practice; and privacy and anti-discrimination laws. A separate Working Group on Law Enforcement and Evidence also has been established, with some overlapping membership, including experts on genetic testing, forensic medicine, DNA profiling, policing and trial practice (civil and criminal, defence and prosecution). As always, attention has been paid to achieving a measure of gender, geographical and interest group balance. Full membership details are provided in the List of Participants, above.

1.7 The Inquiry also has established communications with other bodies that are undertaking parallel projects or research, such as the Ethics Committee of the Human Genome Organisation (HUGO), the United Kingdom Human Genetics Commission, the OECD's Working Party on Information Security and Privacy, the United States Equal Employment Opportunity Commission, and the Ontario Provincial Advisory Committee on New Predictive Genetic Technologies.

1.8 The Advisory Committee and the Working Group will meet during the course of the Inquiry (there have been a total of four meetings to date), to provide general advice and assistance to the ALRC and AHEC. The bodies have particular value in helping the Inquiry to maintain a clear focus and arrange its priorities, as well as in providing quality assurance in the research and consultation effort, and commenting upon reform proposals. However, ultimate responsibility for the report and its recommendations remains with the relevant Commissioners of the ALRC and the members of AHEC.

Defining the scope of the Inquiry

The terms of reference

1.9 The terms of reference for the Inquiry are set out in full, above. Basically, they ask the ALRC and AHEC to have regard to the broader landscape, including 'the rapid advances in human genetic technology' and 'emerging issues about the control of, ownership of, and intellectual property rights in relation to human genetic samples and information'. The terms of reference also acknowledge the breadth of contexts in which the use of genetic information may be relevant, and of potential concern. These include employment; health, including medical research,

pharmaceuticals and health administration; insurance and superannuation; and law enforcement.

1.10 The ‘action’ part of the terms of reference specifically asks the ALRC and AHEC to inquire into and report on whether, and to what extent, a regulatory framework is required to:

- protect the privacy of human genetic samples and information; and
- provide protection from inappropriate discriminatory use of human genetic samples and information; and
- reflect the balance of ethical considerations relevant to the collection and uses of human genetic samples and information in Australia.

1.11 This is to be done in a way that has regard to the range of Australian ethical opinion on application of human genetic information as well as the benefits and potential benefits of the scientific and medical applications of the new technology. The terms of reference also note the ‘global dimensions of issues relating to research, regulation and the protection of interests’.

1.12 As suggested by the terms of reference, the specific drivers for the establishment of the Inquiry were concerns about privacy and discrimination, especially in the contexts of employment and insurance,¹⁴ as well as ethical and other oversight of medical and scientific research, clinical practice, and the collection and use of genetic databases. These matters have been central to the research and consultations thus far.

Matters outside of this Inquiry

1.13 The preceding Issues Paper described the manner in which the Inquiry has applied the terms of reference in practice, and included a brief discussion of a number of related matters that are considered to be outside of the scope of the present project. These include genetically modified organisms; access to assisted reproductive technology; embryonic stem cell research and human reproductive cloning; and gene patenting.¹⁵ Accordingly, no further work has been done in these areas.

14 See Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.24–2.41.

15 Ibid, para 1.29–1.78. The ALRC and AHEC wrote to the Attorney-General and the then Minister for Health and Aged Care noting that the gene patenting issue is a matter of considerable importance, and suggesting that this should be the subject of a separate inquiry under fresh terms of reference. In his letter to the ALRC of 11 January 2002, the Attorney-General agreed that this matter is beyond the scope of the current joint inquiry, and indicated that the government would give consideration to the establishment of a separate inquiry.

Issues Paper 26

1.14 On 15 November 2001, the Inquiry released its first major community consultation paper — the 441-page Issues Paper 26 on the *Protection of Human Genetic Information* (IP 26).¹⁶ That document was organised around four basic ‘building blocks’, which were then applied to a number of specific contexts in which the use of human genetic information already is, or is likely to become, important. The building blocks comprised:

- *Emerging understandings of genetic science* — a ‘basic primer’ on current understandings of modern genetics and genetic testing in the aftermath of the Human Genome Project (Chapter 2). The primer describes: the nature of chromosomes, genes and gene sequences; how variations or mutations in a person’s genetic code may cause a disease, or increase the likelihood that a person may contract a disease in the future; and how such traits may be inherited from biological parents. The chapter notes that, while there are some serious disorders caused by mutations on a single gene (‘monogenic’ disorders), it is overwhelmingly the case that human health is a product of the complex interaction among genes, as well as the complex interaction between a person’s genetic make-up and environmental factors. In these circumstances, the Inquiry cautioned against making policy based on crude notions of ‘genetic essentialism’ or ‘genetic determinism’. The Inquiry has received very positive feedback about the accessibility of this material for non-experts, and we encourage interested persons to consult Chapter 2 of IP 26 to provide some of the technical background to the issues under consideration. (In order to avoid unnecessary duplication, we have not reproduced this material in full in the Discussion Paper).
- *Ethical considerations* — a discussion of basic ideas about the role of ethics (and specifically the sub-field of bioethics) in influencing medical and other human research and in balancing the practices in this area with other individual and societal values and interests (Chapter 3).
- *Privacy laws* — an examination of the existing framework of Australian laws protecting the privacy of genetic information, with special reference to medical records and other health information (Chapter 4). These laws include the extension of federal privacy laws to the private sector in December 2001.

¹⁶ An executive summary of IP 26 was posted on the ALRC’s website, and a short brochure also was prepared to provide basic information about major issues, and the means of obtaining further material or participating in the Inquiry. The Inquiry also experimented with a give-away postcard promotion announcing the establishment of the Inquiry and providing contact details for further information.

- *Anti-discrimination laws* — an examination of existing anti-discrimination legislation, case law and practice in Australia, with special reference to the possible application of disability discrimination laws to the area of discrimination based on actual or perceived genetic status (Chapter 5).

1.15 The Inquiry then considered the application of these building blocks across a broad range of contexts. These include: medical and other human research (Chapter 6); regulation of human tissue banks, genetic databases and genetic registers (Chapter 7); the role of health care practitioners in interpreting and using genetic information (Chapter 8); systemic health administration issues (Chapter 9); the potential use of genetic information in the workplace (Chapter 10); the use of genetic information — including family medical history as well as test results — by the insurance industry for risk-rating purposes (Chapter 11); the use of genetic information to determine access to or eligibility for a range of goods, services and entitlements (Chapter 12); DNA profiling as a tool for law enforcement authorities (Chapter 13); and the use of DNA evidence in criminal and civil proceedings (Chapter 14). All of these matters are pursued in further detail in this Discussion Paper.

1.16 The primary role of IP 26 was to provide sufficient background material to promote informed community discussion and debate about these new and important issues. To this end, IP 26 also posed 68 questions (many of them multi-part questions), to highlight the matters under consideration and to provide a focus for comment and submissions to the Inquiry.

1.17 Nearly 3000 hard copies of IP 26 have been distributed within Australia and overseas. Copies of IP 26 are still available from the ALRC upon request (and at no charge), and the document also may be downloaded from the ALRC's website, at <www.alrc.gov.au>. Surveys of the website indicate that IP 26 has been one of the ALRC's most heavily downloaded documents, confirming the very high level of interest in this Inquiry.

Community consultation processes

1.18 One of the most important features of ALRC inquiries is the commitment to public engagement and community consultation. The ALRC-AHEC media release in February 2001, which responded to the terms of reference, expressly recognised that widespread public consultation would be a key feature of the genetic information inquiry. It was noted then that, while it is essential that the Inquiry familiarise itself with the latest developments in Australia and overseas, and projected advances in this cutting-edge area of scientific research

we also recognise that this is an area of broad community interest and concern — so it is equally important that we consult widely and provide all Australians with an opportunity to have their say.¹⁷

Public forums

1.19 The Inquiry organised a number of well-publicised, and generally well-attended, public forums in November–December 2001 and February–April 2002, in all capital cities and a number of major regional centres, as follows:

- Melbourne, 22 November 2001;
- Hobart, 26 November 2001;
- Perth, 3 December 2001;
- Adelaide, 5 December 2001;
- Brisbane, 12 December 2001;
- Byron Bay/Lismore, 15 December 2001;
- Newcastle, 25 February 2002;
- Canberra, 26 February 2002;
- Wollongong, 4 March 2002;
- Sydney, 12 March 2002;
- Parramatta, 13 March 2002;
- Darwin, 18 March 2002;
- Alice Springs, 19 March 2002;
- Townsville, 3 April 2002; and
- Cairns, 4 April 2002.

1.20 The format of the public forums involved a set presentation from representatives of the ALRC and AHEC, explaining the nature and processes of the Inquiry and highlighting the major issues, followed by comments and questions from the floor. At some meetings there also was a presentation from a leading genetic scientist. Meetings tended to go for a minimum of two hours (the advertised length), and some lasted for close to three hours, to ensure that all attendees had an opportunity to participate and be heard.

17 ALRC-AHEC, 'Public Consultation a Priority on Genetic Information', *Media Release*, 7 February 2001.

Other meetings

1.21 The Inquiry also participated in a number of well-attended meetings and workshops, held at the invitation of community, professional and industry organisations or public authorities, such as the Human Genetics Society of Australasia (HGSA); the Rotary Club; the Committee for the Economic Development of Australia (CEDA); the Victorian Genetic Services Network; the NSW Anti-Discrimination Board; LAWASIA; Royal North Shore Hospital, Sydney; the UNSW School of Community Medicine; Bronte Public School; the Institute of Actuaries of Australia; and a number of seminars and conferences aimed at lawyers and others interested in the regulation of biotechnology.

1.22 The Inquiry also took the opportunity to arrange a large number of targeted meetings with key stakeholders, in order to gain expertise, perspectives and experiences, which are very valuable in informing the Inquiry and helping to develop sound policies that will meet existing concerns and work effectively in practice. As of mid July 2002, 119 such meetings had taken place around Australia. These included meetings with:

- clinical genetics services, clinical geneticists, genetic counsellors and genetics educators;
- genetic support groups and disability advocacy groups;
- organisations concerned with health consumer education and advocacy;
- organisations concerned with indigenous health, medical and legal issues, including the Aboriginal sub-committee of the HREC of the Menzies School of Health and Research, the Central Australia Aboriginal Congress, and Central Australia Aboriginal Legal Aid Service;
- leading genetic research laboratories, such as those at the Queensland Medical Research Institute, the Murdoch Childrens Research Institute, and the Peter MacCallum Cancer Institute;
- family cancer registers, pathology departments and laboratories, genetic testing laboratories, and institutions holding Guthrie card collections;
- federal, state and territory health departments, hospitals and public health officials;
- peak employer groups (eg the Australian Confederation of Commerce and Industry) and trade unions (eg the Australian Council of Trade Unions);

- senior persons involved in the insurance industry, including officers of the peak body, the Insurance and Financial Services Association (IFSA);
- federal, state and territory police officers and police forensic services units and laboratories, as well as the National Institute for Forensic Services and CrimTrac;
- public and private organisations concerned with privacy protection (including the Office of the Federal Privacy Commissioner, and Privacy NSW); and
- public and private organisations concerned with human rights protection (including the federal Human Rights and Equal Opportunities Commission, and the New South Wales Anti-Discrimination Board).

1.23 Members of the Inquiry also made presentations in 2002 to the EINSHAC Conference in Rome (primarily concerned with educating judicial officers about genetic science and the use of expert evidence in this area), and the Seventh International Human Genome (HUGO) Conference in Shanghai (the major international conference for genetic researchers).

1.24 A further 14 meetings were held overseas in Denmark, Sweden, and the Netherlands with representatives from insurers, peak employer and employee bodies, and research ethics committees. In the United States, a meeting was held with a member of the federal Equal Employment Opportunity Commission. In Shanghai, the Inquiry was permitted to act as an observer at a meeting of the HUGO Ethics Committee.

Other means of promoting community engagement

1.25 The ALRC reworked sections of IP 26 in a plain language format for publication in the *Hot Topics* series produced by the State Library of New South Wales' Legal Information Access Centre (LIAC). *Hot Topics* aims to highlight, in an accessible fashion, areas of the law that are subject to change or public debate, with an audience including high school legal studies teachers. *Hot Topic 36: Human Genetic Information* was launched on 10 July 2002 at the State Library of New South Wales, with a panel discussion and question and answer session,¹⁸ before an audience of about 100 people.

¹⁸ Moderated by JJJ FM's Adam Spencer, with panellists Professor David Weisbrot of the ALRC, Professor Ron Trent of Royal Prince Alfred Hospital, genetic counsellor Annie Evans, and Kirsten Edwards of the UTS Innocence Project.

1.26 There has been strong media interest in the Inquiry from the beginning, and this has been sustained throughout the life of the project. The launch of IP 26 attracted substantial media coverage, including television reports. The public forums also received substantial radio and television coverage in most of the cities in which they were held. The media also have referred to the Inquiry for comment on parallel developments in other jurisdictions, such as the release of papers by the United Kingdom Human Genetics Commission. As of mid-July 2002, the Inquiry had recorded about 130 separate radio and television interviews and reports, and newspaper and magazine articles.

1.27 A number of scientific, professional and popular journals, such as *Nature*, *Australian Doctor*, and *HQ* also have provided coverage of particular issues being handled by the Inquiry, as have journals directed at lawyers, industrial relations specialists, and insurance industry personnel.

Written submissions

1.28 The Inquiry has strongly encouraged interested persons and organisations to make written submissions to help advance the policy-making process. A number of preliminary submissions were received based upon the terms of reference and early publicity about the Inquiry. However, most submissions have been received in response to IP 26, addressing the issues and questions specifically raised in that paper.

1.29 As of mid-July 2002, 168 written submissions have been received.¹⁹ The submissions vary substantially in size and style, ranging from short notes written by individuals or families providing personal views and experiences to large, well-researched documents prepared by government departments and agencies, research centres and laboratories, genetic support groups, industry bodies and professional associations. It is not merely being polite to state that the Inquiry has found all of the submissions to be very valuable.

1.30 Much of the information provided in the institutional submissions probably could be obtained through direct approaches to the relevant bodies. However, the insights and experiences offered in the personal submissions are not readily available elsewhere, and the Inquiry deeply appreciates the time and trouble people have gone to in order to provide these. Some of this material is also deeply personal and sensitive, and in recognition of this the Inquiry has left open the option of individuals or groups lodging submissions that are confidential in whole

¹⁹ See List of Participants above for the details. Roughly 200 separate documents have been received; however, some regular correspondents have written what might be considered 'staged submissions', which the Inquiry has aggregated and treated as a single submission in each case. Similarly, some submissions have been updated or corrected over time, but have been treated as a single submission in each case.

or in part. Of the total of 168 submissions to date, 23 have been designated as confidential.

The organisation of this Discussion Paper

1.31 IP 26 contained considerable background information about the issues under consideration. The major differences of substance between IP 26 and this Discussion Paper (DP 66) are that this paper contains:

- the product of the further and deeper research which the Inquiry has been able to undertake since November 2001;
- the benefit of the many meetings and consultations held following the launch of IP 26; and
- the benefit of the many submissions received in response to IP 26, which are quoted and cited throughout this document.

1.32 Most importantly, this Discussion Paper replaces the many questions asked in IP 26 with a series of specific proposals for reform (as well as some new questions) to which the community is invited to respond.

1.33 It is very important to note that these proposals do *not* represent the final views or recommendations of the Inquiry. It is not uncommon in ALRC inquiries, for example, for there to be significant changes of approach between the Discussion Paper stage and the final report. Some of the proposals in DP 66 may represent advanced and relatively firm thinking on the part of the Inquiry — but nevertheless may be influenced and altered by subsequent research, consultations and submissions. Other proposals represent a tentative choice expressed from a number of plausible options. Still other proposals may amount to ‘trial balloons’ to test the winds of public and professional opinion, so that the Inquiry may be in a position later to make a recommendation that does not catch people unawares. While it is quite possible for the Inquiry to abandon or substantially modify proposals for which there is little support, it is more difficult to publicise and gauge support for novel approaches suggested to us during the later consultation process.

1.34 If there are passages in this paper which appear to imply that final conclusions already have been drawn about the direction of the final report and its recommendations, this is unintended and not meant to inhibit full and open discussion of issues and policy choices before the Inquiry’s program of research and consultation is completed. This is not merely a rhetorical device to suggest perceived impartiality — at this middle stage of the process, the members of the Inquiry genuinely are open to reasoned argument about the best possible approaches to regulation in the public interest.

1.35 Readers will notice that the organisation of the material has changed from IP 26, which contained 14 broad chapters. In order to facilitate writing, editing and production of this significantly larger Discussion Paper, the Inquiry has chosen to divide the material covered into ten substantial parts, each of which contains a number of chapters.²⁰ The ALRC experimented with this approach in October 2001 in its lengthy report on the review of the *Judiciary Act 1903* (Cth),²¹ and it appears that the use of smaller and more targeted chapters allows individuals to hone in on those parts of the paper that most interest them.

How you can participate

1.36 As a community consultation document, this Discussion Paper may be obtained in hard copy free of charge from the ALRC, and also is available for downloading free of charge from the ALRC's website.

1.37 As indicated above, the Inquiry places great value on submissions, and strongly encourages interested persons and organisations to provide submissions in response to this Discussion Paper, addressing any or all of the various proposals and questions.

1.38 There is no specified form or format for submissions. Having regard to the time-poor nature of modern life, the Inquiry will gratefully accept everything from doctoral theses to handwritten notes and emailed dot-points that comment on the issues and suggest sensible ways forward. For the same reasons, the Inquiry understands that it cannot sit back and wait for thorough, well-crafted submissions to roll in. Rather, it will be necessary to continue to maintain an active program of direct consultation.

1.39 The Inquiry's final Report and recommendations must be presented to the Attorney-General and the Minister for Health and Ageing by 31 March 2003.

1.40 In order for the Inquiry to make effective use of submissions, they must reach the ALRC no later than Friday, 29 November 2002. Submissions received after that date may be considered if time permits, but the Inquiry cannot guarantee that this will be the case.

In order to be considered for use in the final Report, submissions in response to this Discussion Paper must reach the ALRC no later than

²⁰ Many of the Parts roughly correspond with the chapters in IP 26, but this is not always the case.

²¹ Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 (Cth) and Related Legislation*, Report 92 (2001), ALRC, Sydney.

Friday, 29 November 2002. Details about how to lodge a submission are set out on the inside cover.

1.41 Under the *Australian Law Reform Commission Act 1996* (Cth), s 23, reports presented to the Attorney-General must be tabled in Parliament within 15 sitting days, after which they become public documents. Final reports are provided without charge to all participants in the Inquiry, including those who make submissions. Hard copies of the final Report will be available for sale to others after tabling, but copies also will be freely available for downloading from the ALRC website.

1.42 It is important to note that the final Report of the Inquiry will not be a self-executing document. The Inquiry only may provide considered advice and recommendations — implementation is a matter for others.²²

1.43 In an earlier era, the centrepiece of any significant law reform effort was the recommendation of a major new piece of legislation. However, in a more complex environment in which authority is much more diffused, modern law reform efforts are likely to involve a mix of strategies and approaches, including legislation and subordinate regulations; official standards and codes of practices (such as those promulgated by the NHMRC and the Privacy Commissioner); voluntary industry codes and best practice standards; education and training programs; better coordination of governmental (and intergovernmental) programs, and so on. Thus, the proposals contained in this Discussion Paper are addressed to a range of parties and not merely to government.

1.44 Similarly, although the Inquiry's final Report will be presented to the Attorney-General and the Minister for Health and Ageing, it is likely that some (or many) of the recommendations will be directed to other government departments and agencies; the NHMRC and its committees; the Australian Health Ministers Advisory Council (AHMAC); the Standing Committee of Attorneys-General (SCAG); industry associations (such as IFSA); hospital and public health authorities; individual health practitioners; educational authorities; employer organisations and trade unions; and statutory authorities with responsibility for privacy and discrimination matters (such as the Office of the Federal Privacy Commissioner and the Human Rights and Equal Opportunities Commission), among others.

1.45 It also may be the case that major advances in genetic science and technology will be so rapid that some of the bases for our policy-making in the

22 However, the ALRC has a strong record of having its advice followed. About 60% of the Commission's previous reports have been fully or substantially implemented, about 20% of reports have been partially implemented, and the remaining 20% have not been implemented or are sufficiently recent to be still under consideration.

report may be dated in a relatively short span of years. Chapter 2 seeks to address the ways in which the Inquiry's suggested reforms may have longevity in the context of rapid scientific change. One such way is through the establishment of appropriate institutions, which are charged with the responsibility of advising government on developments in human genetics, as they arise. If no standing body is established to advise governments on these matters, as proposed in Chapter 3 below, then the Inquiry may have to be reconstituted in future to revisit some of these issues.

2. Planning for the Future

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A glimpse of the future?

2.1 The film ‘GATTACA’ was released in 1997. It portrayed life in a ‘not-so-distant future’ in which genetic engineering permits parents to screen embryos before implantation for the purpose of reproduction — avoiding those that are genetically imperfect and selecting those that offer a genetic guarantee of health, stamina and physical attractiveness.¹ One reviewer described the film in the following terms:

The main focus of *Gattaca* is the struggle of a genetically inferior man, Vincent Freeman, to survive and prosper in a world where his kind is routinely discriminated against.

Shortly after they were married, Vincent's parents decided to start a family the old-fashioned way, without any help from doctors and test tubes. The result was a boy who was diagnosed as 99% likely to have a serious heart defect. That rendered Vincent ineligible for all but the most menial of jobs. But his dream was to one day work at The Gattaca Aerospace Corporation and participate in the first-ever manned flight to the moons of Saturn. For most ‘in-valids’, this would have remained a fantasy, but Vincent possessed the determination and drive to make it real.

With the help of a shady middle-man, Vincent locates Jerome Morrow, a genetically superior individual who was paralysed as the result of an accident. He agrees to sell Vincent his identity (including blood and urine on demand, fingerprints, hair and other body debris, etc.). So, equipped with Jerome's genetic resume, which guarantees him work anywhere, Vincent applies for a position at Gattaca. He is accepted and

1 A Niccol, *GATTACA* (1997), Columbia Pictures.

quickly proves his worth to everyone. But, a week before he is to attain his lifelong ambition of making a space flight, he becomes a suspect in a murder investigation and his carefully-guarded secret is in danger of being exposed.²

2.2 With the indulgence of a sympathetic medical officer who chooses not to disclose Vincent's deception, Vincent transcends his 'genetic prophecy'. Despite a life expectancy of only 33 years and 'already 10,000 [heart] beats overdue', in the final scene Vincent is launched into the night sky on his mission into space.

2.3 GATTACA identifies many themes that are central to the present Inquiry: the prospect that genetic science may in time enable a person's genetic destiny to be mapped out at birth, with all their flaws, predispositions and susceptibilities; the prospect that those with better genetic profiles may be favoured over those with weaker profiles, creating a class of 'healthy-ill' or 'worried-well'; and the prospect that those who are genetically disadvantaged may defy scientific predictions and succeed beyond expectations, while those who are genetically advantaged may not fulfil their potential — because, as Vincent Freeman states, 'there is no gene for fate'.

The march of science

2.4 At the time of GATTACA's release, some reviewers described the film as based on a 'chillingly feasible premise'.³ Others, however, thought the science to be suspect, commenting that 'it is highly dubious whether any of the genetic engineering portrayed in the film will ever be possible'.⁴

2.5 The intervening years offer fresh insights into the plausibility of GATTACA's underlying premise. In the five years since the film was released, there have been many important developments in genetic science. Those that have received a deal of media coverage include:

- the cloning of 'Dolly the sheep' (1997) and the subsequent cloning of other animals;
- sex-selection of embryos through a technique of sperm sorting (1998);
- the completion of the first mapping of the human genome by the international consortium of scientists involved in the Human Genome Project (1999);

2 J Bernardinelli, *Gattaca*, <<http://movie-reviews.colossus.net/movies/g/gattaca.html>>, 22 July 2002.

3 Ibid.

4 J O'Ehley, *GATTACA*, <<http://www.sciflicks.com/gattaca/review.html>>, 22 July 2002.

- the successful use of gene therapy by French researchers to treat severe combined immunodeficiency disorder in two infants (2000);⁵
- the alleged reproductive cloning of a human being by an Italian doctor, Dr Severino Antinori (2002); and
- the advent of 'designer babies', such as the case of a deaf lesbian couple in the United States who consciously chose a deaf sperm donor to increase the chance of conceiving a baby with the same disability (2002).⁶

2.6 In addition to advances in genetic science and technology, there have been rapid developments in the uses to which existing genetic technology has been put. For example, the Australian artist Pro Hart has begun to incorporate his genetic material in his paintings in order to facilitate authentication of his artworks and avoid forgery.⁷ One United Kingdom biotechnology company, Sciona, has begun to market an over-the-counter genetic testing service, linking dietary advice to variations on nine selected genes thought responsible for producing enzymes involved in general 'body maintenance'.⁸ More frivolously, the *New York Times* has reported that DNA parentage tests are being used as a basis for a television game show in which a talk-show host announces the test results on air before the putative parents and a studio audience.⁹

2.7 While it is difficult to predict the course of human progress with any pretence of accuracy, the Inquiry is of the view that a number of nascent developments in genetic medicine, science and technology will place increasing pressure on the central issues confronting this Inquiry. These include:

- The further development of gene chip or micro-array technology, which will enable a large number of genetic tests to be performed on a sample simultaneously.
- The likely reduction in the costs of genetic testing as technology is refined and adopted more widely in the community. In such circumstances there may be increasing pressures on governments, employers, insurers and others to uncover genetic information about individuals with whom they interact.

5 R Dobson, 'Gene Therapy Saves Immune Deficient Babies in France' (2000) 320 *British Medical Journal* 1225.

6 D Teather, *Lesbian Couple Have Deaf Baby by Choice*, *The Guardian*, 8 April 2002, <www.guardian.co.uk/international/story/0,3604,680616,00.html>, 3 June 2002.

7 O Hill-Douglas, *Cheeky Pro Hart puts DNA Signature on his Paintings*, *The Age Company Ltd*, <<http://www.theage.com.au/articles/2002/03/06/1015365716233.html>>, 26 July 2002.

8 Sciona, describes itself as 'commercialising research in the areas of nutrigenomics and pharmacogenomics in order to create a range of services that enhance people's lives and well-being.' See Sciona Ltd, *About Sciona*, <www.sciona.com/about/index.htm>, 22 July 2002; J Meek, 'Genetic Testing Rules "Unenforceable"', *The Guardian*, 4 June 2002.

9 A Stanley, 'In DNA Tests, TV Finds Elixir to Raise Ratings', *New York Times*, 19 March 2002.

- The likely increase in the speed of genetic testing, enabling testing to be carried out in minutes rather than days. This may open up the possibility of using genetic screening in new situations, such as border control.
- The expanding medical understanding of the role of genetics in common diseases and conditions (such as asthma and hypertension), as well as expanding pharmacological understanding of the role of genetics in the metabolism of drugs.
- The expanding understanding of the role of genetics in the expression of a range of non-medical traits, including human behaviours such as aggression and addiction.
- The expansion of genetic screening across broad population groups, facilitating the collection of an unprecedented amount of sensitive health information about individuals and communities. Examples in Australia include school-based screening for Tay-Sachs disease and employment-based screening for haemochromatosis through the HaemScreen program.¹⁰ Other countries are developing broader genetic screening programs.
- The increasing capacity of information technology to provide rapid access to personal information (including genetic information) stored in disparate locations. Bioinformatics may permit the linkage of health data from disparate sources, including Guthrie cards, pathology samples, research studies and clinical records. In doing so, the linkages may create new and powerful information, but also heighten concern about the privacy of such information.¹¹
- The introduction of personal identification cards that containing biometric information, including genetic information, and which may be used in a variety of contexts such as access to public services and immigration control.¹²
- Increasing pressures from commercialisation, whether that be from governments selling population genetic data to researchers, as in Iceland, Estonia and Tonga; biotechnology companies seeking entrance to niche markets; large pharmaceutical companies seeking to profit from advances in

10 HaemScreen is a pilot genetic screening program for haemochromatosis run by the Murdoch Children's Research Institute and Genetic Health Services Victoria at the Royal Children's Hospital, Melbourne.

11 An example is Biobank UK, which aims to track 500,000 volunteers for a research study aimed at establishing how genes, lifestyle and environmental factors interact to affect people's health. See *The Wellcome Trust*, <www.wellcome.ac.uk>, 22 July 2002.

12 See, eg, Secretary of State for the Home Department, *Entitlement Cards and Identity Fraud: A Consultation Paper* (2002), London, 104, which considers but rejects as 'too invasive' the use of DNA information in an identity card.

pharmacogenetics; or individuals seeking to patent human genes or genetic processes.

Law reform in times of rapid change

2.8 In the light of these developments, a critical issue for this Inquiry is how to make today's law reform relevant to the scientific developments of tomorrow. The importance and the difficulty of achieving this has been a common theme in submissions made to the Inquiry. For example, the Australian Medical Association remarked that the:

rapidly evolving science of Genetics makes today's prediction very quickly outdated by tomorrow's information.¹³

2.9 Louise Martinovic submitted:

There is widespread community concern that as developments in [human genetics] are occurring rapidly, the law will 'fall behind' and not be able to adequately protect the privacy of the individual against inappropriate discriminatory use of their genetic information.¹⁴

2.10 Graham Whittaker identified the need for both sound prediction and flexible solutions:

We are informed that the results of the current Human Genome Project and subsequent research, also building on existing knowledge, are likely to produce more rapid advances in human genetic technology than have hitherto been achieved. A number of experts have attempted to speculate about future developments, but the future is impossible to predict and so changes to legislation etc need to be a best effort to suit what is most likely to occur, and to allow dynamic modifications ...¹⁵

2.11 Similarly, the Office of the Federal Privacy Commissioner stated that:

It is vital for Australia as a competitive and forward-thinking nation that the institutional measures, which are proposed for the protection of genetic privacy, are capable of accommodating genetic and technological developments and their pace of change.¹⁶

2.12 The Inquiry is conscious of the need for law reform to be sensitive to the dynamic environment in which medical, scientific and technological developments are taking place in the field of human genetics. Below the Inquiry identifies six attributes of the reform process that are aimed at ensuring its recommendations meet the needs that are likely to arise in the short to medium term. Prognostication

13 Australian Medical Association, *Submission G091*, 29 January 2002.

14 L. Martinovic, *Submission G006*, 30 May 2001.

15 G Whittaker, *Submission G085*, 21 January 2002.

16 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

may be more art than science. However, as a leading futurist has suggested, the purpose of thinking ahead in this fashion is not to provide an accurate picture of tomorrow but to improve decision-making in the present.¹⁷

2.13 In summary, it is the Inquiry's view that governments and other public institutions should be sensitive to the dynamic environment in which medical, scientific and technological developments are taking place in the field of human genetics, when they consider proposals to reform laws, codes, guidelines and practices relating to human genetic information. In particular, and as discussed further below, governments and other public institutions should:

- Promote widespread community participation in the formulation of relevant rules and principles;
- Find appropriate balances between competing interests;
- Adopt processes that facilitate contributions from all relevant disciplines;
- Consider the cross-border implications of the issues, whether they be federal or international in character;
- Consider forms of regulation that are flexible and quick to adapt to changing circumstances; and
- Establish and maintain such institutions as are appropriate to address, on an on-going basis, issues relating to the use and protection of human genetic information.

Widespread community participation

2.14 In IP 26, the Inquiry noted that public optimism about the potential benefits flowing from advances in human genetics is tempered by concerns arising from rapid change. The Inquiry stated that:

On the one hand, there is very strong public support for breakthroughs promising better medical diagnosis and treatments, and for assisting with law enforcement (including identification of missing persons); on the other, there is some general fear about uncontrolled or 'mad science', the spectre of eugenics, threats of biological warfare, reports of xenotransplantation (transplants from one species to another), the loss of privacy, and the increased possibilities for genetic discrimination.¹⁸

¹⁷ P Schwartz, *The Art of the Long View: Planning for the Future in an Uncertain World* (1997).

¹⁸ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.7.

2.15 The Inquiry also noted that a federal government agency, Biotechnology Australia, had commissioned a study of public attitudes to biotechnology, which reported as follows:

Most respondents felt that biotechnology is changing at such a rapid pace that developments cannot possibly be anticipated and legislated against. In addition, it was generally felt that Australian society and government are powerless compared to the international financial and political power of the large multinational companies driving biotechnological innovations. A key component of concern was the perception that there are no or inadequate controls over the process, motivations and outcomes of the development and application [of] biotechnology and gene technology in Australia. This was particularly a concern for those applications which were seen to raise complex, and disturbing questions about human life.¹⁹

2.16 The Inquiry considers that it is necessary to ensure broad public consultation and community participation in any reform process if public concerns about human genetics are to be adequately addressed. Community engagement has been fundamental to the methodology of the Australian Law Reform Commission since its inception. As indicated in Chapter 1, that methodology has been followed in the present Inquiry, with the holding of a large number of public meetings; widespread dissemination of IP 26 and genetics brochures; participation in numerous public forums on genetics; and receipt and consideration of over 160 public submissions.²⁰ Similar principles should also be applied to any processes of on-going review that are established after the present Inquiry has reported.

2.17 The Inquiry believes that an open and accountable process that engages with the public is essential for several reasons. It is beneficial:

- for those consulted, because it facilitates civic participation and has a valuable educative function in an area of science that requires lifelong learning;
- for the process of law reform, because those with day to day experience of the law can indicate how law and practice actually affect them; and
- for reform outcomes, because laws, codes and guidelines are more effective when the people who will be regulated by them participate in their formulation.

2.18 Widespread community participation in the process of reform or review is thus seen by the Inquiry as essential to maintaining public trust.

19 Millward Brown Australia, *Biotechnology Public Awareness Survey Final Report*, Biotechnology Australia, <<http://www.biotechnology.gov.au/MBsurveyresults.pdf>>, 1 July 2001, 29.

20 See further, B Opeskin, 'Engaging the Public: Community Participation in the Genetic Information Inquiry' (2002) 80 *Reform* 53.

Balance and compromise

2.19 A second attribute to consider when seeking longevity of reform proposals is the need for balance and compromise. IP 26 identified a major challenge for the Inquiry as finding a ‘sensible path’ through conflicting public concerns with respect to genetic information.²¹ The balance is difficult to achieve in practice because relevant interests often compete or clash. This is evident in the submissions received on many issues currently under investigation.

2.20 One example is the conflict between the interests of genetic researchers, who need to secure the willing and active participation of many data subjects, and the interests of the potential volunteers, who may fear that their participation will generate personal information that subsequently may have to be disclosed to insurers, employers or others. Another example is the conflict between the interests of employers, who must fulfil their common law and statutory duties to provide a healthy and safe work environment for their employees, and the interests of employees, who may fear adverse discrimination because of a genetic susceptibility to a disease triggered, for example, by exposure to hazardous substances in the workplace.

2.21 The need to balance interests has been recognised in the approach of similar bodies overseas. In the Foreword to the recent report of the United Kingdom Human Genetics Commission, Baroness Helena Kennedy remarked:

In the subtitle of this report we talk of balancing interests. This is an important aspect of our work. I am very much aware of the fact that people approach this issue of personal genetic information from varying perspectives. We have tried here to take account of a wide spectrum of views and have attempted to reach conclusions which are morally defensible and sensitive to the different interests involved.²²

2.22 The Inquiry considers that black and white solutions to the complex problems thrown up by human genetics will rarely be appropriate. However, the precise balance to be struck between competing interests need not be the same for all time, nor for all societies. Moreover, a finely-tailored solution need not subjugate one group’s interests to advance those of another: an appropriate balance may be mutually beneficial. The Anti-Discrimination Board of NSW made this point in its submission when addressing the potentially competing interests of medical researchers and data subjects in the regulation of human research.

21 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.15–2.23.

22 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 5.

Fear of genetic discrimination is also likely to impact upon people's willingness to participate in research. ... Rather than acting as an impediment to the development and application of genetic technology, effective anti-discrimination and privacy legislation are critical to realising the public health benefits of genetic information. Conversely, if we fail to provide such protection, discrimination and privacy concerns will act as disincentives to testing and research participation and have negative consequences for individual and public health outcomes.²³

2.23 There is a wealth of policies and ethical pronouncements from international agencies and NGOs that readily use general terms like 'fairness', 'equity', 'reciprocity', 'justice' and 'non-discrimination'. No one could possibly argue with such principles nor the sentiments underlying them. However, the real complexity comes in making (or even attempting to make) the difficult choices involved in balancing legitimate but competing interests in practice. These complexities include taking into account the reality of: the high costs of medical and scientific research and of clinical trials; the current general preference of governments in industrialised countries (including Australia) for market solutions; the trends toward and pressures of privatisation, corporatisation, and commercialisation in such countries; and the limited resources and pools of expertise available for formal regulatory authorities.

Interdisciplinary approach

2.24 A third attribute of successful reform for the future is maintaining an interdisciplinary approach to the issues. The subject matter of this Inquiry is a unique fusion of law and medical science. This is reflected in the identity of the partners to the joint inquiry (the ALRC and AHEC); the expertise of their respective members and staffs; the portfolios of the Ministers to whom the Inquiry will report (the Attorney-General and the Minister for Health and Ageing); the composition of the Advisory Committee;²⁴ the diversity of individuals and organisations with whom consultations have been conducted; and the range of submissions.

2.25 The importance of contributions from people with differing interests and perspectives was echoed in a number of submissions. For example, in the course of rejecting the suggestion that the disclosure of genetic information to a patient's relatives should be left in the hands of professional medical opinion, the Office of the Federal Privacy Commissioner commented that this approach fails to consider that:

23 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

24 See the List of Participants for the full composition of the Advisory Committee.

the need to accommodate a range of competing interests calls for input from a number of disciplines, such as the law, science, ethics as well as health care.²⁵

2.26 In the Inquiry's view, successful law reform now and in the future requires that an interdisciplinary approach to these issues be maintained.

Global perspective

2.27 Medical science is an international discipline and does not conform to state or national boundaries. For this reason, policy makers in the field of human genetics need to be mindful of the implications of proposals in an increasingly borderless world. In practice, the capacity for transborder transactions may limit the capacity to regulate certain kinds of conduct.

2.28 For example, in Chapters 5 and 31 the Inquiry addresses the regulation of human genetic testing, including parentage testing. At present, parentage testing is available from Australian laboratories, which may or may not be accredited according to Australian standards, and from overseas laboratories, which may or may not be accredited in accordance with the standards prevailing in those foreign jurisdictions. If parentage testing is heavily regulated in Australia, one consequence may be to encourage people to use the less regulated facilities of overseas laboratories, whose services are often marketed over the Internet. Similarly, if the conditions for medical research in Australia are excessively stringent, research facilities may move offshore to sites that are more conducive to their particular brand of research.

2.29 This is not to suggest that Australia should adopt the standards of the lowest common denominator by participating in a 'race to the bottom'. Rather, it is to call attention to the need to be aware of the global environment in which information, people, goods and services often may move across borders, whether interstate or international. It is also to call attention to the fact that maintaining high legal and ethical standards in Australia with respect to human genetic information cannot prevent other jurisdictions from developing standards that may not comport with those at home.

2.30 In some contexts international rules are being developed to promote the observance of minimum standards in the protection of human genetic information. In 1997 the United Nations Educational Scientific and Cultural Organisation (UNESCO) adopted the Universal Declaration on the Human Genome and Human Rights. The Declaration seeks to establish high-order principles and is not binding on member States. An example of a binding instrument (though of no direct relevance to Australia) is the Council of Europe's Convention on Human Rights and Biomedicine, which seeks to:

25 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.²⁶

2.31 In conformity with this global context, the Inquiry has investigated the approaches taken in a number of overseas jurisdictions to the protection of human genetic information. The Inquiry has held consultations in Australia with visiting foreign officials, including the Chair of UNESCO's International Bioethics Committee. The Inquiry has also held consultations in a number of European countries with organisations relevant to medical ethics, insurance, employees, employers, privacy and data protection. It is anticipated that this soon will be supplemented by consultations in the United Kingdom, Canada and the United States. Moreover, the Inquiry has developed an extensive network of professional contacts in many jurisdictions, enabling it to keep abreast of current developments in the regulation of human genetic information.

2.32 The Inquiry considers that future regulation of human genetic information should be sensitive to this global environment. An examination of relevant developments in other jurisdictions will enable informed choices to be made for Australia based on international best practice in the field.

Flexible regulation

2.33 Many submissions to the Inquiry have identified a critical ingredient in the regulation of human genetic information — the need for flexible mechanisms that are capable of adapting with appropriate speed to on-going developments in genetic science and medicine.

2.34 The following quotations are representative of a widespread concern among those who made submissions to the Inquiry:

We must avoid placing unrealistic expectations on legislative solutions as they are by no means a universal panacea. We need to be mindful that there are also some drawbacks to a fixed legislative approach, particularly in an area which is undergoing rapid change.²⁷

Any legislation is likely to be inadequate to deal with the rapid changes in the area of genetic information. Therefore there needs to be constant surveillance of the ethical, privacy and discrimination issues.²⁸

26 *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*, Council of Europe, (entered into force on 1 December 1999). As at 7 June 2002 there were 13 states parties.

27 Centre for Law and Genetics, *Submission G048*, 14 January 2002. See also M Otlowski, *Submission G159*, 24 April 2002.

28 Aboriginal and Torres Strait Islander Social Justice Commissioner — Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

[The Australian Academy of Science] also notes that this area of research is moving very quickly, and that laws can be difficult to amend if they no longer reflect the state of scientific knowledge and medical practice.²⁹

The NHMRC Guidelines do not have the same legal effect as legislation; they are not binding. The guidelines do however, have the advantage of being capable of rapid amendment and are therefore considered by some to be a better option for regulation than the enactment of 'genetic specific' legislation.³⁰

[The Investment and Financial Services Association] recommends that the industry be regulated by a mandatory Industry Standard, rather than legislation, as a Standard can be rapidly updated in line with scientific advances and changes in community attitudes.³¹

2.35 The Inquiry considers that there will be circumstances in which legislative solutions are entirely appropriate in setting benchmarks that are binding, enforceable and visible in protecting human genetic information. Accordingly, many proposals in this Discussion Paper suggest amendments to existing legislative regimes in order to afford better protection to human genetic information.

2.36 However, the Inquiry generally endorses the view expressed in the above submissions in so far as they call for an awareness of the drawbacks of legislation in responding to the need for reform in times of rapid advances in science and technology. Although it is not possible to endorse a particular regulatory solution in advance for all circumstances, the Inquiry's proposals recognise the need for a range of flexible solutions, including guidelines, codes of practice and better education.

2.37 It also may be appropriate in some circumstances to adopt co-regulatory approaches, where legislation establishes a basic framework supplemented by more detailed industry or professional codes. The *Privacy Act 1988* (Cth) provides one such model, with its National Privacy Principles (NPPs) promulgated by the Office of the Federal Privacy Commissioner (OFPC); its approved (organisation-based) privacy codes; and the possibility of exemptions pursuant to the OFPC's public interest determinations.³²

2.38 The importance of flexibility also suggests that it is desirable to undertake periodic review of this area to ensure that laws and practices meet society's needs as human genetics develops over time.

29 Australian Academy of Science, *Submission G097*, 21 January 2002.

30 L. Martinovic, *Submission G006*, 30 May 2001.

31 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

32 *Privacy Act 1988* (Cth) Pt IIIA, Pt VI.

Appropriate institutions

2.39 Finally, the Inquiry believes that in order for reform to be successful in meeting the challenges of the future, it is essential to establish and maintain appropriate institutions.

2.40 Bodies like the ALRC and AHEC have an important function to perform in developing a policy framework for protecting human genetic information. However, the present Inquiry is limited by its terms of reference: once the Inquiry reports to the relevant Ministers in March 2003 it has no formal function to perform in relation to this project. The ALRC, in particular, is limited by its constituting Act to reporting on matters referred to it by the Attorney-General.³³

2.41 However, advances in scientific knowledge will continue apace, requiring social and political responses. In Chapter 3 the Inquiry proposes the establishment of a standing body, which would have a continuing role in advising government on all aspects of human genetic science, as developments occur. Such a body has been established already in the United Kingdom under the name of the Human Genetics Commission.³⁴ As Chapter 3 indicates, there is broad support in submissions to the Inquiry for the establishment of such a body in Australia, with many of the submissions linking the need for a standing body to the challenges posed by rapidly changing science.

The scale of reform

2.42 This chapter has advocated a forward-looking approach to law reform, which acknowledges the dynamic nature of the medicine and science of human genetics. However, this does not imply that reform of the present regulatory framework is necessary on a grand scale. Reform may be effective even though the recommended changes in some areas are small.

2.43 Many chapters of this Discussion Paper advance proposals for reform that represent modest amendments to existing laws and practices — to extend coverage to genetic information, or clarify or modify the current position. Whenever it has been feasible to do so, the Inquiry has sought to build on existing institutions, laws and practices, rather than seek to erect a new edifice to deal with the challenges posed by human genetic information. In this way, the Inquiry seeks to recommend targeted reform that is efficient, cost-effective and capable of being achieved.

33 *Australian Law Reform Commission Act 1996* (Cth) ss 20–26.

34 Human Genetics Commission, *Topics*, <<http://www.hgc.gov.uk/topics.htm>>, 22 July 2002.

3. A Standing Advisory Body on Human Genetics

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Introduction

The future for genetic technology

3.1 In common with many developed countries, Australia has a policy, expressed in the Federal Government's *Innovation Statement*,¹ which places great reliance for our economic future on the emerging high technologies, including human genetic technology. Significant steps have been taken to implement this policy:

- The *National Statement on Ethical Conduct in Research Involving Humans* (hereafter the *National Statement*)² has set down a comprehensive national ethical regulatory framework for the conduct of research in general and genetic research in particular.³ (See Part D of this Discussion Paper.)

1 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future*, <<http://backingaus.innovation.gov.au/default.htm>>, 24 July 2002.

2 Prepared by the Australian Health Ethics Committee under the relevant provisions of the *National Health and Medical Research Council Act 1992* (Cth) and endorsed by the Australian Vice Chancellors' Committee, the Australian Research Council and the various learned Academies in 1999.

3 Ibid, Principles 16.1–16.23 and the section on Human Tissue (Principle 15).

- Biotechnology Australia is a whole of government initiative⁴ to coordinate efforts to develop biotechnology for the benefit of the Australian community.⁵
- The Ralph Report on taxation reform has recommended reforms to income tax arrangements to ensure that the Australian taxation regime for biotechnology companies is consistent with other OECD nations, as a means of encouraging investment in Australian biotechnology.⁶
- A major review of health and medical research in Australia has been undertaken. The Wills Report⁷ refers particularly to the need to take advantage of advances in biotechnology to improve the health of the Australian population, to build the economy and to create valuable jobs.⁸ It recognises that this window of opportunity would close given the pace of change unless Australia acts promptly.
- The Federal Government's announcement on 29 January 2002 that, as part of a shift towards setting national priority areas for research, one-third (or approximately \$170 million) of the Australian Research Council's funding grants for 2003 would be reserved for four designated key areas of scientific research, one of which is genome/phenome research.⁹

3.2 These initiatives recognise that the preconditions to economic growth in the genetic technology sector include reasonable access to research tools (including human biological material), security of investment and effective and appropriate regulation.

3.3 A central tenet of Biotechnology Australia is to ensure that 'consistent with safeguarding human health and ensuring environment protection, that Australia captures the benefits of biotechnology for the Australian community,

4 Involving the Commonwealth Departments of Industry, Tourism and Resources; Environment and Heritage; Agriculture, Fisheries and Forestry; Health and Ageing; and Education, Science and Training.

5 Commonwealth of Australia, *Australian Biotechnology: Progress and Achievements*, <http://www.biotechnology.gov.au/Industry_Research/National_Strategy/prop?biotech_prog_achiev.pdf> 16 July 2002.

6 Review of Business Taxation, *A Tax System Redesigned: More Certain, Equitable and Durable: Report* (1999), Commonwealth of Australia, Canberra (Ralph Report).

7 Health and Medical Research Strategic Review, *The Virtuous Cycle, Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra (Wills Report).

8 Ibid, 1.

9 See Dr Brendan Nelson, Minister for Education, Science and Training, Minister for Education Science and Training, *Backing Australia's Ability — Funding for Research Priorities Announced*, <http://www.dest.gov.au/ministers/nelson/jan02/n06_290102.htm>, 29 January 2002. See also D Illing, 'Nelson says Research Quality Won't Suffer', *The Australian*, 6 February 2002. The other designated areas are nano and bio-materials; complex/intelligent systems; and photon science and technology.

industry and environment'.¹⁰ The former federal Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, emphasised

the driving imperative of identifying and managing any risks associated with the technology before all other matters, only then can we be truly confident about reaping the broader benefits.¹¹

3.4 The establishment of the genetic technology industry must be accompanied by appropriate legal and ethical regulatory regimes to protect the community and the research participant.¹²

3.5 Genetic science and technology is developing apace, and will provide the basis for other applied sub-branches of medical and scientific research, including bio-informatics,¹³ proteomics,¹⁴ and pharmacogenetics.¹⁵ It is of equal importance that these rapid developments are accompanied by informed consideration of the ethical, legal and social implications of the science, as well as the development of secure and appropriate ethical and regulatory frameworks.

3.6 As discussed in some detail in the IP 26,¹⁶ the pace of scientific advancement in biotechnology and in other related fields creates a degree of social ambivalence about the potential benefits and detriments of change:

On the one hand, there is very strong public support for breakthroughs promising better medical diagnosis and treatments, and for assisting with law enforcement (including identification of missing persons); on the other, there is some general fear about uncontrolled or 'mad science', the spectre of eugenics, threats of biological warfare, reports of xenotransplantation (transplants from one species to another), the loss of privacy, and the increased possibilities for genetic discrimination.¹⁷

3.7 It is an important lesson for Australians that, because of recent crises in Europe over foot and mouth disease, Creutzfeldt-Jakob Disease (CJD), genetically modified (GM) foods, human cloning, nuclear fallout from the Chernobyl disaster — and perceived inadequate government and corporate responses to these events — Europeans appear to be losing faith in the ability of public authorities to

10 See Commonwealth of Australia, *Australian Biotechnology: Progress and Achievements*, <http://www.biotechnology.gov.au/Industry_Research/National_Strategy/prop?biotech_prog_achiev.pdf> 16 July 2002.

11 In the Second Reading Speech for the Gene Technology Bill 2000 (Cth). See Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 22 June 2000, 18104 (The Hon Dr Michael Wooldridge (Minister for Health and Aged Care)).

12 See Commonwealth of Australia, *Australian Biotechnology: Progress and Achievements*, <http://www.biotechnology.gov.au/Industry_Research/National_Strategy/prop?biotech_prog_achiev.pdf> , 16 July 2002.

13 Harnessing the power of new information technology to advances in genetic science and technology.

14 Studying the genetic influences on protein production.

15 Tailoring drug remedies to an individual or group's particular genetic characteristics.

16 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.6–2.14.

17 Ibid, para 2.7.

regulate biotechnology adequately in the public interest.¹⁸ These surveys indicate a deepening suspicion of public authorities, technical experts and commercial organisations operating in this area, as well as a high (and growing) degree of scepticism about international institutions, farmers' associations and religious organisations as sources of information about biotechnology.¹⁹

3.8 By way of contrast, recent Australian surveys commissioned by Biotechnology Australia have found an *increased* level of trust in Australian government agencies as both a source of factual information and as regulators. The CSIRO was regarded as a credible source of information by 85% of respondents; the Australia New Zealand Food Authority and the Office of Gene Technology Regulator both scored 73%; and Biotechnology Australia was rated as credible by 58% of respondents.²⁰

3.9 However, this survey also found a high level of anxiety about the pace of biotechnological change (at least in part pushed along by serious concerns about human reproductive cloning) and society's capacity to regulate it effectively:

Most respondents felt that biotechnology is changing at such a rapid pace that developments cannot possibly be anticipated and legislated against. In addition, it was generally felt that Australian society and government are powerless compared to the international financial and political power of the large multinational companies driving biotechnological innovations. A key component of concern was the perception that there are no or inadequate controls over the process, motivations and outcomes of the development and application [of] biotechnology and gene technology in Australia. This was particularly a concern for those applications which were seen to raise complex and disturbing questions about human life.²¹

Advisory and regulatory approaches

3.10 The terms of reference for this Inquiry ask whether, and to what extent, a *regulatory framework* is required to protect the privacy, and protection from inappropriate discriminatory use, of human genetic samples and information. As noted in IP 26:

18 Only 45% of Europeans agreed with the statement that their governments regulate biotechnology well enough, compared with 29% who disagree, and 26% who are not sure: Eurobarometer 52.1, *The Europeans and Biotechnology*, <<http://europa.eu.int/comm/research/quality-of-life/eurobarometer.html>>, 1 October 2001.

19 Consumer organisations, the medical profession and environmental protection organisations fared best, while universities, animal protection organisations and the media (20%) had modest levels of support. See *Ibid*.

20 Millward Brown Australia, *Biotechnology Public Awareness Survey Final Report*, Biotechnology Australia, <<http://www.biotechnology.gov.au/MBsurveyresults.pdf>>, 1 July 2001.

21 *Ibid*, 29.

successfully fulfilling this brief not only involves providing adequate protections against the *unlawful* use of genetic information, but also putting into place measures aimed at ensuring that where such information may be used lawfully, it is used properly, fairly and intelligently.²²

The trend towards a national approach

3.11 The current methods of regulation and conflict resolution involve a patchwork of federal, state and territory laws; official guidelines; personal and professional ethics; institutional restraints; peer review and pressure; oversight by public funding authorities and professional associations; supervision by public regulatory and complaints-handling authorities; private interests; and market pressures.

3.12 One fundamental question is the extent to which a national approach to the regulation of human genetics may be required, rather than relying upon the traditional mix of federal, state and territory laws as well as other formal and informal mechanisms.

3.13 The location of regulatory authority in a federal system is always a matter of some contention. Uniformity has obvious advantages in terms of clarity and certainty. However, in a rapidly developing area of science and technology, there also may be something to be said for allowing innovation and experimentation on a state-by-state basis. Given the wide array of activities covered by this paper, and the constitutional limitations on the exercise of federal legislative power,²³ only a cooperative approach involving the Commonwealth, the States and the Territories would assure the successful establishment of a comprehensive national scheme.²⁴

3.14 To a significant extent, this shift towards a national approach is already taking place (see Part C). For example, the extension of privacy protections to cover the private sector was achieved through federal law, regulations and processes, and is overseen by the Federal Privacy Commissioner (see Chapter 7). Aspects of federal anti-discrimination law and industrial law already cover the field

22 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.20.

23 Section 51 of the Constitution specifies the areas in which the Commonwealth Parliament may legislate, such as with respect to interstate and international trade and commerce, taxation, defence, immigration, insurance, and intellectual property rights. In addition, the Commonwealth might hang the exercise of legislative power on a general peg within s 51, such as the implementation of treaty obligations under the external affairs power: s 51(xxix). The advantages of dispersed rather than centralised legislative power are outlined in G de Q Walker, *Ten Advantages of a Federal Constitution* (2001) Vol 49, Centre for Independent Studies, Sydney.

24 There are a number of ways in which this could be achieved technically, ranging from a referral of powers (most unlikely), to the adoption of uniform laws by each jurisdiction. The recent difficulties in achieving a national approach to corporate regulation that also survives constitutional scrutiny by the High Court indicates the traps in this area: see *Re Wakim; Ex parte McNally* (1999) 198 CLR 511.

(see Chapters 8 and 27). Intellectual property rights for advances in genetics are determined according to federal laws and international agreements.²⁵

3.15 The regulation of ‘therapeutic devices’ now has a national framework through the Therapeutic Goods Administration (see below). The regulation of plant and animal genetics in Australia is now the responsibility of the federal Office of the Gene Technology Regulator (OGTR) (see below). In June 2001, the Council of Australian Governments (COAG) — representing the federal, state and territory governments — agreed it was strongly in the public interest to adopt a national approach to human cloning, stem cell research and related matters. As a consequence, legislation is currently before federal Parliament that would establish a new principal committee of the National Health and Medical Research Committee (NHMRC) to regulate research involving human embryos (including embryonic stem cells) and to prohibit reproductive human cloning (see below).

3.16 In Canada, which has a federal system similar to Australia’s, there also have been strong moves towards a national approach to biotechnology regulation. The Premiers of all provinces and territories have agreed to make genetics one of five priority areas for national work, and at the August 2001 Premiers Conference, Ontario committed to producing a report on genetics and human health. The resulting report, *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, was accepted unanimously at a special Premiers Conference in Vancouver on 24–25 January 2002. The Report calls for concerted national action aimed at

the development of a shared vision across jurisdictions and for the development of shared resources. In short, it is a call for a comprehensive, patient-centred framework to assist jurisdictions in maximizing the benefits offered by new technologies and to set paths for collaborative work to better understand and address the risks. A comprehensive framework, if developed, could move Canada and all provinces and territories into the forefront of preparing for the impact of genetics. This preparation will need to take several forms. There is a strong need for greater public engagement, for increased capacity in our health system to incorporate change, and for examining new ways in which we regulate and protect.²⁶

3.17 The Federal Government of Canada subsequently has agreed to accept the Report as the basis for national (federal and provincial) work in genetics, and a working group (the Coordinating Committee on Genetics and Health) has been

25 Especially the *Patents Act 1990* (Cth) and the *World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) annexed to the Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994, ATS 8, (entered into force on 1 January 1995), which Australia incorporated into domestic law with the *Patents (World Trade Organization Amendments) Act 1994* (Cth). See Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, paras 1.65–1.78.

26 Province of Ontario, *Report to Premiers — Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf>, 21 July 2002.

established to look at a whole range of implementation issues, including whether to establish the ‘interjurisdictional co-ordinating body’ recommended by the Report,²⁷ along the lines of the UK Human Genetics Commission (discussed further below).

The Therapeutic Goods Administration

3.18 The *Therapeutic Goods Act 1989* (Cth),²⁸ administered by the Therapeutic Goods Administration (TGA),²⁹ provides a national framework for the regulation of therapeutic goods in Australia,³⁰ to ensure the quality, safety and efficacy of all medicines and medical devices and any other product represented in any way as having a therapeutic value.³¹

3.19 The TGA states that for the purposes of evaluation, assessment and monitoring activities, a therapeutic good is a product for use in humans that is used in, or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- the replacement or modification of parts of the anatomy.³²

3.20 Clearly, genetic testing technology falls within this list. The market for therapeutic goods is obviously a national (and international) one, and thus it is sensible and efficient for assessment and enforcement activities to be conducted at the national level, as happens in practice. However, although the Act provides for ‘national control’ in this area through the TGA, only Victoria, New South Wales and Tasmania have passed the necessary complementary legislation to formalise these arrangements.

27 Ibid, Recommendations 14–15, xxi.

28 The Act came into effect on 15 February 1991.

29 A Division of the Commonwealth Department of Health and Ageing.

30 The governments of Australian and New Zealand have agreed in principle to move towards a joint agency to regulate therapeutic goods in both countries: see below.

31 ‘Therapeutic goods’ are defined very broadly in s 3 of the Act; under s 7, a particular good may be gazetted as being, or not being, a therapeutic good.

32 See Therapeutic Goods Administration, *TGA General Information*, <<http://www.health.gov.au/tga/docs/html/tga/tgaginfo.htm>>, 28 July 2002.

The Office of the Gene Technology Regulator

3.21 The regulation of plant and animal genetics is now the responsibility of the Office of the Gene Technology Regulator (OGTR). The establishing legislation, the *Gene Technology Act 2000* (Cth), states that it 'is the intention of the Parliament that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States'.³³

3.22 From 1975 until recently, the federal government had in place a voluntary system for the regulation of genetically modified organisms (GMOs), under the guidance of the Genetic Manipulation Advisory Committee (GMAC) and its predecessors. There appears to have been a high level of compliance with recommendations made by GMAC. However, GMAC operated within an administrative system, with no legally enforceable auditing or monitoring of compliance and no legal basis for the imposition of penalties or other sanctions for non-compliance. While the voluntary system was considered to have provided sound technical advice, there were increasing concerns in the industry and among the general community about the lack of formal rules and standards, and questions about the degree and efficacy ethical oversight, creating uncertainty in the market and among the public.

3.23 In 1998, legislation was developed collaboratively by the federal, state and territory governments, after public consultation, to replace the voluntary system with a more formal system of regulation aimed at protecting the health and safety of Australians and the Australian environment. The *Gene Technology Act 2000* (Cth), which came into effect on 21 June 2001, applies to all dealings with GMOs including experimentation, production, breeding, and importation of a GMO, as well as using a GMO in the manufacture of another thing.

3.24 Specifically, the Act:

- establishes the Office of the Gene Technology Regulator (OGTR) to administer the legislation and make decisions under the legislation;
- establishes a scheme to assess the risks to human health and the environment associated with various dealings with GMOs;
- prohibits persons from dealing with GMOs (for example, research, manufacture, production, commercial release and import) unless the dealing:

33 Section 5. See also Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 1.31–1.34.

is exempt;³⁴ is classified as a Notifiable Low Risk Dealing (NLRD);³⁵ is specifically licensed by the OGTR;³⁶ or has been placed on the Register of GMOs;³⁷

- provides for monitoring and enforcement of the legislation, including through the certification of containment facilities³⁸ and accreditation of organisations³⁹ (which requires the maintenance of an Institutional Biosafety Committee);
- creates a number of advisory committees (see below);⁴⁰ and
- creates a centralised, publicly available database of all GMOs and GM products approved in Australia.

3.25 The Gene Technology Regulator is an independent statutory officeholder, appointed by the Governor-General (on the advice of the Executive Council) with the agreement of at least a majority of Australian jurisdictions. A Ministerial Council comprising the relevant ministers from all Australian jurisdictions provides broad oversight and policy guidance.

3.26 ‘Genetically modified organism’ is defined as:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the *initial organism*), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

34 Exempt status may be granted where the Regulator is confident that a particular dealing involves a very low risk (eg contained research involving a very well understood process for creating and studying a GMO). This means that no licence is required, provided that the activity remains within the specified parameters. No exemptions may be granted for any release of a GMO into the environment (such as field trials and commercial releases).

35 Where the dealing already has been demonstrated to pose minimal risk to workers, the general public or the environment, and may be allowed to operate under conditions specified in the regulations. This will include, among other things, requirements that the specified dealings be undertaken only in contained facilities, overseen by Institutional Biosafety Committees (IBCs) and notified to the Regulator. See s 74 of the Act.

36 The licensing system is based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public. See ss 40-72 of the Act.

37 Where the dealings already have been licensed for a certain period of time, and the Regulator is satisfied that the dealings are sufficiently safe that they can be undertaken by anyone, and that safety does not depend on oversight by a licence holder. See *Gene Technology Act 2000* (Cth) ss 76-81.

38 Ibid, ss 83-90.

39 Ibid, ss 91-98.

40 Ibid, Pt 8.

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.⁴¹

3.27 'Gene technology' is defined as

any technique for the modification of genes or other genetic material, but does not include: (a) sexual reproduction; or (b) homologous recombination; or (c) any other technique specified in the regulations for the purposes of this paragraph.

3.28 In other words, 'conventional' plant and animal breeding techniques are *not* meant to be caught by the Act — but the boundaries between conventional techniques and 'modern biotechnology' are constantly requiring re-appraisal.

3.29 Under s 27 of the Act, the OGTR has the following functions:

- (a) to perform functions in relation to GMO licences as set out in Part 5;
- (b) to develop draft policy principles and policy guidelines, as requested by the Ministerial Council;
- (c) to develop codes of practice;
- (d) to issue technical and procedural guidelines in relation to GMOs;
- (e) to provide information and advice to other regulatory agencies about GMOs and GM products;
- (f) to provide information and advice to the public about the regulation of GMOs;
- (g) to provide advice to the Ministerial Council about:
 - (i) the operations of the Regulator and the Gene Technology Technical Advisory Committee; and
 - (ii) the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;
- (h) to undertake or commission research in relation to risk assessment and the biosafety of GMOs;

41 Ibid, s 10.

- (i) to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- (j) to monitor international practice in relation to the regulation of GMOs;
- (k) to maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia;
- (l) such other functions as are conferred on the Regulator by this Act, the regulations or any other law.

3.30 Under the Act, the OGTR is not meant to over-ride existing product approval processes (such as those operated by the Therapeutic Goods Administration (TGA) or Food Standards Australia New Zealand (FSANZ)),⁴² but rather to complement those schemes and to provide relevant specialist expertise. For example, FSANZ maintains a list of genetically modified foods that are approved for use in Australia and New Zealand.⁴³

3.31 The OGTR also continues to work collaboratively with officials from all State and Territory governments on the implementation and management of the national regulatory framework, as well as with other Commonwealth departments, agencies and regulators (such as the Therapeutic Goods Administration), and its international counterparts.⁴⁴

3.32 The OGTR manages its operations (including monitoring, compliance and enforcement) with a staff of about 50, and an annual budget of approximately \$8 million. The intention is that the operations of the OGTR ultimately should be 100% cost-recovered; however, the Commonwealth Government committed to providing full funding for the first two years of operation, in express recognition of the potential impact of cost recovery on research organisations and small businesses involved with gene technology. This matter will be considered in a future review of the OGTR.

3.33 As noted above, the Act also establishes three key advisory committees⁴⁵ to assist (upon the request of either) the Regulator and the Ministerial Council on

42 Until 1 July 2002, known as the Australia New Zealand Food Authority (ANZFA).

43 A food that is, or contains, a non-approved genetically modified food or ingredient is illegal. Since December 2001, if a genetically modified version of the food exists anywhere on the international market, the Australia New Zealand *Food Standards Code* will require documentary evidence for each food to show whether or not it is genetically modified. Foods that contain novel DNA and/or a novel protein will be required to be labelled 'genetically modified'. As of August 2001, these included two forms of soybean, three forms of canola, seven forms of corn, three forms of potato, one form of sugar beet, and three forms of cotton.

44 Gene Technology Regulator, *Quarterly Report for the Period 1 July to 30 September 2001* (2002), 6–7, 21–22.

45 *Gene Technology Act 2000* (Cth) Pt 8. Committee members receive a sitting fee, determined from time-to-time by the federal Remuneration Tribunal: *Gene Technology Act 2000* (Cth) ss 103, 109 and 114.

Gene Technology. Appointments to each committee are made by the responsible Minister (currently the Minister for Health and Ageing) following consultation with the States; the OGTR; appropriate scientific, consumer, health, environmental and industry groups; and other Ministers, as appropriate.⁴⁶

3.34 The Gene Technology Technical Advisory Committee (GTTAC),⁴⁷ which replaces the old GMAC, and provides advice on scientific and technical matters including: gene technology, GMOs and GM products; applications made under the Act; the biosafety aspects of gene technology; and the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products, and the content of such principles, guidelines and codes. Up to 20 members may be chosen for their skills or expertise in one or more of a number of relevant areas including: molecular biology, microbiology or biochemistry; ecology; genetics; entomology; botany; agricultural or aquacultural systems; biosafety engineering; public health; occupational health and safety; risk assessment; clinical medicine; pharmacology; toxicology; and immunology.⁴⁸

3.35 The Gene Technology Community Consultative Committee (GTCCC) is a broadly based consultative committee which provides advice on community concerns regarding gene technology and the need for (and content of) policy guidelines and codes of practice, as well as contributing to the development of the procedural and policy documents guiding the OGTR's decision-making. Up to 12 members may be appointed, selected for their skills or experience in one or more of a number of areas of relevance to gene technology, including: the environmental issues; consumer issues; the impact of gene technology on the community; biotechnology industry issues; gene technology research issues; public health issues; primary production issues; and local government issues.⁴⁹

3.36 The Gene Technology Ethics Committee (GTEC) provides advice on ethical considerations, and the development of appropriate ethical guidelines, policies and codes of practice in relation to gene technology. Up to 12 members may be appointed, selected for their skills or experience in one or more of a number of areas, including: ethics and the environment; health ethics; applied ethics; law; religious practices; population health; agricultural practices; animal health and welfare; consumer concerns with respect to gene technology; and environmental systems.⁵⁰

⁴⁶ *Gene Technology Act 2000* (Cth) ss 100(4), 108(2), and 111(4).

⁴⁷ *Ibid*, ss 100–105.

⁴⁸ *Ibid*, s 100(5).

⁴⁹ *Ibid*, s 108(3).

⁵⁰ *Ibid*, s 111(5).

3.37 As currently operating, the full committees meet only 2-3 times per year, but working committees and sub-committees are active in developing research and policy advice around particular issues.

The proposed Embryo Research Licensing Committee of the NHMRC

3.38 In September 2001, a report of the House of Representatives Standing Committee on Legal and Constitutional Affairs recommended a uniform, national approach to legislation and the establishment of a national licensing body to regulate human cloning and research using cloning techniques.⁵¹

3.39 On 5 April 2002, the Council of Australian Governments (COAG), representing the Commonwealth, State and Territory governments, agreed to adopt a nationally consistent approach to legislation dealing with human cloning, stem cell research and related matters, with a national regulatory framework for the licensing and monitoring of embryonic stem cell research (under specified conditions).⁵²

3.40 On 27 June 2002, the Prime Minister, the Hon John Howard MP, introduced the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. The Bill creates a number of serious criminal offences (carrying maximum penalties of between 5 to 15 years) relating to (among other things) intentionally creating (cl 8), implanting (cl 9), importing or exporting (cl 10) a human clone;⁵³ intentionally creating heritable alterations to the human genome (germ line therapy) (cl 17); intentionally creating a chimeric or hybrid embryo (that is, combining human and animal cells) (cl 19); commercial trading in human eggs, human sperm or human embryos (cl 22); and various unauthorised uses of embryonic stem cells (cll 25–27).

3.41 However, for these purposes, the most important feature of the Bill is that it would establish a new principal committee of the NHMRC — the Embryo Research Licensing Committee — to regulate all research in Australia involving

51 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Parliament of the Commonwealth of Australia, Canberra.

52 M Metherell and D Smith, 'Stem-cell Go-ahead as PM Gives Way', *The Sydney Morning Herald*, 6 April 2002, 1; J Kerin, 'States Agree to PM's Stem-cell Limits', *The Australian* (Sydney), 6 April 2002, 4. The conditions involve use only of 'spare' embryos created for IVF purposes before 5 April 2002 rather than created/cloned purely for research; general consent for such medical research from the parents; AHEC to oversee the existing regime to ensure that embryos are not created for the purpose of scientific research; and a three-year sunset clause for these laws, with this area to be reviewed within that period.

53 As a stop-gap measure, the Act contained three provisions imposing a ban on human cloning and the creation of hybrid embryos: *Gene Technology Act 2000* (Cth) ss 192B, 192C, 192D. These sections will be repealed and replaced by the current Bill.

human embryos (including embryonic stem cells), through a national system of licensing (cll 35–43), monitoring and sanctions for breach (cll 48–55).⁵⁴

3.42 According to the Regulation Impact Statement tabled with the Bill, this new national regulatory system has been necessitated by:

- the current lack of consistency in regulatory coverage of human cloning and other unacceptable practices across the jurisdictions;
- the absence of a comprehensive, nationally consistent system for the regulation of research involving human embryos;
- the fundamental ethical issues posed by destruction of embryos for research and other uses;
- the ‘uneven playing field’ for researchers created by the inconsistent regulation, which may reduce the competitiveness of some researchers relative to their counterparts in other jurisdictions; and
- the impact that the current lack of certainty or national consistency in the regulatory environment may have on Australia’s international competitiveness.

3.43 Under cl 29 of the Bill, the Embryo Research Licensing Committee has responsibilities for fully administering the licensing system; establishing and maintaining a publicly available database containing information about licensed embryo research; monitoring compliance with the legislation (this may be delegated to another federal or State officer) and taking any necessary enforcement action; and providing advice to applicants on the licensing requirements and the preparation of applications.

3.44 Under cl 31(1), the Committee is to be comprised of nine members, including:

- (a) a member of AHEC;
- (b) a person with expertise in research ethics;
- (c) a person with expertise in a relevant area of research;
- (d) a person with expertise in assisted reproductive technology;
- (e) a person with expertise in a relevant area of law;

54 According to the Bill’s Explanatory Memorandum, constitutional authority for legislating for these functions rests upon the corporations power (s 51(xx)); the trade and commerce power (s 51(i)); the external affairs power (s 51(xxix)); powers of the Parliament in relation to the Commonwealth (s 52); the census and statistics power (s 51(xi)); and ‘incidental’ power (s 51(xxxix)).

- (f) a person with expertise in consumer health issues as they relate to disability and disease;
- (g) a person with expertise in consumer issues relating to assisted reproductive technology;
- (h) a person with expertise in the regulation of assisted reproductive technology; and
- (i) a person with expertise in embryology.

3.45 Members are to be appointed by the Minister after consultation with the States and Territories, and with relevant organisations. The Minister also must have regard to the desirability of ensuring that the Committee as a whole comprises members from different States and Territories (cl 31(6)). Both the appointment of the Chair of the Committee, and the person with expertise in the regulation of assisted reproductive technology, requires the agreement of the majority of the States and Territories (cl 31(5)). Consistent with other NHMRC committees, all membership will be on a part-time basis, for a period of up to three years, with the possibility of re-appointment (cl 32).

3.46 The Committee must report to Parliament annually, and may do so at any time (cll 33-34). An independent review of the operation of the Act is called for after two years, having regard to (a) developments in technology in relation to assisted reproductive technology; (b) developments in medical research and scientific research and the potential therapeutic applications of such research; and (c) community standards (cl 61). Consistent with the COAG agreement there is also a three-year sunset provision in place with respect to the authorised use under license of an ‘excess ART embryo’,⁵⁵ which will, in effect, require a review of that compromise position.

3.47 The Financial Impact Statement contained in the Explanatory Memorandum estimates that:

Following the passage of the legislation, costs are realistically expected to be approximately \$3m per annum, with an upper maximum of \$6m. This involves a fixed cost to support the NHMRC Licensing Committee and provide for ongoing compliance monitoring related to the prohibited practices.

The international trend towards standing advisory bodies

3.48 It was pointed out to the Inquiry in many public meetings and consultations, with some degree of irony, that it is interesting that the regulation of gene technology with respect to plants and animals has been formalised, and government now has a high level source of advice in this area — but the same is not yet true with respect to *human* genetics.

⁵⁵ Clause 60, which provides for the repeal of cll 36(3)(b), 39(1)(c), 39(3).

3.49 In IP 26, the Inquiry referred to the clear international trend towards the appointment of standing bodies to advise governments on human genetics and biotechnology.⁵⁶ These developments provide us with a number of different models for consideration — although care is needed in making direct comparisons, since each body has its own particular set of functions, relationships with other public authorities, pattern of membership, and so on.

3.50 As one submission noted:

Although most [of these standing bodies] include a broad mix of people with expertise in relevant scientific and social scientific areas, they vary in some important respects:

- The area of expertise of members and the balance varies. This affects the tone and direction of [the] committee's deliberations.
- Levels of funding also vary dramatically.
- Committees operate with variable levels of transparency.
- Some committees aim for consensus, whilst others recognise the problems this entails.
- Some have the attention of government, whereas others seem to be a mechanism for distancing government from controversial issues.⁵⁷

The UK Human Genetics Commission

3.51 The Human Genetics Commission (HGC) was established following a comprehensive review by the British government in May 1999 of the regulatory and advisory framework for biotechnology, and replaces an earlier advisory committee. While that review indicated that the then existing system for regulating individual products and processes was operated satisfactorily, it was concluded that changes were needed to make the advisory framework:

- more transparent, in order to gain public and professional confidence;
- more streamlined, in order to avoid gaps, overlaps and fragmentation;
- capable of dealing with rapid developments, and to able take broad social and ethical issues fully into account.

56 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.151 and following.

57 K Liddell, *Submission G141*, 23 March 2002.

3.52 The HGC now plays a key role in the UK's advisory and regulatory framework, including:

- assisting in the identification of gaps, overlaps, fragmentation or other problems, and ways of addressing them, by promoting co-ordination between bodies in the advisory and regulatory framework for human genetics;
- developing an overview of the regulatory and advisory framework, enabling the HGC to advise Ministers as needed on issues relevant to the framework as a whole;
- managing change, by providing information which will inform Ministers' decisions on the practical implications of advances, by identifying current and potential developments in human genetics and their implications for the National Health Service (NHS) and providing guidance as needed on general issues around the introduction and use of novel technologies, including in the NHS; and
- providing advice to Ministers, to inform decisions on broad social and ethical issues, in particular information on the current situation, likely developments and the views, wishes and concerns of the public and other stakeholders.

3.53 The HGC already has published a number of useful research and information documents, commissioned a survey of public opinion, and engaged in a significant level of public consultation.⁵⁸ In May 2002, the HGC published its report *Inside Information*, the findings and recommendations of which are considered in various parts of this Discussion Paper.⁵⁹

3.54 The 22 part-time members of the HGC cover a wide range of expertise, interests and experience, including clinical genetics, genetic research, general medical practice, law, bioethics, theology, disability advocacy, nursing, pharmaceutical research, consumer protection, journalism, and family studies, as well as the chair of the Human Fertilisation and Embryology Authority and the nominees of the Chief Medical Officers from each of the four home countries in the UK. Appointments are usually for three years and may be renewable. The

58 Human Genetics Commission, *The Human Genetics Commission Website*, <<http://www.hgc.gov.uk/>>, 15 July 2002.

59 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, Department of Health (UK), <<http://www.hgc.gov.uk/insideinformation/index.htm#report>>, 30 July 2002.

Secretariat for the HGC is provided by officials of the Department of Health and the Office of Science and Technology, and is based in the Department.⁶⁰

3.55 In order to develop its projects, the HGC has operated through a number of Working Groups and Sub-Groups (comprised of HGC members and co-opted experts), including the Working Group on the Storage, Protection and Use of Genetic Information (6 HGC members plus 1 co-opted); the Working Group on Genetic Testing Services supplied Direct to the Public (10 HGC members); the Public Involvement in Genetics Sub-Group (6 HGC members plus 3 co-opted); and the Horizon-Scanning Sub-Group (4 HGC members plus 3 co-opted).

3.56 In a particularly interesting initiative, the HGC also has set up a Community Consultative Panel of 106 people, to provide the direct insights and experiences of people with a genetic disorder and to act as a sounding board for the HGC's reports and recommendations. The Panel includes people who have experience of single gene, chromosomal and multifactorial disorders, and of early and late onset disorders. Some Panel members are themselves affected, others are carriers or have experience as a parent of a child affected by a genetic disorder or as a carer for someone in the family who is affected.⁶¹

The European Life Sciences High Level Group

3.57 In April 2000, the European Union's Research Commissioner established an 11-member Life Sciences High Level Group (LSHLG), 'to meet the need for high-level advice on the life sciences and technologies'. Duties include keeping the Research Commissioner informed about 'the current situation in this field and on imminent or foreseeable developments', as well as contributing to:

the organisation and animation of a Life Sciences Discussion Platform, enabling scientists to engage in debate with the various 'stakeholders' interested in the beneficial application and dissemination of the new knowledge.⁶²

The US President's Council on Bioethics

3.58 In 1995, the US National Bioethics Advisory Commission (NBAC) was established pursuant to an Executive Order by then President Bill Clinton.⁶³ The

60 According to the HGC's first annual report, the budget for its operations in the financial year 2000/2001 — not including the staff costs of the Secretariat — was approximately £250,000, plus specific project funding of £102,500. See Human Genetics Commission, *First Annual Report 2001*, <http://www.hgc.gov.uk/business_publications_annualreport_first.pdf>, 56.

61 See the Human Genetics Commission website: Human Genetics Commission, *HGC's Consultative Panel of People Affected by a Genetic Disorder*, Department of Health (UK), <<http://www.hgc.gov.uk/cpanel/index.htm>>, 30 July 2002.

62 See The European Commission, *Genetics and the Future of Europe*, <<http://europa.eu.int/comm/research/quality-of-life/genetics.html>>, 5 October 2001.

63 *Executive Order 12975*, 3 October 1995, United States. See Office of the Press Secretary of the White House, *Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission*, <<http://www.georgetown.edu/research/nrcbl/nbac/about/eo12975.htm>>, 30 July 2002.

NBAC was charged with reviewing and making recommendations regarding the appropriateness of all governmental ‘programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior’, as well as ‘the clinical applications of that research’.⁶⁴

3.59 As a first priority, the NBAC was directed to consider the

protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting.⁶⁵

3.60 The NBAC’s membership consisted of

not more than 18 non-government members appointed by the President. At least one member shall be selected from each of the following categories of primary expertise: (1) philosophy/theology; (2) social/behavioral science; (3) law; (4) medicine/allied health professions; and (5) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.⁶⁶

3.61 The NBAC originally had a two year sunset clause. This was extended twice,⁶⁷ but the Charter of the NBAC was allowed to lapse on 3 October 2001.⁶⁸

3.62 President George W. Bush established the President’s Council on Bioethics by Executive Order in November 2001;⁶⁹ appointments were made and the Council commenced operations early in 2002.⁷⁰

64 *Executive Order 12975*, 3 October 1995, United States, s 4.

65 *Ibid*, s 5.

66 The original membership provision of *Ibid* (s 3) was repealed and replaced in September 1999 by *Executive Order 13137: Further Amendment to Executive Order 12975*, 16 September 1999, United States, s 2. See Office of the Press Secretary of the White House, *Further Amendment to Executive Order 12975, as Amended, National Bioethics Advisory Commission*, <http://www.georgetown.edu/research/nrcbl/nbac/nbac_extended.html>, 30 July 2002.

67 *Further Amendment To Executive Order 12975*, 16 May 1997, United States; *Executive Order 13137: Further Amendment to Executive Order 12975*, 16 September 1999, United States: see Office of the Press Secretary of the White House, *Further Amendment To Executive Order 12975, Extension of the National Bioethics Advisory Commission*, <<http://www.georgetown.edu/research/nrcbl/nbac/about/further.htm>>, 30 July 2002 and Office of the Press Secretary of the White House, *Further Amendment to Executive Order 12975, as Amended, National Bioethics Advisory Commission*, <http://www.georgetown.edu/research/nrcbl/nbac/nbac_extended.html>, 30 July 2002.

68 See National Bioethics Advisory Commission, *NBAC*, National Reference Center for Bioethics Literature, <<http://www.georgetown.edu/research/nrcbl/nbac/>>, 30 July 2002.

69 *Executive Order 13237*, 28 November 2001, United States: see The President’s Council on Bioethics, *Creation of The President’s Council on Bioethics*, <<http://www.bioethics.gov/executive.html>>, 30 July 2002.

70 The President’s Council on Bioethics, *President Names Members of Bioethics Council*, <<http://www.bioethics.gov/whpress.html>>, 30 July 2002.

3.63 The Council's stated purpose is to advise the President on bioethical issues related to advances in biomedical science and technology. In connection with its advisory role, the Council's mission includes:

1. to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology;
2. to explore specific ethical and policy questions related to these developments;
3. to provide a forum for a national discussion of bioethical issues;
4. to facilitate a greater understanding of bioethical issues; and
5. to explore possibilities for useful international collaboration on bioethical issues.⁷¹

3.64 According to the Executive Order, appointments are for a period of two years, and membership is to be drawn 'the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences. The first group of 17 appointments includes mainly scientists, ethicists, lawyers, philosophers and social scientists — and, interestingly, no one from the biotechnology industry.'⁷²

The Canadian Biotechnology Advisory Committee

3.65 The Canadian Biotechnology Advisory Committee (CBAC), is a 21-member group established in 1999 to provide independent advice to the seven Ministers of the federal Biotechnology Ministerial Coordinating Committee (BMCC)⁷³ on a broad range of ethical, social, regulatory, economic, environmental and health issues related to the development and application of biotechnology. In this respect, the body is similar in nature to Biotechnology Australia.

3.66 The CBAC's mandate is to advise BMCC on the full range of strategic and policy directions and priorities related to the development and application of biotechnology in Canada, but it is not involved in specific regulatory decisions. The CBAC is to have regard to the ethical, social, regulatory, economic, environmental and health aspects of biotechnology, with a brief to:

- optimize the economic, health, safety and environmental benefits of biotechnology in a sustainable way in Canada through the CBS;

71 *Executive Order 13237*, 28 November 2001, United States: see The President's Council on Bioethics, *Creation of The President's Council on Bioethics*, <<http://www.bioethics.gov/executive.html>>, 30 July 2002.

72 The President's Council on Bioethics, *President Names Members of Bioethics Council*, <<http://www.bioethics.gov/whpress.html>>, 30 July 2002.

73 These include the Ministers of Agriculture and Agri-Food; Environment; Fisheries and Oceans; Foreign Affairs and International Trade; Health; Industry; and Natural Resources.

- ensure the science base which supports the governments regulatory role is maintained and internationally competitive;
- incorporate social and ethical considerations into policy making; and
- enhance public awareness and facilitate an open, transparent national conversation on key issues around the development and application of biotechnology in Canada.⁷⁴

3.67 The 17 members of the CBAC are drawn from a wide range of backgrounds and cover many areas of expertise, including clinical medicine; medical research; nutrition; agriculture; agricultural economics; veterinary science; health law; biochemistry, molecular biology and genetics; bioethics; environmental law; environmental studies and sustainable development; and business, as well as members of the general public.

3.68 All members are part of the CBAC's 'Committee of the Whole'. The organisation's management structure then involves an Executive Committee, comprising the Chair and the heads of the three Standing Committees (Stewardship, Citizen Engagement and Economic and Social Development). There are also Steering Committees for each of the CBAC's 'special projects', which currently are: The Regulation of Genetically Modified Foods; Protection and Exploitation of Biotechnological Intellectual Property; Incorporating Social and Ethical Considerations into Biotechnology; The Use of Novel Genetically-Based Interventions; and Genetic Privacy.⁷⁵

The Ontario Advisory Committee on Genetics

3.69 In April 2000, the Canadian Province of Ontario's Ministry of Health and Long-Term Care (MOHLTC) established an Advisory Committee on New Predictive Genetic Technologies 'to help Ontario navigate the new frontier of human genetic medicine and science',⁷⁶ with a mandate to:

develop a policy framework for introducing new genetic predictive testing and services into Ontario's health care system. This framework would help ensure that the provincial health system promotes wellness and improves health outcomes in advance of the appearance of disease. The Committee would also develop guidelines, principles, broad criteria and advice to guide decisions on how new genetic services should be incorporated into the province's health care system.⁷⁷

74 See Canadian Biotechnology Advisory Committee, *Mandate*, <<http://www.cbac-cccb.ca/english/mandate.aro>>, 30 July 2002.

75 See Canadian Biotechnology Advisory Committee, *CBAC Organization*, <<http://www.cbac-cccb.ca/english/organization.aro>>, 30 July 2002.

76 *Report of the Provincial Advisory Committee on New Predictive Technologies*, Canada, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep01/genetic_report.pdf>, 30 July 2002, 1.

77 Ibid.

3.70 The multidisciplinary Advisory Committee included: geneticists; a genetic counsellor; family physicians; genetic researchers; laboratory directors; academics in law, ethics and medicine; educators; a clinical epidemiologist; and an expert in psychosocial issues; as well as representatives from the Canadian Cancer Society, the Heart and Stroke Foundation, the Huntington Society of Canada, the Ontario Association of Medical Laboratories, the Ontario College of Family Physicians, the Ontario Hospital Association, and the MOHLTC.

3.71 The work of the Committee was divided among six sub-committees, which were able to co-opt additional expertise, as needed: education; evaluation; clinical practice; psychosocial issues; laboratory practice; and legal and ethical issues.

3.72 The Report has a number of interesting things to say about the impacts of the new genetic technology on health systems, clinical practice, patients and the general community, as discussed in the relevant sections of this Discussion Paper. However, the central recommendation was that:

the need for further consultation and implementation be recognized through an ongoing process. With this in mind, it is recommended that Ontario establish a Provincial Genetics Advisory Committee ...⁷⁸

3.73 The suggested areas of coverage for this proposed permanent advisory committee include:

- New developments in the genetic sciences;
- Evaluation of existing genetic services;
- Recommendations on the timely provision of new genetic tests and services following formal evaluation of proposed genetic testing by the committee;
- Legal and social issues;
- Human and infrastructure resource requirements for genetic services;
- Educational needs for Ontarians, including professions involved in all aspects of the provision of genetic services;
- A process for the implementation of new genetic services that includes both public and private laboratories; and
- Any other areas as requested by the provincial government.⁷⁹

⁷⁸ Ibid, 70.

⁷⁹ Ibid.

3.74 The Report also recommended that the advisory committee's membership should be broadly constituted:

reflective of the broad based expertise necessary to achieve its mandate including geneticists, genetic counsellors, health economists, legal/ethical experts, epidemiologists, laboratory scientists, mental health professionals, and community representatives, including members of health related voluntary organizations.⁸⁰

3.75 Another issue considered was to whom the advisory committee should report. Although it was acknowledged that many of the issues which will arise for the committee would fall within the jurisdiction of other departments, such as Education, Finance, and Consumer and Commercial Relations, it was decided that it would be best for the committee to be situated in the Ministry for Health and Long-Term Care, since the core of its responsibilities will be connected to patient interests and the improvement of the publicly funded health care system. The Report also sensibly proposed that the new advisory committee maintain close liaison with other relevant committees, such as those that deal with the nature and quality of laboratory services.⁸¹

3.76 On 24 July 2002, the Minister for Health and Long-Term announced the establishment of the Ontario Advisory Committee on Genetics, chaired by the President of the Canadian College of Medical Geneticists, Dr Ronald Carter, with a brief to:

provide advice to the government about the newest developments in genetic sciences and new genetic tests to benefit the people of Ontario. ... The committee's mandate will also include clinical evaluation of existing genetic services and recommendations on the timeliness of new genetic tests and services following formal evaluation of proposed genetic testing by the committee.⁸²

The proposed Canadian 'interjurisdictional co-ordinating body'

3.77 As noted above, the leading work done by Ontario on genetics was developed into a national report entitled *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*,⁸³ which was accepted by the Premiers of all Canadian provinces and territories at a special Premiers Conference in January 2002. The Report recommended the establishment of an 'interjurisdictional co-ordinating body'⁸⁴ or human genetics commission, along the lines of the UK Human Genetics Commission, to provide national leadership, oversight and regulation in this area:

80 Ibid.

81 Ibid.

82 Ontario Ministry of Health and Long-Term Care, *Clement Names Chair of the Genetics Advisory Committee*, <<http://www.gov.on.ca/health>>, 27 July 2002.

83 Province of Ontario, *Report to Premiers — Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf>, 21 July 2002.

84 Ibid, Recommendations 14–15, xxi.

The report urges governments to work together to ensure appropriate and comparable quality standards are in place across all jurisdictions providing genetic testing including: appropriate criteria for deciding when to test, monitoring processes for lab quality, protocols for ensuring appropriate counselling and support, and processes regarding test reviews for accuracy and reliability.

The report notes the need for appropriate capacity to monitor trends in medical genetics and assist all jurisdictions in addressing the ethical, legal and service delivery issues they will face. Stressing the need for a coordinated approach, the report suggests the possible creation of a human genetics commission to assist all jurisdictions.

The report also notes the importance of ensuring comparable quality assurance regimes and standards are in place and urges jurisdictions to cooperate in developing common approaches. In terms of federal review and approval processes, the report stresses the need for vigilance in the review and approval of new kit-based forms of genetic tests.⁸⁵

3.78 The federal government of Canada has accepted the report as the basis for developing a national (federal and provincial) approach to challenges of the new genetics. A working group (the Coordinating Committee on Genetics and Health) has been established to consider a range of implementation issues, including whether and how to establish a Canadian human genetics commission.

A Human Genetics Commission of Australia (HGCA)?

Is there a need?

3.79 It may be said that there once was a time when the suggested solution to every significant social issue was the establishment of a specialised agency or tribunal to deal with it. However, as a general matter, it is now the ALRC's strong preference to utilise or build upon existing institutions wherever possible, and the Commission:

is reluctant to recommend the establishment of a new body if the functions envisaged for the [new body] could be as efficiently and effectively carried out by existing agencies.⁸⁶

3.80 However, it is sometimes the case that the establishment of a new federal body is necessary and desirable,⁸⁷ such as where:

⁸⁵ Ibid, iv.

⁸⁶ Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), ALRC, Sydney, para 4.78. The discussion about 'federal agency non-proliferation' occurred in the course of concluding not to recommend the establishment of a new Federal Legal Services Forum, as had been mooted in the preceding Discussion Paper.

⁸⁷ For example, within the Attorney-General's portfolio, the Government recently has funded the establishment of a National Judicial College of Australia, and a National Pro Bono Resource Centre.

- there are no plausible institutional alternatives, even with a re-arrangement of functions or an addition of budget and staff for an existing body;
- such action represents an efficient and effective use of public funds; and
- the federal government has, or wants to have, a stake in the area and can contribute positively by providing leadership or coordination at the national level.⁸⁸

3.81 Everything written and said about the emerging genetic science and technology — including in the public meetings of, and submissions to, the Inquiry — emphasises the rapid speed at which developments are taking place.

3.82 In IP 26, the Inquiry noted that:

The pace of biotechnological change equally affects Australia, and Australian governments arguably have the same need for ready access to the best possible advice about current and potential developments in human genetics and their implications for health care and human rights. As discussed above, there is a continuing need for our laws, and the fundamental concepts underlying those laws, to be reviewed and revised to address advances made by human genetic science and technology. However, no such standing body on human genetics currently exists in Australia.⁸⁹

3.83 In this particular case of human genetics, the pace of change challenges the capacity of governments to develop sound policy and put in place effective regulatory strategies — although this also could be argued, for example, in relation to new information and communications technologies, the growth of the internet and related e-commerce applications. However, the ‘new genetics’ also contains special and further challenges for the way in which our society defines the ‘normal’, and the way in which people think about themselves and their own humanity.

3.84 The American political philosopher Professor Francis Fukuyama⁹⁰ recently wrote (in moving beyond his forecast ‘end of history’ to ‘our post-human future’) that:

Some new technologies are frightening from the start, and the need to establish political controls over their development and use is obvious to all. When the first atomic bomb was detonated at Alamogordo, New Mexico, in the summer of 1945, not one of the witnesses to this event failed to understand that a terrible new potential for destruction had been created. Nuclear weapons were thus from the very beginning

88 And only where, of course, the Commonwealth has Constitutional authority to act: see footnote 156, below.

89 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.158.

90 The Bernard L. Schwartz Professor of International Political Economy at the School of Advanced International Affairs, Johns Hopkins University. Prof Fukuyama is also a member of the President’s Council on Bioethics.

ringed with political controls. Individuals could not freely develop nuclear technology on their own or traffic in the parts necessary to create atomic bombs, and in time, nations that became signatories to the 1968 non-proliferation treaty agreed to control international trade in nuclear technology.

Other new technologies appear to be much more benign, and are consequently subject to little or no regulation. Personal computers and the Internet, for example, promised to create wealth, increase access to information, and foster community among their users. ...

Biotechnology falls somewhere between these extremes. Transgenic crops and human genetic engineering make people far more uneasy than do personal computers or the Internet. But biotechnology also promises important benefits for human health and well-being. When presented with an advance like the ability to cure cystic fibrosis or diabetes, it is hard for people to articulate reasons why their unease with the technology should stand in the way of progress. It is easiest to object to a new biotechnology if its development leads to a botched clinical trial or to a deadly allergic reaction to a genetically modified food. But the real threat of biotechnology is far more subtle and therefore harder to weigh in any utilitarian calculus. It lies in the possibilities of human cloning, 'designer babies' – eugenic selection for intelligence, sex, and personality – and eventually, the end of the human species as such.

In the face of the challenge from a technology like this, where good and bad are intimately connected, there can be only one possible response: We must regulate its development — and set up institutions that will discriminate between those technological advances that further human flourishing, and those that pose a threat to human dignity and well-being. These regulatory institutions must have the power to enforce these discriminations on a national and, ultimately, an international level.⁹¹

3.85 Fukuyama — an unlikely champion of heavy-handed regulation, given his previous writing — goes on to suggest that the new biotechnology raises so many challenges to the survival of society as we know it that formal regulation is required:

It has been a long time since anyone has proposed that what the world needs is more regulation. Regulation — and particularly international regulation — is not something that should be called for lightly. Before the Reagan-Thatcher revolutions of the 1980s, many sectors of the economies of North America, Europe, and Japan were vastly overregulated, and many continue to be so today. Regulation brings with it many inefficiencies and even pathologies. But in the end, there are certain types of social problems that can only be addressed through formal government control, and biotechnology is one of them.⁹²

3.86 As noted above, Australian governments have chosen to take direct, concerted action to prohibit various activities, such as human reproductive cloning and the creation of chimeric embryos, and have proposed giving the new regulator, the Embryo Research Licensing Committee of the NHMRC, strong powers, with significant criminal penalties attaching to any intentional breach.

91 Advanced excerpts from F Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002) Profile Books, London.

92 Ibid.

3.87 However, this Inquiry is concerned primarily with protecting individuals against the adverse effects of the misuse of genetic information (loss of privacy, unfair discrimination) and of poor ethical practices (loss of autonomy), rather than the potential direct threat to the future of the human genome that may be occasioned by certain types of experimentation. The balanced strategy we are proposing relies more on providing high level advice to government policy-makers, and putting in place measures to ensure more careful and intelligent handling of genetic information and samples, with a number of targeted interventions in certain cases (such as most employment circumstances) where the potential harm from the misuse or misunderstanding of genetic information is great, and the impositions are minor by comparison.

3.88 There is thus a critical need to ensure that the general community is much better informed about genetics and human health, and disabused of unbalanced notions of genetic determinism. While there is currently strong public support for genetic research, there is always the danger of a backlash if the promise of such work is over-sold or poorly understood. A recent editorial in the *British Medical Journal* put the case well:

Over time, the tendency has been to expand diagnostic and treatment boundaries, and to include in the 'disease' category people with milder manifestations of pathology and lower levels of risk. Genetic tests for markers that may not result in symptoms for half a century or more could be new examples of a process of premature medicalisation of attaching the 'disease' label before it has been established that prevention or treatment is clearly beneficial. Treating the presence of a genetic marker as though it were the clinical disease can be very unhelpful. ...

Unless it is established that a genetic variant is a pointer to beneficial action, there is a potential for inappropriate medicalisation through the spread of poorly understood tests. The perceptions of risk resulting from such tests may bear little relation to the scientific facts and uncertainties. Inflated ideas about risks could result in people carrying such polymorphisms being treated unfairly in many areas, including employment or insurance. ...

The antidote to genetics as a driver of medicalisation lies in remaining sceptical and level headed. Genetic claims, tests, and products should be treated in the same way that other medical markers and interventions are increasingly treated: with rigorous evaluation. The successful management of genetic medicalisation will depend on clinical evaluation, integrity, and transparency and on providing accurate information to consumers and patients. Public education about interventions based on genetic science will also be needed to prevent inappropriate social responses that may either lead to discrimination or, conversely, prohibit the adoption of tests and treatments that can reduce or prevent disability. Genetic technologies have the potential to be of major benefit to society, but their introduction must be measured, attentive to the social and ethical considerations of the day, and, most importantly, based on best evidence.⁹³

93 D Melzer and R Zimmern, 'Genetics and Medicalisation' (2002) 324 *British Medical Journal* 863.

3.89 Later in this chapter, the enhancement of public and professional education about human genetics is assigned to the proposed new Human Genetics Commission of Australia as one of its areas of shared responsibility.

Submissions about a standing advisory body

3.90 In IP 26, the Inquiry asked whether ‘we need our own version of the UK’s HGC’.⁹⁴ The submissions strongly favoured such an approach on its own merits, as well as by way of contrast with the possibility of trying to develop hard legislative or regulatory prescriptions at this point in time.

3.91 The Commonwealth Department of Health and Ageing submitted that:

A national mechanism or ‘standing body’ may be helpful in ensuring the provision of integrated advice to government on a range of human genetic matters. The recently established UK Human Genetics Commission provides one possible model that could be examined.

All jurisdictions are grappling with the issues relating to the protection of health information generally. Given the potential to create a ‘railway gauge’ scenario of differing legislative regimes across jurisdictions, the Department strongly supports the adoption of a *nationally consistent* approach to the protection of health (including genetic) information. Notwithstanding the moves in this direction with federal privacy legislation, there is a need for national coordination and leadership in developing standards, guidelines, and codes of conduct, particularly in relation to the commercial uses of genetic information.

The NHMRC, through its Research Committee, Health Advisory Committee and AHEC, has important responsibilities in advising government in relation to public health standards, medical and public health research, and ethics. The AHMAC has established a number of important mechanisms for developing national approaches to health care issues. Notwithstanding the valuable contributions of these existing advisory mechanisms, the Department notes that a national mechanism or ‘standing body’ may be helpful to coordinate government advice and policy development on the complex issues raised by the rapid developments in human genetic information and technologies.

The recently established UK Human Genetics Commission and the breadth of matters within its purview provides one possible model that could be examined. Such a body could support a coordinated national effort to ensure that the potential benefits of emerging technological advances, particularly in relation to health, are realised for both individuals and the public while minimising any potential risks. Should such a body be established, its composition should be broadly based and might include medical practitioners, ethicists, researchers, geneticists, privacy and anti-discrimination expertise, insurance and actuarial expertise, genetic counsellors and educators, lawyers, consumer representatives, disability advocates and media representatives.⁹⁵

94 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.159.

95 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

3.92 The Institute of Actuaries of Australia, which has taken a strong interest in this area in recent times because of the potential effects of emerging genetic science on insurance and other industries,⁹⁶ submitted that:

Given the very rapid progress taking place in genetics it is likely that community views will also change rapidly. New issues are likely to emerge requiring fresh thinking on suitable controls or on the continued applicability of controls that are already in place. In times of rapid change, there would be benefit to the Government in having a standing body available to alert it to matters of interest and to provide advice, this body should include consumers and experts from all interested disciplines.⁹⁷

3.93 The Human Genetics Society of Australasia (HGSA), whose membership comprises most of clinical geneticists and many of those practising in laboratory-based human genetics in Australia (and the region), wrote that:

The HGSA believes an independent Genetic Advisory Committee should be established to advise the Government in relation to the use of genetic testing in insurance and employment. There may also be a role for such a committee to provide ongoing advice to the Government on the complex issues, which will continue to arise from the rapidly evolving field of human genetics. It is recognised that existing government committees and working groups are considering various aspects of the impact of genetics in the health care system, and may make similar recommendations in the future. This committee might be envisaged to have a similar role to the UK Human Genetics Commission (HGC). The HGC was established following a comprehensive review of the regulatory and advisory framework of biotechnology. Its aim is to be transparent, in order to gain public and professional confidence; be streamlined, in order to avoid gaps, overlaps and fragmentation; ensure capacity to deal with rapid developments, and to take broad social and ethical issues fully into account within the field of human genetics.⁹⁸

3.94 The Australian Academy of Science noted that

this area of research is moving very quickly, and that laws can be difficult to amend if they no longer reflect the state of scientific knowledge and medical practice. Therefore, we urge the creation of an Australian Standing Advisory Body with both public and professional representatives to regulate issues in this area, similar to the UK Human Genetics Commission.⁹⁹

3.95 The Genetics Advisory Committee of the Victorian Department of Human Services supported the establishment of a standing body

to advise government on all aspects of human genetics, not just regulation/privacy. These issues could be viewed as a subset of the need to have national uniformity in population screening tests, indications and availability of other genetic tests, indications and availability of other genetic tests (eg whether through Medicare

⁹⁶ A Doble and others, *Genetics in Society 2001* (2001) Institute of Actuaries of Australia.

⁹⁷ Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

⁹⁸ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

⁹⁹ Australian Academy of Science, *Submission G097*, 21 January 2002.

subsidy or through specific programs which receive block funding, eg the Family Cancer Genetics Service), a national approach to better information and training for health professional as well as information to the public.¹⁰⁰

3.96 The Australian Medical Association submitted that:

It is important that a more uniform, national approach to the protection of human genetic information is developed. This is to ensure that all Australians are afforded the same rights and protection.

The AMA believes that gene technology has the potential to revolutionise both preventative medicine and the management of a vast range of medical conditions. We are keen to see the development in this country of a framework that provides for an acceptable medical use of genetic information based not only on the best available scientific evidence but also relevant social, ethical and legal considerations. The AMA's position statement on *Human Genetic Issues* acknowledges this ...

A standing body should be established to advise the government on issues related to human genetics. This body should have wide community representation to ensure that a diversity of opinions is considered.¹⁰¹

3.97 The National Council of Jewish Women of Australia wrote that a broad-based national advisory committee should be set up:

to advise and alert the Government of the day to potential problems IN ADVANCE of them becoming major problems in our community.¹⁰²

3.98 Privacy New South Wales submitted that:

The establishment of such a body is critical, particularly whilst genetic privacy regulation in Australia remains undeveloped and as the efficacy of any new legislation is monitored. The model provided by the UK's Human Genetics Commission includes appropriate representation in terms of expert and lay membership.¹⁰³

[This body] will also meet Government needs to:

1. ensure an effective strategic advisory and regulatory structure that identifies and maximises benefits from potential advances in human genetics;
2. address broad ethical, legal and social implications arising from advances;
3. manage the process of change as practical applications of advances are introduced, and

100 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

101 Australian Medical Association, *Submission G091*, 29 January 2002.

102 National Council of Jewish Women of Australia, *Submission G008*, 21 May 2001.

103 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

4. introduce public education initiatives.¹⁰⁴

3.99 The Association of Genetic Support of Australasia wrote that:

We believe a standing body to advise the government on issues related to human genetics should be established. It is important that its representation includes those with skills to address the breadth of issues generated by the new developments in technology. The UK and Canada have embraced this policy, recognising the need for continued assessment of the impact of the new genetics and the need for development of new policies and the revision of old to meet new challenges.¹⁰⁵

3.100 The Office of the Federal Privacy Commissioner noted that:

there is a need for a body of sufficient authority and status to serve as a focus and as a paradigm for the work of our social institutions. A multi-disciplinary body would be capable of identifying and responding to the influences of, and the interplay between, science, the health and legal professions, research and commerce. With these capacities, it would be an invaluable source of advice for government.¹⁰⁶

3.101 The Australian Privacy Charter Council wrote that:

These issues are too important to only be the subject of a one-off inquiry, however thorough. We are attracted to the idea of a standing committee or commission, properly resourced and genuinely independent, to monitor developments, and to play an adjudicative role in relation to exceptional uses, retention, data linkage etc.¹⁰⁷

3.102 Mr Henry Wellmore submitted that:

The area is so large and has the potential for such major social ramifications that there needs to be established a standing body to advise the government. The membership of this body should contain all the stakeholders and should be given the time and resources to develop the required expertise to address the present and future issues.¹⁰⁸

3.103 The Neurofibromatosis Association of Australia wrote that:

We see the creation of such a body as extremely important. The issues related to human genetics are complex and there does not currently seem to be a formalised structure in Australia for advising the Government nor educating the public about them.

We believe that the body would need to be provided with adequate funding to operate effectively. Ideally it should have membership drawn from a wide range of backgrounds in similar fashion to the UK Human Genetics Commission and the Canadian Biotechnology Advisory Committee described in the Issues Paper. There should be representation from disability support and advocacy groups and from disability rights groups such as People with Disabilities (NSW) Inc.

¹⁰⁴ Ibid.

¹⁰⁵ Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

¹⁰⁶ Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

¹⁰⁷ Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

¹⁰⁸ H Wellmore, *Submission G064*, 5 January 2002.

We see the role of such a body as not just participating in the regulatory framework, but also as being a focus for public education on issues related to human genetics. We see the creation of such a body as being an important outcome of this current inquiry.¹⁰⁹

3.104 Support in similar terms came from the Australian Society for Medical Research;¹¹⁰ the NSW Nurses' Association;¹¹¹ the NSW Genetics Service Advisory Committee;¹¹² Women's Health Victoria;¹¹³ the Australian Huntington's Disease Association (NSW) Inc;¹¹⁴ the Androgen Insensitivity Syndrome (AIS) Support Group Australia;¹¹⁵ the Disability Discrimination Legal Service;¹¹⁶ the Queensland University of Technology's Human Research Ethics Committee;¹¹⁷ Sydney IVF Ltd;¹¹⁸ and a number of individuals and support groups with particular interests and experience in this area.¹¹⁹

3.105 There were several submissions that were more equivocal about establishing a national standing body. Dr Paul Komesaroff and Professor Nick Saunders of Monash University wrote that they did not favour 'the development of a central regulatory authority' to deal with genetic information, since 'one of the great strengths of the Australian system has been its decentralised nature and the diverse range of views it is thereby able to sustain'.¹²⁰ The Inquiry would agree, in so far as this caution is directed at the establishment of a central *regulatory* authority for medical and scientific research. In Part D of this paper, the Inquiry proposes that the present decentralised, peer review system be maintained in this area, albeit with a number of suggestions aimed at improved performance.

3.106 Dr Komesaroff and Professor Saunders did acknowledge that:

This does not mean that there should not be a public forum or consultative body which could focus public debate and convey the range of views in the community to government. However, if this were the purpose of the body envisaged ... its terms of reference would have to be carefully formulated in these terms and its discretionary power limited.¹²¹

109 Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

110 Australian Society for Medical Research, *Submission G124*, 18 March 2002.

111 New South Wales Nurses' Association, *Submission G090*, 21 January 2002.

112 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

113 Womens Health Victoria, *Submission G076*, 3 January 2002.

114 Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002.

115 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

116 Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

117 Queensland University of Technology, *Submission G109*, 14 March 2002.

118 Sydney IVF Limited, *Submission G062*, 14 January 2002.

119 L Martinovic, *Submission G006*, 30 May 2001; J Torrens, *Submission G029*, 11 January 2002; *Confidential Submission G058CON*, 13 January 2002; F Richards, *Submission G044*, 14 January 2002; *Confidential Submission G058CON*, 13 January 2002; *Confidential Submission G058CON*, 13 January 2002; J Boyle, *Submission G057*, 14 January 2002; and *Confidential Submission G058CON*, 13 January 2002.

120 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002. Dr Komesaroff is Director of the Monash Centre for the Study of Ethics in Medicine and Society, and Prof Saunders is Dean of the Faculty of Medicine, Nursing and Health Sciences at Monash University.

121 Ibid.

3.107 The University of Tasmania-based Centre for Law and Genetics expressed strong support for the development of ‘an integrated national approach to the protection of human genetic information’.¹²² However, the Centre queried whether it is ‘necessary to establish a specific standing body to advise government on the issues involved’, suggesting instead that the partners in the current inquiry, the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) could maintain a watching brief on medico-legal matters and questions of regulation and ethical guidance.¹²³

3.108 However, the Centre’s submission does go on to recommend that ‘an independent body with multi-disciplinary expertise’ be established to provide advice on the circumstances in which employers may use genetic testing,¹²⁴ and also that an expert committee be established to advise the insurance industry about the scientific and actuarial relevance of genetic tests.¹²⁵ The Inquiry agrees with the need for establishing a source of independent advice in both of these circumstances, but prefers at this time for these matters to be included among the list of responsibilities assigned to a ‘one-stop shop’ national advisory body on human genetics (as discussed below).

3.109 The Life Sciences Network suggested that the NHMRC could have this role added to its agenda, rather than creating another standing body, noting that:

Research encompassing human genetic information is moving quickly and rather than continually amending legislation so it reflects the most recent state of scientific and medical knowledge and practice, it may be more practical to build upon the flexible and responsive approach of the NHMRC.¹²⁶

3.110 However, the Life Sciences Network’s submission was mainly concerned with matters of scientific and medical research — which the Inquiry agrees is the province of the NHMRC — rather than with some of the other matters, such as insurance and employment uses, which could be dealt with by a more generalist advisory body.

3.111 Submissions from the Queensland Government¹²⁷ and the Commonwealth Attorney-General’s Department¹²⁸ reserved judgment on the merit of establishing a standing advisory committee, pending further details on constitution, role, functions and interactions with other relevant bodies. Another submission noted the ‘international trend to appoint standing advisory bodies to deal with human genetics and biotechnology’ but cautioned that ‘one should not

122 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

123 Ibid.

124 Ibid.

125 Ibid.

126 Life Sciences Network, *Submission G129*, 19 March 2002.

127 Queensland Government, *Submission G161*, 16 May 2002.

128 Commonwealth Attorney-General’s Department, *Submission G158*, 7 May 2002.

assume that advisory commissions are obviously the best way to formulate public policy, or that their design is a straightforward matter', and that care needs to be taken in ensuring balanced membership and integrating the views of members with the contrary beliefs of other experts and with public opinion data.¹²⁹

Proposed functions

High-level advice to government

3.112 As noted above, many submissions emphasised the need for governments to receive cutting-edge advice about a range of complex issues raised by the rapidly developing field of human genetics, which integrates a broad range of expertise, experiences and perspectives. Again, as the Commonwealth Department of Health and Ageing put it:

A national mechanism or 'standing body' may be helpful in ensuring the provision of integrated advice to government on a range of human genetic matters. ... Notwithstanding the moves in this direction with federal privacy legislation, there is a need for national coordination and leadership in developing standards, guidelines, and codes of conduct, particularly in relation to the commercial uses of genetic information. ...

Notwithstanding the valuable contributions of ... existing advisory mechanisms [such as the NHMRC and AHMAC], the Department notes that a national mechanism or 'standing body' may be helpful to coordinate government advice and policy development on the complex issues raised by the rapid developments in human genetic information and technologies.¹³⁰

3.113 In this respect, the standing body envisaged by the Inquiry would have a role somewhat similar to that of the UK's Human Genetics Commission, but more closely aligned with the harder-edge approach of the new Ontario Provincial Genetics Advisory Committee (see above). The Inquiry sees a Human Genetics Commission of Australia (HGCA):

- providing on-going, high-level technical advice to Australian governments about existing and emerging issues in human genetics, and informed intelligence about likely 'over-the-horizon' issues;
- providing similar high-level advice on the ethical, legal and social implications arising from these developments;
- providing national leadership in managing the process of change smoothly and effectively — which includes engagement of the public on these issues and taking seriously community concerns and insecurities about the nature and pace of such change;

¹²⁹ K Liddell, *Submission G141*, 23 March 2002.

¹³⁰ Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

- providing a mechanism to assist with developing a more consistent national approach to these issues, including harmonised legislation and practices where appropriate;
- providing direct expertise and a consultative mechanism for the development of policy statements and national guidelines in this area, where appropriate in association with other governmental agencies or the relevant industries and organisations;
- assisting in the development of community, school, university and professional education about human genetics; and
- providing a focus for the coordination and integration of various national — and perhaps regional and international — programs and initiatives.

Determining testing policy, especially in ‘sensitive’ areas

3.114 Not all ‘genetic tests’ raise the same ethical, privacy and discrimination concerns. Some genetic tests for diagnostic purposes may simply be more accurate and less invasive than other alternatives. For example, a buccal swab submitted for DNA analysis would be preferable in most respects to a liver biopsy performed to determine whether a person has haemochromatosis, or a ‘sweat test’ conducted on an infant to diagnose whether the child has cystic fibrosis (CF). Many other current and future tests, however, will fall into a ‘grey zone’, without clear indications whether or not they should be characterised as ‘genetic’ tests, or as ‘diagnostic’ rather than ‘predictive’ or ‘research-related’ procedures.¹³¹

3.115 Part F of this Discussion Paper deals with issues relating to the regulation of access to genetic testing. Some of our proposals for reform in this area turn on the existence of an expert, independent body that can provide leadership in, among other things, identifying genetic (and related) tests that do have particular concerns or sensitivities attached to them, and thus may require special treatment. For example, restrictions may be placed on the ordering (‘request pathways’) of some tests, unless a counselling regime is in place, or the medical practitioner has particular qualifications, or both.

3.116 Similarly, the Therapeutic Goods Administration (TGA) operates a classification system for medical devices, rating products between 1 (lowest risk) and 4 (highest risk). The level of regulatory control is proportional to the degree of risk associated with the product, taking into account the benefits offered by use of the device, its intended purpose, and the effectiveness of the risk management techniques applied during design, manufacture and use. For medical devices rated

¹³¹ See Pt B, below, on genetic testing and information.

within 'class 1' a manufacturer's declaration is sufficient, but for products in 'class 4' there is full scrutiny of the product, and licensing of the manufacturer.¹³²

3.117 By and large, this rating is done on technical, and increasingly internationally harmonised, 'rules based' standards. However, it is still open to the TGA to increase the risk classification where there is evidence that it would be imperative to do so for public policy reasons. For example, silicon gel breast implants should be in 'class 2' according to the technical rules, but lingering concerns about the safety experience with breast implants in Australia led to the imposition of 'class 3' status, with a higher level of scrutiny by the regulator.

3.118 Following advice from the Inter-Governmental Committee on AIDS, Hepatitis and Related Diseases (IGCAHRD), medical practitioners and dentists do not have access to new 'rapid tests' for HIV-AIDS or Hepatitis C because of the view that, in general, they do not have the expertise to read the test results accurately nor to provide the proper counselling. Instead, test kits for HIV-AIDS and Hepatitis C are only supplied to laboratories that participate in the National Reference Laboratory's Quality Assurance program for those tests.

3.119 It is certainly possible that some genetic tests could be seen to fall in this category, requiring special rules and processes. The TGA has its own expert committees and advisory panels, but discussions with senior officials has indicated that the TGA would welcome the recommendations of an independent, national advisory body on human genetics to assist it with setting the policy parameters for regulation in this area.

3.120 Official reports in the United States¹³³ and Canada¹³⁴ have recognised that the approval process for genetic testing technology should go beyond a simple technical assessment of the product and include a second compulsory stage, as such tests are 'likely to raise many clinical, ethical or legal issues [that] would require a rigorous and formal evaluation by a multidisciplinary team'.¹³⁵ The Canadian report also notes that special concerns are raised by the possible availability in future of kit and home-based testing through direct-to-consumer marketing and over the internet. The report suggests that these issues would be appropriate ones

132 See Therapeutic Goods Administration, *Medical Devices*, <<http://www.health.gov.au/tga/devices/devices.htm>>, 30 July 2002.

133 N Holtzman and M Watson, *Promoting Safe and Effective Genetic Testing in the United States: Final Report of the Task Force on Genetic Testing* (1997), National Institutes of Health — Department of Energy Working Group on Ethical, Legal and Social Implications of Human Genome Research.

134 Province of Ontario, *Report to Premiers — Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf>, 21 July 2002.

135 Ibid, 79. See also I Blancquaert and others, 'Oversight Mechanisms for Technology Transfer in Molecular Genetics' (2001) 2 *ISUMA Canadian Journal of Policy Research* 103.

for policy advice, education and oversight by a national coordinating body, such as a human genetics commission.¹³⁶

3.121 The Genetics Advisory Committee of the Victorian Department of Human Services submitted that:

the existing ethical framework for regulation of research is adequate to protect privacy, and should not be further regulated.

We believe that a national body should be established to advise government on all aspects of human genetics, not just issues of regulation/privacy. These issues could be viewed as a subset of the need to have national uniformity in population screening tests, indications and availability of other genetic tests (eg whether through Medicare subsidy or through specific programs which receive block funding, eg the Family Cancer Genetics Services), a national approach to better information and training for health professionals as well as information for the public. Significant progress on these issues have been made with the formation of the MSAC review of genetics services, and the National Public Health Partnership's Public Health Genetics Working Group. We support the development of these national approaches.¹³⁷

Policy development in critical areas: insurance, employment

3.122 The Inquiry sees a key role for this standing body in providing advice to governments, industry, service providers and others about the permissible uses of genetic information and testing technology — both from a technical standpoint as well as in consideration of the ethical, legal and social implications — across a range of sensitive areas, such as insurance and employment.

3.123 For example, in the United Kingdom, a Genetics and Insurance Committee (GAIC) has been given the role of determining applications for the approval of specific genetic tests for use by the insurance industry, having regard to the scientific and actuarial relevance of the test. Under the British insurance industry's voluntary code, insurers only will take account of genetic tests for risk rating that have been authorised for this purpose by GAIC,¹³⁸ which comprises representatives from the insurance industry, actuaries, scientific community, and general community. Such authorisation has been granted for a number of genetic tests.¹³⁹

136 Province of Ontario, *Report to Premiers — Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf>, 21 July 2002, iii and viii.

137 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

138 Association of British Insurers, *Genetic Testing: ABI Code of Practice* (1999), Association of British Insurers, London, Principle 33.

139 See Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 11.163–11.168. See Pt G of this Discussion Paper.

3.124 No such body currently exists in Australia, although a number of submissions stressed the need for this sort of function to be performed here. For example, the Human Genetics Society of Australasia (HGSA) wrote that:

The HGSA recommends that in the final ALRC/AHEC report a recommendation should be made to set up an independent committee in Australia to make recommendations to the government regarding issues related to genetic testing in insurance. The committee should be made up of representatives from medical genetics, scientific genetics, the law and ethics, as well as lay representation and the insurance industry.¹⁴⁰

3.125 The Australian Huntington's Disease Association (NSW) submitted that there is a need for an

independent advisory committee appropriate for use/interpretation of genetic tests and information for insurance purposes.¹⁴¹

3.126 The Australian Academy of Science wrote that

insurance is a good example of an area that will be best addressed by a Standing Advisory Body with regulatory powers, rather than legislation.¹⁴²

3.127 Genetic counsellor Ms Jackie Boyle noted that:

Genetics is a rapidly changing area. A standing body would be able to look at the implications of existing and new genetic tests as they become available. It may be able to produce useful research and information documents. It is important that institutions such as insurance companies have accurate and up to date information.¹⁴³

3.128 A number of submissions drew together the need for expert advice in the area of insurance with emerging concerns about the potential for the use (and misuse) of genetic testing by employers. For example, the Centre for Law and Genetics submitted, with respect to insurance, that:

The prospects for ensuring that accurate and reliable information is uniformly available to agents and brokers would be greatly enhanced if this responsibility was shared between the insurance industry and government, through the work of an expert committee established for the specific purpose of evaluating the scientific and actuarial relevance of genetic tests proposed for use by the insurance industry in setting insurance premiums, along the lines of the Genetics and Insurance Committee (GAIC) established in the United Kingdom.¹⁴⁴

140 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

141 Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002.

142 Australian Academy of Science, *Submission G097*, 21 January 2002.

143 J Boyle, *Submission G057*, 14 January 2002.

144 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

3.129 With respect to employment, the Centre argued that:

the legitimacy of requiring genetic testing in a given situation should itself be the subject of independent review to ensure that the criteria for justifying genetic have been established. Further, it is essential that the testing undertaken is reliable and accurate and that an objective, scientifically well founded assessment is made of that test result. Responsibility for regulation and oversight of the use of genetic testing should be vested in an independent body with multi-disciplinary expertise specifically set up for this purpose.¹⁴⁵

3.130 The Office of the NSW Privacy Commissioner wrote that:

The establishment of ... an advisory committee will be important, not only in guaranteeing the validity and relevance of genetic testing information before it can be used by insurers or employers, but also in ensuring transparency and accountability in order to gain public and professional confidence.¹⁴⁶

3.131 The NSW Privacy Commissioner also suggested that the advisory committee should review the use of genetic test and family history information by insurance companies in light of advances in genetics,¹⁴⁷ and also recommended that:

the use and disclosure of genetic information should be prohibited in general and health insurance until specific tests are approved by an independent review body, such as the proposed Genetics Advisory Committee.¹⁴⁸

3.132 In Parts G and H of this paper, the Inquiry considers in much greater detail the use of genetic testing and information in the contexts of insurance and employment, and a number of specific proposals for reform are built around the establishment of an independent standing body that can provide this kind of technical and policy advice.

Public and professional education

3.133 There is little doubt that, for the benefit of the entire community, the revolutionary progress in genetic science needs to be matched with a major effort aimed at significantly raising public and professional awareness and understanding of these advances, and their ramifications for policy and practice.

3.134 There has been some criticism of the Human Genome Project for spending billions on scientific research, and some considerable amount on

145 Ibid.

146 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

147 Ibid.

148 Ibid.

bioethics,¹⁴⁹ but very little on public education. For example, the Director of Roche Genetics, Klaus Lindpainter, has argued that public education

is as much a key challenge to researchers as linking genes to function. The lack of public understanding will slow the introduction of breakthroughs on the scientific side and slow the drive to put data and patient protection mechanisms in place as genomic research moves from the lab to the clinic. All of this will rely on all of us engaging in a dialogue with the public.¹⁵⁰

3.135 The Ontario Advisory Committee on New Predictive Genetic Technologies recommended developing and promoting a genetics educational program for everyone in that Province, including health professionals and policy makers, to meet public and professional needs. They also recommended developing a specific education program for each new predictive genetic test approved as an ‘insured service’ (that is, for which a rebate may be claimed under the provincial public health insurance scheme):

Until recently, much of the practice of genetics involved diagnosing rare inherited disorders, estimating risk for family members, and providing prenatal diagnosis. There was little need for most health care providers to have any more than a rudimentary knowledge of genetics. Now, there is an urgent need for the Ministries of Education and of Colleges and Universities to review the curricula of secondary and post-secondary schools and incorporate core genetic issues.¹⁵¹

3.136 Many submissions to the Inquiry also stressed the need to commence a concerted effort at greater public and professional education in this area, and a number linked this to the establishment of a standing advisory body. For example, Women’s Health Victoria submitted that:

There is definitely a need to educate health professionals better about practical and ethical principles involved in genetic testing and information. This could be one of the functions of the standing body on human genetic information.¹⁵²

3.137 The Genetics Advisory Committee of the Victorian Department of Human Services wrote that a standing advisory commission should lead

a national approach to better information and training for health professional as well as information to the public.¹⁵³

149 About 3–5% of the budget of the public consortium involved in the Human Genome Project was dedicated to exploring the ethical, legal and social implications (ELSI) of the medical and scientific research: see <<http://www.ornl.gov/hgmis/resource/elsi.html>>. The private company involved in the human genome mapping exercise, Celera Genomics, is thought to have spent less than this on ELSI studies and public educational initiatives.

150 K Howard, *Human Genome Project “Flat on its Face”, Must Educate the Public*, <<http://www.genomeweb.com/articles/view.asp?Article=20026418210>>, 1 April 2002.

151 *Report of the Provincial Advisory Committee on New Predictive Technologies*, Canada, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep01/genetic_report.pdf>, 30 July 2002.

152 Womens Health Victoria, *Submission G076*, 3 January 2002.

3.138 The Androgen Insensitivity Syndrome (AIS) Support Group Australia wrote that:

A genetic SAC would also be responsible for considering potential avenues of education of the wider community about the uses of genetic information.¹⁵⁴

3.139 The Neurofibromatosis Association of Australia submitted that:

We see the role of such a body as not just participating in the regulatory framework, but also as being a focus for public education on issues related to human genetics. We see the creation of such a body as being an important outcome of this current inquiry.¹⁵⁵

3.140 The Office of the Federal Privacy Commissioner wrote that:

To achieve the necessary social acceptance of genetic and technological advances, it will be essential for our institutions to operate within the following 'learning framework'. Which should encourage them to:

- keep abreast of advances in genetic knowledge, learning from their own experience and the experience of the scientific and medical applications of advances in genetic knowledge;
- in particular, ensure that health professionals and medical researchers learn from the community support groups representing those with genetic disorders in developing policies and strategies;
- incorporate that knowledge and experience in their decision-making processes;
- ensure that their decisions are transparent and accountable;
- provide the community with best possible means of understanding developments in genetic knowledge and of participating fully in the decisions which may dramatically affect their lives;
- be receptive and responsive to community perceptions, concerns and to the promotion of their legitimate interests; and
- regard as paramount an ethical approach to all their activities and outcomes.¹⁵⁶

153 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

154 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

155 Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

156 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

3.141 Although the HGCA may be in a good position to promote, advise and assist educational initiatives, this will be more at the ‘big picture’ level, and it is not anticipated that this body will be a direct provider of education. Thus, this will be another area of shared responsibility in which the HGCA will need to work closely with other groups and institutions, such as state and territory school curriculum authorities, university medical schools, the Royal Colleges, the Human Genetics Society of Australasia, and so on. Professional education in relation to genetics is dealt with in more detail in Part F of this Discussion Paper.

Structure and membership

Establishment as a statutory authority

3.142 The Inquiry’s preference at this time is for the standing advisory body to be established as an independent, federal statutory authority¹⁵⁷ — the Human Genetics Commission of Australia (HGCA) — in order best to:

- make clear its independence, and thus preserve public confidence in its findings and advice;
- encourage communications with the HGCA, even where the material is personal and sensitive and people might feel uncomfortable about so communicating with ‘the government’;
- demonstrate its status as a permanent agency;
- demonstrate its status as a multidisciplinary body, whose work extends beyond a single government department;
- develop and maintain both in-house expertise and networks of experts and stakeholders;
- ensure sufficient budget resources to fulfil its mission; and
- provide it with sufficient operational flexibility to deploy its resources most effectively.

3.143 Given the subject matter covered, the HGCA should have strong links with a number of relevant federal ministries, including the Department of Health and Ageing; the Attorney-General’s Department; the Department of Education,

¹⁵⁷ The Inquiry believes that the Commonwealth has power under the Constitution to establish the HGCA, having regard to its powers to make laws in respect of, among other things: insurance (s 51(xiv)); patents (s 51(xviii)); corporations (s 51(xx)); race (s 51(xxvi)); immigration (s 51(xxvii)); external affairs (s 51(xxix)); and incidental matters (s 51(xxxix)).

Science and Training; and the Department of Employment and Workplace Relations. If it is felt that the HGCA requires a direct relationship with a particular department, the Inquiry agrees with the view of the Canadian authorities that this logically should be the Department of Health and Ageing, since the central concerns of this body will be related to human health.

3.144 As with all federal statutory authorities, the HGCA should be accountable to the Commonwealth Parliament for its activities and use of public funds through an annual report (and such other reports as it wishes to make from time to time) and through the Senate Budget Estimates Committee process.

Composition

3.145 The run of submissions strongly emphasised the need for balanced and broad-based membership, with both 'expert' and community representation.¹⁵⁸ Similarly, a public opinion survey conducted by the University of Western Australia in 2000 also found strong support for an advisory group that comprised members of the general public as well as scientists, medical professionals and others.¹⁵⁹

3.146 The Commonwealth Department of Health and Ageing submitted that:

Should such a body be established, its composition should be broadly based and might include medical practitioners, ethicists, researchers, geneticists, privacy and anti-discrimination expertise, insurance and actuarial expertise, genetic counsellors and educators, lawyers, consumer representatives, disability advocates and media representatives.¹⁶⁰

3.147 The Disability Discrimination Legal Service (DDLS) wrote that:

The DDLS considers that such a standing body should be established and that it includes researchers with specific expertise in genetic counselling and ethical concerns, representation that reflects the special and direct ways in which people with

158 *Confidential Submission G058CON*, 13 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Nurses' Association, *Submission G090*, 21 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002; Australian Academy of Science, *Submission G097*, 21 January 2002; Institute of Actuaries of Australia, *Submission G105*, 7 March 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Queensland University of Technology, *Submission G109*, 14 March 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; Australian Society for Medical Research, *Submission G124*, 18 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002; *Confidential Submission G058CON*, 13 January 2002; Disability Discrimination Legal Service, *Submission G146*, 28 March 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

159 University of Western Australia Survey Research Centre, *Attitudes Towards Human Genome Epidemiology*, University of Western Australia, <<http://www.gshh.uwa.edu.au/survey.html>>, 1 October 2001.

160 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

disabilities are affected by human genetic information, as well as broad community representation. Essential with this representation is the need to have consumer representation by groups directly affected by human genetic information — the ‘nothing about us without us’ principle. Great care should be applied to balancing representation of such a body to ensure that insurance and industry representatives do not have undue influence, particularly in consideration of issues relating to discrimination based on the use of human genetic information.¹⁶¹

3.148 Other submissions variously highlighted the need to include (in no particular order): genetics professionals and researchers;¹⁶² health consumer representatives;¹⁶³ lawyers (covering privacy, discrimination and health law matters);¹⁶⁴ insurance industry representatives;¹⁶⁵ actuaries;¹⁶⁶ employers and trade union representatives;¹⁶⁷ clinical geneticists and medical practitioners;¹⁶⁸

¹⁶¹ Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

¹⁶² F Richards, *Submission G044*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G058CON*, 13 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Sydney IVF Limited, *Submission G062*, 14 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

¹⁶³ F Richards, *Submission G044*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Institute of Actuaries of Australia, *Submission G105*, 7 March 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

¹⁶⁴ F Richards, *Submission G044*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G058CON*, 13 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

¹⁶⁵ F Richards, *Submission G044*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Sydney IVF Limited, *Submission G062*, 14 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

¹⁶⁶ Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

¹⁶⁷ F Richards, *Submission G044*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002.

¹⁶⁸ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G058CON*, 13 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

ethicists;¹⁶⁹ genetic counsellors;¹⁷⁰ journalists;¹⁷¹ and representatives of genetic support groups and disability advocacy groups.¹⁷²

3.149 The Inquiry agrees with the submissions that the HGCA will need a wide spectrum of expertise, including both expert and community-based representation.¹⁷³ To the list above, the Inquiry would add representation from indigenous communities, given the importance and sensitivity of many of the issues in this area to Aboriginal and Torres Strait Islander communities (see Chapter 32).

3.150 As discussed above, the Inquiry believes that a national approach and harmonised laws, practices and systems are needed to protect human genetic information most effectively. Given the fact that many of the areas under review, including health care, are shared federal-state responsibilities, HGCA membership also should contain some jurisdictional balance, perhaps involving some positions dedicated for representatives from state and territory health officials. (For example, one from a large population state, and one from a small population state or territory.)

3.151 An alternative, or perhaps additional, strategy would be to consult the States and Territories with respect to other appointments. For example, the Chairs of the NMHRC and AHEC (and the proposed Embryo Research Licensing Committee) only may be appointed by the federal Minister for Health and Ageing after consultation with her State and Territory counterparts,¹⁷⁴ as well as other relevant Ministers and organisations.

3.152 Given the wide-ranging brief and thus the likely large size of the potential membership group, an effective structure might resemble that of the NHMRC, which involves a central Council with substantial diversity,¹⁷⁵ as well as a number

169 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

170 *Confidential Submission G058CON*, 13 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

171 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

172 *Confidential Submission G058CON*, 13 January 2002; Sydney IVF Limited, *Submission G062*, 14 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; Disability Discrimination Legal Service, *Submission G146*, 28 March 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

173 See the *National Health and Medical Research Council Act 1992* (Cth) s 20.

174 *Ibid* ss 21(2), 36(4). The NHMRC also contains representatives from each state and territory health authority: s 20(d).

175 For example, under s 20, the membership must contain persons with a background, knowledge or expertise in indigenous health needs, health care training, medicine, nursing, science, the trade union movement, business, consumer issues, social welfare services, environmental issues and public health issues. Under s 21, the Minister must seek nominations from the relevant bodies in each category before making the appointment.

of ‘principal committees’,¹⁷⁶ and other committees and working groups established from time to time for specific purposes. Without wishing to be overly prescriptive at this stage, it appears to the Inquiry that the HGCA would need at least two principal committees of its own, including:

- a Technical Committee—to provide the required technical, scientific and medical advice needed; and
- an Ethical, Legal and Social Implications Committee—to ensure that such matters and a broad range of social perspectives are always given full consideration.

3.153 Most, if not all, of the policy advice sought from the HGCA will involve a mix of these issues—for example, the identification of ‘sensitive’ genetic tests that require restricted access or additional counselling and support; advice to the TGA about risk classification; and advice to insurers and employers about permissible uses and interpretations of genetic testing — so that the Committees often will need to sit together, or at least contain some degree of cross-membership.

Resources

3.154 The HGCA should be given sufficient budget resources to fulfil its mission. Apart from the need to provide funds for appointees, the budget should allow for a secretariat, the development of significant in-house expertise, the ability to commission research and expert consultants where the need arises, and the need to engage the public through a website, publications, public meetings and other means.¹⁷⁷

Operate in public

3.155 The Inquiry believes that, as a general rule, meetings of the HGCA and its sub-committees should be open to the public (including media representatives), in order to ensure a high degree of transparency and accountability, maintain public confidence in the integrity of its operations, and promote public engagement.

3.156 The submission from the Australian Academy of Science also emphasised the importance of openness:

¹⁷⁶ Chairs of the principal committees are automatically members of the NHMRC under s 20(c). The number of principal committees will increase to five with the establishment of the Embryo Research Licensing Committee, as discussed earlier.

¹⁷⁷ As a rough guide, the OGTR has an annual budget of \$8 million (but also has ‘policing’ responsibilities), and the proposed new Embryo Research Licensing Committee has a projected budget of \$3–6 million per annum.

It is important that discussions of matters of principle by this body should be conducted in public, so that the public is aware of the issues and the way in which differences of opinion are resolved.¹⁷⁸

Need for effective liaison

3.157 It will be necessary for the HGCA to maintain close liaison with other relevant governmental departments and authorities, to ensure that there is no duplication of efforts, nor any gaps in coverage with respect to the effective protection of human genetic information.

3.158 For example, there should be regular communication and consultation¹⁷⁹ with: the NHMRC and its committees, including AHEC, the proposed new Embryo Research Licensing Committee, and the Gene Therapy Research Advisory Panel (GTRAP); the Australian Health Ministers Advisory Council (AHMAC) and its working parties; the Commonwealth Department of Health and Ageing; the Office of the Gene Technology Regulator (OGTR); the Therapeutic Goods Administration (TGA); the Office of the Federal Privacy Commissioner; Australian Law Reform Commission (ALRC); the Human Rights and Equal Opportunity Commission (HREOC); Biotechnology Australia; and other appropriate bodies.

A regional or international dimension?

3.159 The Inquiry's terms of reference are focussed on determining the best regulatory framework for Australia, and the proposals in this Discussion Paper are geared towards that end. However, if at some time in the future the Federal Government saw an advantage in taking a regional, or an international, approach to the protection of human genetic information, there is nothing in the pattern of proposals that would restrict this.

3.160 For example, the HGCA easily could be 'regionalised', in the same way that Food Standards Australia New Zealand (FSANZ)¹⁸⁰ is a statutory authority that spans the Tasman, with responsibility for developing food standards based on scientific and technical criteria.¹⁸¹ The Australian and New Zealand governments also recently have agreed in principle to establish a single Trans-Tasman body to

178 Australian Academy of Science, *Submission G097*, 21 January 2002.

179 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002; Queensland Government, *Submission G161*, 16 May 2002.

180 Previously known as the Australia New Zealand Food Authority (ANZFA), established under the *Australia New Zealand Food Authority Act 1991* (Cth).

181 Parliamentary Secretary to the Federal Minister for Health and Ageing, *New Food Standards Australia New Zealand Launched*, <<http://www.health.gov.au/mediarel/yr2002/tw/tw02020.htm>>, 1 July 2002.

take over the combined roles of the Australian Therapeutic Goods Administration and the equivalent NZ body (Medsafe) in regulating therapeutic goods.¹⁸²

3.161 Similarly, if the Australian Government considered that it was a pacesetter in this field, it could move in time to share this expertise with other countries in the region, or internationally, along the lines of the work of the Australian Centre for International Agricultural Research (ACIAR), a statutory authority established with a mandate to mobilise Australia's research capacity to help solve agricultural research problems in developing countries.¹⁸³

Review or sunset clauses?

3.162 In common with standing practice, the Inquiry suggests that the HGCA be subject to a basic review after two years, and a more thorough independent review after five years, and this be provided for in the constitutive legislation.

3.163 Although 'sunset clauses' are also now common in respect of new statutory authorities, the Inquiry does not favour using this device in the present case. In the view of the Inquiry, complex issues about how to deal with advances in genetic science and technology will not cease to exist in three or five or 10 years; indeed, such concerns are likely to continue, if not accelerate, for some years to come. If it happens that the HGCA comes to outlive its usefulness, it will not be a difficult matter for the Parliament to pass legislation abolishing it.

Proposal 3–1. A Human Genetics Commission of Australia (HGCA) should be established under federal legislation as an independent, stand-alone, statutory authority with sufficient resources to fulfil its mission.

Proposal 3–2. As a general matter, the role of the HGCA should be to provide:

- on-going, high-level technical advice to Australian governments about existing and emerging issues in human genetics;
- similar high-level advice on the ethical, legal and social implications arising from these developments;

182 See Therapeutic Good Administration and Medsafe, *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Goods*, <<http://www.health.gov.au/tga/docs/pdf/ttgprop.pdf>>, 30 July 2002.

183 *Australian Centre for International Agricultural Research Act 1982* (Cth); see also Australian Centre for International Agricultural Research, *About ACIAR*, <<http://www.aciar.gov.au/about/aciar.htm>>, 30 July 2002.

- national leadership in managing the process of change, including engagement of the public on these issues;
- direct expertise and a consultative mechanism for the development of policy statements and national guidelines in this area, where appropriate in association with other governmental agencies or the relevant industries and organisations;
- assistance with the development of community, school, university and professional education about human genetics; and
- a focus for the coordination and integration of various national — and perhaps regional and international — programs and initiatives.

Proposal 3–3. The HGCA also should have specific responsibility for:

- identifying genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment — such as through restricted clinical request pathways or through the assignment of a higher risk classification by the Therapeutic Goods Administration;
- approving specific genetic tests for use by the insurance industry for risk-rating purposes, or by employers for compelling occupational health and safety reasons; and
- performing any similar function or providing expert advice on any other matters relating to human genetics, upon the request of the responsible minister or ministers.

Proposal 3–4. The HGCA structure should involve at least two principal committees: (a) a Technical Committee, and (b) an Ethical, Legal and Social Implications Committee.

Proposal 3–5. Appointments to the HGCA should ensure a balanced and broad-based range of expertise, experiences and perspectives relevant to the use and protection of human genetic information. The appointments process should involve consultation with appropriate communities and stakeholders.

Proposal 3–6. As a general rule, meetings of the HGCA and its committees should be open to the public.

Proposal 3–7. The HGCA should liaise closely with other relevant governmental departments, authorities and entities (such as the NMHRC and its committees, state and territory departments of health, the TGA, the OGTR, and AHMAC) to promote a national approach to the protection of human genetic information.

Part B. Genetic Testing and Information

4. Genetic Testing

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What is genetic testing?

4.1 Genetic information may come from many sources. As discussed in Chapter 6, these sources include a person's family medical history, a clinical examination that diagnoses a genetic disorder, or a scientific test.

4.2 Scientific tests that reveal genetic information may themselves be of varying types.

- Some genetic tests directly analyse DNA or RNA. For example, testing of genetic sequence may be undertaken by targeting a segment of DNA or RNA using a technological process known as polymerase chain reaction (PCR). This process, which was developed through the pioneering work of Kary Mullis and others at the Cetus Corporation in California in 1985 and led to the award of a Nobel Prize, enables the DNA from a single cell to be reproduced in large amounts (ie amplified) for testing.¹
- Some tests do not analyse DNA or RNA material directly but test the biological products of particular genes. The measurement of certain proteins produced by genes may reveal valuable information about gene function

¹ R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 19.

itself. For example, since the 1960s newborn screening programs have tested for phenylketonuria, galactosaemia and other genetic disorders. Some of these tests do not involve PCR analysis but still provide valuable genetic information.

- Some routine biochemical tests of non-genetic substances may also reveal genetic information. For example, a positive test for high cholesterol or occult faecal blood may be the consequence of mutations in the genes conferring susceptibility to heart disease or colon cancer, respectively.² In an appropriate clinical setting, results of these biochemical tests may provide strong indicators of particular genetic disorders.
- Moreover, some medical imaging processes reveal important genetic information. For example, nuchal translucency is an imaging procedure that is sometimes performed on a human foetus in utero. By measuring the presence of abnormal swelling under the skin at the back of the foetus's neck, clinicians can predict a likelihood that the baby will have the genetic condition of Down Syndrome.

4.3 During the course of the Inquiry different views emerged as to which of the four types of tests described above should properly be regarded as genetic tests. There was general agreement that the first and second categories (namely, the direct testing of genetic material and the testing of the biological products of genes) are appropriately described in this way. However, the status of the latter two categories was contested. Some people appeared content to describe these tests as genetic tests; others took the view that they are non-genetic tests that may reveal genetic information.

4.4 The difference in description may assume importance in situations in which particular regulatory consequences flow from the classification of a test as genetic or otherwise. For example, the peak body representing life insurers in Australia, the Investment and Financial Services Association (IFSA), has developed a genetic testing policy for the industry, which regulates the use of genetic tests in underwriting life insurance products. For the purpose of the policy, a 'genetic test' is defined to mean

the direct analysis of DNA, RNA, genes or chromosomes for the purpose of determining inherited predisposition to a particular disease or group of diseases, but excluding DNA, RNA, gene or chromosome tests for acquired disease.³

2 J Beckwith and J Alper, 'Reconsidering Genetic Anti-discrimination Legislation' (1998) 26 *The Journal of Law, Medicine and Ethics* 205, 207.

3 See Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

4.5 This narrow definition corresponds most closely with the first category of tests described above. The effect is to leave a broad class of non-genetic tests, which are not covered by the industry policy and may therefore be dealt with in the traditional, and more liberal, fashion.

4.6 In many circumstances, however, this Inquiry is not concerned with the description of a particular test as genetic or otherwise. Rather it is concerned with the protection of genetic information, however it may be derived. For this reason, the Inquiry does not consider it necessary to propose a comprehensive definition of what a genetic test is. The Inquiry acknowledges that the direct testing of genetic material and the testing of the biological products of genes form part of the core conception of genetic testing for the purpose of the Inquiry. Beyond this, much will depend on the context in which the question is asked. It is unlikely that the same answers will be given in the areas of medical research, clinical diagnosis, criminal investigation or the many other circumstances in which genetic information may be sought and used.

Purposes of genetic tests

4.7 Genetic testing can be divided into two broad categories based on the purpose of the testing, namely, medical testing and identification testing. These categories are not fixed: genetic testing sought for one purpose can sometimes reveal unintended information, such as where medical testing reveals incidental information about parentage or lack of parentage.

4.8 There are numerous reasons for seeking genetic tests. Although the description given to a test varies according to context and user, the following are the most common types of genetic tests discussed in this Discussion Paper.

- **Diagnostic testing** is performed to make or confirm a diagnosis of a specific disorder in a person who generally already has signs or symptoms of that disorder.
- **Predictive or presymptomatic testing** is performed on a person who generally has no signs or symptoms of a specific disorder at the time of testing, in order to determine whether or not that person has genetic variants that increase the likelihood that the person may, or will, develop the disorder in the future. Predictive testing is often performed in relation to genetic disorders that are not evident at birth but have their onset during adulthood. Predictive testing is also called presymptomatic testing where an individual's family medical history suggests that he or she may have the genetic disorder but symptoms of it are not yet manifest.

- **Genetic carrier testing** is performed on a person to determine whether or not that person has a genetic or chromosomal abnormality that does not generally affect the person's health but increases his or her chance of having children with the disorder in question.⁴ The outcome of such testing can influence future reproductive decisions.
- **Screening testing** is performed on people who are not necessarily known to be at increased risk of a particular genetic disorder. Screening tests can be conducted on individuals, groups and entire populations, such as with postnatal screening using Guthrie cards. Cascade screening is a form of screening that is targeted to specific groups and triggered by a heightened risk identified by family medical history information. In some cases screening testing is an extension of genetic carrier testing since it allows asymptomatic individuals in the community to be tested to see if they carry a genetic defect. This information might be helpful in family planning, and would also be helpful if it allowed preventive measures to be implemented to avoid disease.⁵
- **Pre-implantation and prenatal testing** is performed on a foetus in utero (or pre-implantation in the case of embryos used in artificial reproductive technology procedures).⁶ Prenatal genetic testing is typically performed where there are 'at risk' parents, such as parents who are carriers of mutated alleles for cystic fibrosis, Tay-Sachs disease, or β -thalassaemia. In the longer term, early detection through prenatal diagnosis may permit use of therapies such as blood transfusion or surgical correction.
- **Research testing** involves the systematic analysis of genetic information to advance medical or scientific knowledge about how genes influence the health of individuals and populations. Genetic research testing may be conducted on identified or de-identified samples and generally requires the approval of a Human Research Ethics Committee, which oversees issues of consent and other ethical concerns.⁷
- **Identification testing or forensic testing** is performed on non-coding or 'junk' DNA, with respect to a number of agreed core loci, to construct a unique DNA profile for identification purposes. It is used in criminal investigations to exclude or identify a suspect; in searches for missing persons; in the identification of deceased persons; and in establishing kinship

4 Individuals sometimes experience mild health effects as a result of being carriers of the relevant mutation.

5 For example, the knowledge that someone carried the genetic defect for haemochromatosis might allow the relatively simple option of blood letting to prevent complications from the condition.

6 See also the discussion of prenatal and pre-implantation testing in IP 26: Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Ch 1.

7 See Ch 10 for further discussion.

for various purposes, including family law proceedings, immigration, and so on.⁸

Who seeks genetic testing and why?

4.9 Genetic testing is sought in various contexts for different purposes. The uses of genetic testing will expand over time as the testing processes become easier to undertake and their practical uses become clearer. Moreover, genetic testing is likely to expand due to the increasing knowledge that is becoming available about human genes as a result of the Human Genome Project. For example, in the future it is possible that pharmacogenetic technologies will change the way that pharmaceutical products are developed and delivered to patients.

4.10 Moreover, individuals appear to be increasingly inventive in the use of existing genetic technologies. During the course of the Inquiry there have been reports of novel uses of genetic testing in Australia and overseas. For example, an Australian artist is reported to have started the practice of mixing bodily samples with his paint so that DNA testing may be used to authenticate his artworks.⁹

4.11 The principal current users of genetic testing are identified below.

- **Medical practitioners** use genetic testing to diagnose patients for treatment as well as for predictive, presymptomatic, screening and prenatal purposes. Practitioners request the various types of genetic tests through 'request pathways', which may involve referral of the patient to a clinical geneticist and also pre-test and post-test counselling.
- **Medical researchers** use genetic testing to advance medical or scientific knowledge about how genes influence the health of individuals and populations. Genetic testing for research purposes may be conducted in concert with medical practitioners, who liaise with participating patients.
- **Individuals** generally cannot obtain direct access to clinical genetic testing by laboratories in Australia. Thus diagnostic, predictive, presymptomatic, genetic carrier, screening, pre-implantation and prenatal genetic testing must generally be sought through a medical practitioner. However, some laboratories offer identification testing, particularly parentage testing, directly to individuals.
- **Police** use genetic testing in law enforcement primarily for the purpose of identification, such as to identify victims, deceased persons and suspects.

⁸ See Ch 31–38 for further discussion.

⁹ O Hill-Douglas, *Cheeky Pro Hart puts DNA Signature on his Paintings*, The Age Company Ltd, <<http://www.theage.com.au/articles/2002/03/06/1015365716233.html>>, 26 July 2002.

- **Lawyers and litigants** use genetic testing as evidence in criminal and civil cases. In criminal cases, genetic testing may be used to prosecute offenders, obtain acquittals, and to press for reversal of convictions on appeal. Litigants also use genetic testing in civil cases, for example, to establish parentage in family law or succession matters. In the future, genetic testing may also be used by litigants in negligence actions to establish or defend a claim.
- **Employers** may seek to use genetic testing to screen or monitor employees or job applicants. Although this type of testing is not common in Australia at present, overseas experience suggests that these uses are likely to expand in the future. Employers may seek to conduct genetic testing to reduce workers compensation claims, comply with occupational health and safety obligations, or increase productivity by screening out employees who are most likely to be absent from work due to illness. The testing may take the form of predictive or presymptomatic testing to identify whether an individual who is currently asymptomatic has a gene that increases the likelihood that he or she will develop a disorder as a result of the workplace environment. Testing may also screen for genes or disorders that are unrelated to the workplace but which may render an individual undesirable to an employer.
- **Insurers** may use genetic testing as a component of the underwriting process in applications for personal insurance, where health information is collected to assess the risk that applicants bring to the insurance pool. The testing may take the form of diagnostic, predictive or presymptomatic testing, particularly in relation to life insurance.
- **Government agencies** may use genetic testing for purposes of identification, as well as in determining eligibility for certain programs. For example, in some cases the Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) uses genetic testing to establish family linkage for the purposes of Australia's immigration programs.

Who performs genetic testing?

4.12 Genetic testing is available from publicly or privately operated laboratories. These laboratories may be accredited or non-accredited. A national scheme of accreditation exists in Australia through the National Association of Testing Authorities, Australia (NATA). Accreditation is discussed further in Chapter 5.

Publicly operated genetic testing laboratories

4.13 Federal, state and territory governments operate genetic testing laboratories, which are usually attached to or affiliated with public hospitals or universities. Additionally, some laboratories function within a particular government department that utilises genetic testing. Some publicly funded laboratories provide genetic testing services to both the government and private sectors. For example, the Australian Federal Police (AFP) has its own forensic services division, which performs DNA identification testing exclusively for the AFP, while in South Australia the Forensic Science Centre is government funded but provides testing services to government and the private sector.

4.14 Publicly funded genetic testing laboratories operate as service-orientated testing laboratories to government, community and health professionals, or as research-orientated testing laboratories, or both.

Privately operated genetic testing laboratories

4.15 Privately operated genetic testing laboratories are sometimes affiliated with private hospitals or universities, but may also be operated as independent profit-making entities. As with public laboratories, private genetic testing laboratories may offer service-orientated testing or research testing. Private laboratories sometimes also provide genetic testing services to government on an ad-hoc basis or under contract.

Access to genetic testing

4.16 Access to genetic testing in Australia is affected by a number of factors. These include the availability of genetic tests, the cost of testing (including the availability of public and private health insurance), the request pathways through which tests are ordered and laboratory protocols in relation to the performance of testing. These issues are dealt with separately below.

Availability of genetic testing

4.17 The Human Genetics Society of Australasia (HGSA) maintains a register of medical genetic tests that are available in Australia and the laboratories that provide the tests. According to the HGSA, there are presently around 220 DNA diagnostic tests available from 41 laboratories across Australia.¹⁰

¹⁰ Not all tests are available from all laboratories. The register does not include newborn screening, laboratories that test for cystic fibrosis or forensic testing laboratories used for identification testing.

4.18 Some genetic tests offered overseas are not available in Australia. Likewise, some types of tests offered in Australia are not available, or not widely performed in other countries. The availability of genetic testing in Australia is dependent not only upon genetic testing technology, but on decisions about what constitutes ethical testing, and on a cost-benefit analysis of a particular test, where it is funded by the public purse. In addition, the availability of a genetic test in a particular laboratory may reflect the research interests of that laboratory. For example, a laboratory that undertakes research in a particular genetic disease might also offer, as part of its research work, a DNA diagnostic service in that disease.

4.19 The availability of genetic identification testing varies between States and between laboratories within a State. Identification testing is available in Australia from 21 NATA accredited laboratories and an unknown number of non-accredited laboratories for law enforcement, parentage, immigration and other purposes.

4.20 The availability of genetic testing is not limited to Australian laboratories. The marketing of genetic testing through mail order and the Internet has facilitated access to genetic testing from overseas laboratories, sometimes at lower cost. The regulation of genetic testing performed overseas is discussed in Chapter 5.

Cost of genetic testing

4.21 Genetic testing is still a relatively slow and expensive process. However, technology is advancing rapidly. The development of automated 'DNA chip' technology may soon make it technically possible and financially practicable to conduct multiplex testing, in which screening is conducted for numerous genetic mutations simultaneously in a single test procedure.¹¹ It may soon be the case that the genetic information available will outstrip the capacity of health systems to interpret it and to counsel patients effectively.¹²

4.22 As with other health services, effective access to genetic testing depends on the cost to consumers of testing procedures and on the rebates provided by public and private health insurers. The cost of genetic testing procedures varies, from less than \$100 to more than \$1000, depending on a number of factors.¹³

- **Test methodology.** Low complexity tests (eg single gene mutation) are less expensive than high complexity tests (eg full gene sequencing).

11 Also known as 'gene chips', 'biochips' and 'DNA microarrays'. See S Moore, 'Making Chips to Probe Genes', *IEEE Spectrum*, 1 March 2001, 54.

12 American Medical Association Council on Ethical and Judicial Affairs, 'Multiplex Genetic Testing' (1998) 28(4) *Hastings Center Report* 15.

13 See, eg, Children's Health System and University of Washington, *Gene Tests, Gene Clinics*, <www.genetests.org>, 22 July 2002.

- **Laboratory testing strategy.** Some laboratories test for a large number of mutations at once; others test in stepwise fashion, beginning with the most common mutations.
- **Number of individuals tested.** Several family members may need to be tested to obtain a meaningful test result.
- **Contractual agreements.** Private and public hospitals, insurers and laboratories negotiate contracts to set the price of testing and the amount of reimbursement.¹⁴
- **Specimen handling.** Some cell types require culturing or other special handling before testing.
- **Additional services.** Genetic consultation or counselling is usually recommended and sometimes required before genetic testing is performed. These fees should be considered in the total cost.

Medicare

4.23 Medicare is Australia's public health insurance scheme. Introduced in 1984 to replace Medibank, its objectives are to make health care affordable for all Australians, to give all Australians access to health care services with priority according to clinical need, and to provide a high quality of care.¹⁵

4.24 Medicare agreements currently subsidise many cytogenetic tests including chorionic villus sampling, alpha feto protein, and nuchal translucency. The Medicare Benefits Schedule (MBS) also subsidises genetic tests for only two of the approximately 220 genetic conditions that are tested for in Australia — haemochromatosis and Factor V Leiden.¹⁶

4.25 Under current arrangements, if medical practitioners wish to have a new test listed in the MBS, they must apply to the Medical Services Advisory Committee (MSAC). MSAC provides advice to the federal Minister for Health and Ageing about the strength of evidence relating to the safety, effectiveness and cost effectiveness of new and emerging medical services and technologies and under what circumstances public funding, including listing on the MBS, should be supported.

14 See Medicare Benefits Schedule, Items 66794 and 65168.

15 See Medicare website: Commonwealth of Australia, *HIC*, <<http://www.hic.gov.au/>>, 22 July 2002.

16 Under the current Medicare Benefits Schedule (MBS), the fee charged for haemochromatosis testing or Factor V Leiden testing is \$36, which attracts a 75% or 85% rebate.

4.26 MSAC has a process for assessing whether new medical technologies and procedures should be put on the MBS. MSAC is currently in the process of assessing the genetic test for Fragile X syndrome, which has been proposed as an alternative to the currently funded chromosomal tests for this condition.¹⁷

Private health insurance

4.27 Private health insurance currently provides very limited coverage for genetic testing. Private health insurers do not subsidise testing sought in outpatient services. Rather, they generally provide a subsidy only if genetic testing is required as part of a patient's treatment regime when admitted into hospital and only if MBS also provides a rebate for the test.

Request pathways

4.28 A 'request pathway' describes the steps that must be taken in order to obtain a genetic test, including referrals for testing and genetic counselling, and the law and practice that guides laboratory protocols. The request pathway for genetic testing varies according to the type of testing sought, the laboratory from which the test is sought, and the health professional who requests it.

4.29 Medical genetic testing usually requires referral from a medical practitioner as well as pre-test and post-test counselling. The request pathway for identification testing is less regulated. Generally it is available without referral or counselling; in some cases it is available without the consent of the person being tested. The request pathways for genetic testing form part of a broader discussion of the regulation of genetic testing, which is considered in Chapters 18–20.

Reliability of genetic testing

4.30 The reliability of genetic testing is an issue that underpins the use of much genetic information. The possible stigmatisation and discrimination that may flow from genetic testing are central concerns for this Inquiry. Some genetic tests are not entirely reliable for a number of reasons, both technical and non-technical. When a genetic test is not completely reliable, the effect of stigmatisation and discrimination becomes particularly acute. Issues related to the reliability of genetic information, including the interpretation of test results, are considered in Chapter 6. Reliability of genetic testing, which refers to the scientific or technical reliability of the test, is discussed below.

¹⁷ See MSAC website for further information: Commonwealth of Australia, *Medical Services Advisory Committee*, <www.health.gov.au/msac/app1035.htm>, 22 July 2002.

Scientific reliability

4.31 The scientific reliability of a genetic test may be affected by a number of factors including sample contamination, incorrect laboratory testing procedures, mislabelling, and transcription errors. Although there has been considerable attention paid in recent years to developing policies in relation to the ethical and lawful use of genetic information, there has been less discussion about the impact of erroneous information.

4.32 Every laboratory testing procedure, no matter how well-established, involves the possibility of error. This is equally true of genetic testing. For example, the PCR method of DNA amplification allows minute quantities of DNA to be replicated in a way that facilitates testing. Yet there is a danger that the sample may be contaminated with extraneous genetic material, such as from previously amplified products or from the operator, which could generate copies of irrelevant DNA. There are also occasional errors with the sequence fidelity of amplified products, resulting in reading errors.¹⁸

4.33 The scientific reliability of a genetic test is measured by the 'sensitivity' and 'specificity' of the test. These are technical terms but, in essence, refer respectively to the statistical likelihood that a 'true-positive' will return a positive test result and that a 'true-negative' will test negative. Clinicians and patients desire 100% accuracy. However, few laboratory tests are currently more than 98% sensitive and specific.¹⁹

4.34 Moreover, every test result requires individual interpretation, with a further opportunity for error to be introduced. Because genetic tests are considered to be 'scientific', many non-experts may invest excessive confidence in their significance and predictive value.²⁰ As a result, a small number of people who take genetic tests will receive inaccurate information about their condition. Whether this involves the trauma of a false positive or the spurious re-assurance of a false negative, either type of error is likely to have crucial implications for the individual who might plan his or her life on the basis of the test result. Moreover, because members of a family share genes and DNA, any error in a genetic test may have long term implications both for the person tested and his or her family. Predictive tests are particularly important in this respect because of the likelihood of a long delay before the error is recognised.

18 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 20.

19 R Linsk, *Consultation*, Sydney, 20 February 2001.

20 In the forensic context, see Ch 34–39.

Fraud

4.35 Another problem with the reliability of genetic testing procedures is the possibility of fraud. The Inquiry has received a number of submissions suggesting that laboratory protocols do not sufficiently protect against intentional interference with laboratory samples tested.²¹ One submission from a lawyer described his client's concerns about misreported parentage testing results in the following terms:

It is our client's contention that the man in the case, being very wealthy, was able to bribe the testers, or at least falsify the tests. Whether this is the case or not, the temptation to do so could be great. There seems to be secrecy about the tests in Family Law cases (the mother, for instance may not be present during the testing). There are few safeguards, and it would seem that accreditation of testers is haphazard and loose. Moreover, as your reports states (paragraph 13-68), there are ample opportunities for contamination, mislabelling and degradation of samples. ... It would also appear that not all those who advertise and conduct DNA testing procedures are accredited by NATA. Nor do they appear to be governed by any sense of professional obligation. The one tester who, in our client's case, tested positively, has refused to reveal the results. One's suspicions are aroused that this is due to his fears that the "solidarity" of his colleagues in this field would be compromised if he did so.²²

4.36 As discussed in Chapter 5, the scientific reliability of genetic testing is regulated by accreditation standards, which are administered by NATA and other bodies. However, the accreditation of a laboratory in accordance with the best technical and scientific standards is no guarantee against intentional deception by its employees. Although the Inquiry has no evidence of the incidence of fraudulent testing in Australia, the possibility of fraud identified in the above submission indicates that this matter is one of continuing concern.

21 N Turner, *Submission G083*, 14 January 2002; *Confidential Submission G074ACON*, 10 January 2002.

22 N Turner, *Submission G083*, 14 January 2002. See also *Confidential Submission G074ACON*, 10 January 2002.

5. Regulating Access to Genetic Testing

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Introduction

5.1 To date, medical practitioners have been the primary ‘gatekeepers’ of access to genetic testing and the genetic information derived from it, at least for clinical purposes. However, there are other paths by which genetic testing may be accessed. These include direct access to testing services provided by laboratories and over-the-counter or home use genetic testing kits.

5.2 This chapter focuses on regulating access to genetic testing, other than through a medical practitioner as part of health service provision.¹ The chapter examines genetic testing request pathways — the steps by which genetic testing services may be obtained from laboratories — and the implications of these pathways for individual access to testing services. The quality assurance and accreditation standards that regulate genetic testing laboratories are also discussed. The chapter then focuses on issues concerning the availability and use of over-the-

¹ A number of these issues are also examined in the context of parentage testing (see Ch 31).

counter or home use genetic testing. Finally, the chapter considers whether, in view of present and potential future access by individuals to genetic testing services, there should be additional legal protection against the taking and testing of genetic samples without the knowledge and consent of the individual concerned through the use of criminal sanctions.

Access to genetic testing and request pathways

5.3 The 'request pathway' describes the steps that individuals must take in order to obtain a genetic test. The request pathways for genetic testing vary according to the type of testing sought, the laboratory concerned, and whether there is a request from a health professional. The request pathway and the consequent ability of individuals to gain independent access to genetic testing may be constrained by laboratory and health professional practices and protocols.

5.4 Genetic testing for medical purposes usually requires a referral from a medical practitioner. The National Pathology Accreditation Advisory Council (NPAAC) Standards for Pathology Laboratories state that:

The laboratory shall ensure that all specimens are fully identified and, except in the case of certain urgent histopathology specimens, are labelled and accompanied by a written request signed by a medical or dental practitioner or other authorised person.²

5.5 Medical practitioners may request various types of genetic test, which may in turn require referral to a medical specialist, such as a clinical geneticist, or to a genetic counsellor.³

5.6 The request pathway for DNA identification testing is less constrained and varies depending on the context and the laboratory in question. Some accredited DNA forensic laboratories provide testing services to law enforcement agencies only. Others also offer their services directly to the public, where it might be used, for example, by litigants seeking to verify or challenge evidence presented by crown prosecutors.

5.7 Parentage and other kinship testing is available from at least nine accredited laboratories,⁴ from non-accredited laboratories, and from overseas laboratories that market their services over the Internet. While parentage tests that are required for family law proceedings are subject to stringent chain of custody

2 National Pathology Accreditation Advisory Council, *Standards for Pathology Laboratories* (1998), Commonwealth of Australia, Canberra, Standard 5 – Specimens: see Commonwealth Department of Health and Ageing, *Standards for Pathology Laboratories*, <<http://www.health.gov.au/npaac/docs/stanplab.htm>>, 23 July 2002.

3 Issues relating to the ordering of genetic tests by medical practitioners are discussed further in Ch 20.

4 National Association of Testing Authorities, *NATA Directories*, <<http://www.nata.asn.au/cgi-bin/natadir/page.cgi>>, 22 July 2002.

and consent requirements, other parentage testing is not. These issues are discussed in detail Chapter 31.

Quality assurance and accreditation standards

5.8 In Australia, the technical competence of genetic testing is regulated by an accreditation scheme operated by the National Association of Testing Authorities, Australia (NATA). NATA is an independent, private, not-for-profit company that operates as an association.⁵

5.9 NPAAC provides policy guidance to NATA in respect of the standards that must be adopted by pathology laboratories for NATA accreditation.⁶ NPAAC was established to make recommendations to the Commonwealth, States and Territories on matters relating to the accreditation of pathology laboratories and the maintenance of uniform standards of practice in pathology laboratories throughout Australia.

NATA accreditation

5.10 NATA operates a national accreditation system by which recognition is given to the competence of public and private genetic testing laboratories. NATA accredits both laboratories in a number of fields, including medical testing (of which genetic testing is a component) and forensic science (of which parentage testing is a component).⁷ The medical testing accreditation scheme is run jointly with the Royal College of Pathologists of Australasia (RCPA).

5.11 The Commonwealth government recognises NATA as the sole national accreditation body for establishing competent laboratory practice.⁸ According to a memorandum of understanding entered into in 1998, the Commonwealth has agreed to:

- use NATA accredited laboratories to meet its own testing needs wherever possible;

5 The NATA Board guides and monitors its activities and is drawn from the NATA Council, which comprises elected members and representatives from industry, government and professional bodies: National Association of Testing Authorities Australia, *About NATA and Accreditation* (2000).

6 See National Pathology Accreditation Advisory Council, *Functions*, <<http://www.health.gov.au/npaac/functions.htm>>, 24 July 2002.

7 There are currently 4,689 accredited laboratories in the field of medical testing and 133 laboratories in the field of forensic science. Of these, 55 laboratories are accredited for genetic testing, nine for forensic DNA typing, and nine for parentage testing. See National Association of Testing Authorities, *NATA Directories*, <<http://www.nata.asn.au/cgi-bin/natadir/page.cgi>>, 22 July 2002.

8 National Association of Testing Authorities, *Memorandum of Understanding between the Commonwealth of Australia and the National Association of Testing Authorities, Australia*, <<http://www.nata.asn.au/downloads/moa3-98.pdf>>, 22 July 2002.

- encourage state governments and other instrumentalities to adopt a similar approach; and
- commit Commonwealth government laboratories to obtain and maintain NATA accreditation.⁹

5.12 In order to obtain Medicare fees for medical services under the *Health Insurance Act 1973* (Cth), pathology laboratories must be accredited. To achieve accreditation, laboratories must comply with standards and guidelines published by NPAAC as assessed by a qualified independent body — in practice, NATA.¹⁰

Accreditation standards

5.13 There is a range of relevant standards for NATA accreditation of genetic testing. These include general requirements for competence to carry out tests or calibrations,¹¹ supplementary standards applicable to medical testing generally,¹² and supplementary standards applicable to specific forms of genetic testing.¹³

5.14 The accreditation criteria for cytogenetic and molecular genetic testing specify the management and technical requirements that each laboratory must maintain, including:

- quality systems that should provide laboratory management with continuing confidence that results and conclusions are accurate and reliable;
- records to show that staff members have been properly trained and proof of qualifications and membership of professional societies;
- documented test and calibration methods and method validation;
- instructions, safety precautions and requirements for specimen collection; and

9 NATA website: National Association of Testing Authorities Australia, *Government Requirement for NATA*, <http://www.nata.asn.au/govt_reg/govreq2.htm>, 24 July 2002.

10 See *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 1999* (Cth). The Principles are determined by the Minister for Health and Ageing under the *Health Insurance Act 1973* (Cth) s 23DNA.

11 Standards Australia, *AS ISO/IEC 17025: 1999 Australian Standard: General Requirements for the Competence of Testing and Calibration Laboratories* (1999), 1999, Sydney.

12 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Medical Testing* (2000), National Association of Testing Authorities, Australia.

13 National Pathology Accreditation Advisory Council, *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques*, 2729 (2000), Commonwealth of Australia, Canberra; National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia.

- test reports and calibration certificates.¹⁴

5.15 Similarly, accreditation criteria for DNA identification testing (including parentage testing) cover the level of training of personnel, accommodation and environmental conditions in the laboratory, test and calibration methods and method of validation used, and quality assurance protocols and procedures.¹⁵

5.16 Standards applicable to parentage testing provide, among other things, that laboratories must have documented policies for the interpretation of data for each method of DNA analysis¹⁶ and that parentage test reports must comply with the *Family Law Regulations 1984* (Cth).¹⁷

5.17 The Inquiry considers that the NATA laboratory accreditation system is an effective means of ensuring minimum standards of technical proficiency in laboratory testing, provided that the laboratories' adherence to accreditation criteria is properly monitored and the criteria are kept up to date.

Non-accredited genetic testing

5.18 Non-accredited genetic testing may be provided within Australia by a non-accredited laboratory or by an accredited laboratory that does not comply with the accreditation criteria in respect of a particular test or category of genetic testing. For example, NATA permits accredited laboratories to conduct parentage testing that does not comply with NATA requirements, provided that the laboratories do not hold themselves out as accredited for the purposes of that particular test.¹⁸ Overseas laboratories also may offer non-accredited testing services advertised through media such as the Internet. Non-accredited genetic testing is sometimes provided through over-the-counter or home use testing kits.

5.19 By definition, non-accredited testing need not comply with accreditation standards. The lack of applicable standards may raise concerns in relation to quality control and, at least in relation to parentage testing, consent to testing and chain of custody issues.

14 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Medical Testing* (2000), National Association of Testing Authorities, Australia.

15 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia.

16 Ibid, para 5.4.1. See B Atchison and N Redman, 'Interpreting DNA Evidence in Paternity Cases' (2000) 32 *Australian Journal of Forensic Sciences* 75.

17 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia, Sec 3, Pt B Supplementary Requirements for Accreditation: Parentage Testing, para 5.10.2(a).

18 National Association of Testing Authorities Australia, *Correspondence*, 12 April 2002.

5.20 While submissions and consultations highlighted a range of concerns about the availability of non-accredited genetic testing, to date these have related almost exclusively to parentage testing.¹⁹ As discussed in Chapter 31, in the interests of accurate and reliable parentage testing, the Inquiry proposes that NATA accreditation should be mandatory for all Australian laboratories conducting DNA parentage testing.

5.21 The Inquiry is considering whether non-accredited genetic testing, other than parentage testing, should also be prohibited in Australia. One option would be to enact legislation to require laboratories that conduct genetic testing to be accredited by NATA and to comply with accreditation standards in respect of all genetic testing.

5.22 Leaving aside issues relating to how such a proposal might be implemented, especially given constitutional limits on the legislative powers of the Commonwealth Parliament, a range of objections might be raised by such a proposal. Except in relation to parentage testing and over-the-counter or home use testing kits, the Inquiry has not been made aware of any specific concerns about harm caused by non-accredited genetic testing.

5.23 The ambit of any legislation requiring accreditation would have to be carefully considered. For example, the Inquiry understands that, at present, most research laboratories are not NATA accredited.²⁰ This does not mean that research laboratories fail to meet stringent standards of technical competence and quality assurance, but rather that there is no need for research laboratories to obtain accreditation, since they do not seek fees under Medicare and their test results are for internal use and not generally for reporting to patients or clients. If a general prohibition were adopted, there may need to be an exception made for genetic testing conducted in the course of medical research. Alternatively, a distinction may need to be drawn between testing used to provide clinical or medical advice, and testing used for research (in the course of which new genetic tests may be developed).

5.24 An alternative or additional means of discouraging the use of some non-accredited genetic testing would be to restrict its use as evidence in court proceedings. For example, legislation might provide that genetic test results are admissible as evidence only where the testing is conducted by an accredited laboratory in accordance with the NATA accreditation standards.²¹ In the case of

19 C Andersen, *Submission G002*, 14 January 2002; A Mercae, *Submission G031*, 12 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Victoria Police, *Submission G086*, 21 January 2002; Australian Medical Council, *Submission G065*, 15 January 2002.

20 ALRC/AHEC, *Meeting*, 9 May 2002.

21 This has been proposed in relation to parentage testing. See Ch 31.

genetic testing conducted overseas, the legislation could require that the testing be conducted to equivalent accreditation standards recognised by NATA.²²

5.25 There may be no compelling argument to regulate genetic testing in these ways when medical testing generally is not subject to a similar regime. Moreover, ensuring accreditation of all genetic testing performed in Australia will not necessarily overcome concerns about access by individuals to non-accredited genetic testing conducted overseas.

Question 5–1. Should legislation be enacted to require laboratories that conduct genetic testing to be accredited by the National Association of Testing Authorities, Australia (NATA) and to comply with accreditation standards in respect of all genetic testing?

Question 5–2. Should genetic test results be admissible as evidence in court proceedings only where the testing is conducted by (a) an accredited Australian laboratory in accordance with the relevant accreditation standards, or (b) an overseas laboratory that complies with equivalent standards?

Reform of accreditation standards

5.26 Compliance with NATA's current accreditation standards for genetic testing does not necessarily address concerns that extend beyond the issue of technical proficiency of the testing process. For example, NATA accreditation standards do not address the concern that individuals who obtain genetic test results may not have the results adequately interpreted, or that they may not have an opportunity to be referred to genetic counselling. Further, accreditation does not generally address issues of consent, although in the case of parentage testing for family law proceedings it may do so indirectly (see Chapter 31).

5.27 Some submissions raised concerns about relying on accreditation standards to provide safeguards in relation to the ethical conduct of genetic testing. Colin Andersen noted that accreditation standards do not currently address concerns about privacy, consent, counselling or chain of custody in genetic testing — rather they operate on 'the purely technical level of laboratory procedures'.²³

22 NATA recognises genetic testing performed in other countries where it complies with international standards. NATA has established mutual recognition agreements with over 33 laboratory accreditation bodies in 24 countries: National Association of Testing Authorities, *Mutual Recognition Agreements*, <<http://www.nata.asn.au/downloads/mrasummary.pdf>>, 22 July 2002.

23 C Andersen, *Submission G002*, 14 January 2002.

5.28 While the primary focus of laboratory accreditation should remain on matters of technical proficiency and scientific reliability, the Inquiry considers that NPAAC should investigate these broader concerns. In particular, NPAAC should inquire into whether accreditation standards should ensure that laboratories conduct genetic testing only on bodily samples collected with the consent of the individual to whom the sample relates, or as approved by a Human Research Ethics Committee.²⁴

Proposal 5–1. The National Pathology Accreditation Advisory Council (NPAAC), in consultation with NATA and the Royal College of Pathologists of Australasia (RCPA), should consider whether accreditation standards should ensure that laboratories conduct genetic testing only on bodily samples collected with the appropriate consent of the individual to whom the sample relates or as approved by a Human Research Ethics Committee (HREC).

Home use genetic testing

What is home use testing?

5.29 Over-the-counter or home use genetic testing may refer to two different forms of testing. One form of testing is a process similar to ‘do-it-yourself’ (DIY) pregnancy testing, in which the test is performed and interpreted by the person at home. At present, this form of genetic testing is not available in Australia.

5.30 The second form is a test in which the person collects a bodily sample at home and sends it to a laboratory for analysis.²⁵ Kits for home use testing may be made available through pharmacists or other retailers, by mail order or over the Internet. They may be expected to provide instructions on how to collect and store bodily samples, implements to collect samples (for example, buccal swabs), and vials or other containers in which to store and send the samples. The samples are forwarded through the mail to the company offering the services, and they may be tested either by an Australian laboratory or an overseas laboratory, either of which may or may not be accredited.

5.31 DNA parentage testing is currently available in this second form by mail order and over the Internet. While the Inquiry is not aware of any other forms of home use genetic testing being offered by Australian businesses, home use genetic

²⁴ See Pt D.

²⁵ The distinction between these two forms of home use (or ‘home-based’) testing is outlined in relation to HIV testing in Australian National Council on AIDS and Related Diseases & Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy* (1998) Commonwealth of Australia, 35.

testing for medical and identification purposes is being offered by overseas organisations.

5.32 For example, a United Kingdom biotechnology company, Sciona, has been marketing a genetic testing service on the Internet and through The Body Shop retail chain. Sciona claims that the testing service ‘offers a personalised dietary report generated by combining information from a lifestyle questionnaire and an understanding of your genes’.²⁶ For £120, customers are sent a self-sampling kit for the collection of a DNA sample and a lifestyle questionnaire, which is processed to produce a report that claims to provide individualised recommendations on what to eat to ensure that body and diet work ‘in harmony’.²⁷

5.33 Sciona and The Body Shop have both been criticised by GeneWatch UK,²⁸ which is concerned that the tests are unregulated and misleading. GeneWatch claims that Sciona’s genetic tests mislead subscribers into thinking that ‘good genes can cope with a bad diet or with smoking or excessive drinking’. It has expressed its concern that subscribers are not informed about the privacy implications for future research or the discrimination implications for insurance or employment.²⁹ The Body Shop has now withdrawn the kits from sale through its retail outlets.

5.34 In the United States, DNA identification kits are being marketed as a means for parents to collect and store DNA samples at home, which can later be used to trace missing persons.³⁰

5.35 While the focus of concerns about home use testing in Australia has been on parentage testing, it may only be a matter of time before home use medical and DNA identification test kits are marketed directly to the public. The Department of Health and Ageing observed, in relation to medical testing, that:

[t]he current genetic testing environment does not suggest that a wave of individuals will suddenly start to self-refer for testing, although the possibility cannot be discounted in light of previous experience with coronary artery calcium scoring which has been marketed directly to the public in the past.³¹

26 See Sciona’s website: Sciona Ltd, *About Sciona*, <www.sciona.com/about/index.htm>, 22 July 2002.

27 See BBC News, *Row over Gene Testing Kit*, <<http://news.bbc.co.uk/1/hi/sci/tech/1868767.stm>>, 26 July 2002.

28 GeneWatch UK is ‘an independent organisation concerned with the ethics and risks of genetic engineering’: GeneWatch, *Home Page*, <www.genewatch.org>, 24 July 2002.

29 See GeneWatch, *Body Shop’s Genetic Tests Misleading and Unethical*, <www.genewatch.org/HumanGen/Press_Releases/pr22.htm>, 13 March 2002.

30 R Willing, ‘Child DNA Kits Become Businesses’ Favorite Freebie’, *USA Today*, 12 May 2002.

31 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

Concerns about home use genetic testing

5.36 The availability of home use genetic testing raises a range of concerns. These include the following:

- error and fraud are more likely where the collection of a genetic sample is conducted without the supervision of a medical practitioner or the testing laboratory;
- problems may arise due to contamination of the sample or because the chain of custody of the sample is not verifiable;
- where the consent of the individual (or their parent or guardian) to whom the sample relates is required, the validity of the consent cannot be assured; and
- individuals are less likely to be provided with appropriate information about the implications of the genetic test or to be assisted in decision making by genetic counselling, when compared with a test that is arranged through a medical practitioner.

5.37 In 1997, the United Kingdom Advisory Committee on Genetic Testing (ACGT) prepared a Code of Practice in respect of genetic testing services supplied directly to the public.³² The ACGT concluded that, in relation to testing for inherited dominant and X-linked disorders, and for adult-onset genetic disorders, direct provision of testing should be limited, for the following reasons:

a. Many tests results are complex and cannot be interpreted meaningfully without a medical or family history, which cannot be incorporated adequately into a mail-order or over-the-counter test procedures.

b. There will be many test results where prediction of a high chance of a serious health outcome will still be accompanied by uncertainty about when, if ever, the disease will strike, how severe it might be, and whether current symptoms (that may have triggered the request for a test) are in any way linked to the disease in question. In these cases, provided there are adequate safeguards against unjustified discrimination in insurance and employment, ACGT believes a person's interests are best served and protected by requesting a test through their medical practitioner.³³

32 Advisory Committee on Genetic Testing, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public* (1997), Department of Health, London.

33 Ibid, 4: The ACGT recognised a limited role for the provision of genetic testing services direct to the public 'centred around those tests which determine carrier status for inherited recessive disorders, where such status carries no significant direct health implications for the carrier individual'. The Human Genetic Commission has recently released a consultation paper on the supply of genetic tests direct to the public: Human Genetics Commission, *Supply of Genetic Tests Direct to the Public: A Consultation Document*, <<http://www.hgc.gov.uk/testingconsultation/index.htm>>, 24 July 2002.

5.38 In Canada, an Ontario report has concluded that federal standards for approval of home use genetic testing should be carefully examined and monitored and that the federal government should ensure that ‘direct to consumer marketing of genetic testing should at minimum be clearly circumscribed if not entirely prohibited for certain forms of testing’.³⁴

5.39 IP 26 asked whether the availability of genetic testing should be regulated so that it may be conducted only on the request of a medical practitioner.³⁵ Many submissions that addressed this question identified ethical concerns relating to home use genetic testing and suggested further regulation. The Australian Medical Association (AMA) submitted that:

... genetic testing should be regulated to ensure that only registered medical practitioners are allowed to request that testing be performed. Genetic testing should not be performed in the absence of counselling. For this reason we are strongly opposed to the availability of ‘home-based’ testing kits due to the significant risk of physical or emotional harm that may result to individuals who submit to genetic testing without this counselling. There is also significant risk of genetic testing being performed on individuals without their consent if home testing kits are allowed. The AMA considers it necessary to enact legislation to ban this type of product.³⁶

5.40 The Department of Health and Ageing recognised the ethical problems raised by home use testing but submitted that there may be other ways to address these problems other than by requiring that genetic testing be accessed only through medical practitioners.

In general, care must be taken not to implicitly assent to a proposition that because genetic testing is a medical service, medical practitioners should *ipso facto* mediate it. Where individuals do self-order tests, guidelines could assist testing services to meet their ethical obligations in relation to informing consent, e.g., directing consumers to information on pre- and post-test counselling and support services.³⁷

5.41 Similarly, the Office of the Federal Privacy Commissioner (OFPC) submitted that access to mail-order genetic testing cannot be effectively and comprehensively regulated so that testing would be conducted only on the request of a medical practitioner and by an accredited laboratory.³⁸ The OFPC noted that:

[i]f the sale of mail-order genetic tests and ‘DIY’ test kits by Australian companies continues, there should be widespread and comprehensive consumer education policies devised. There are valuable lessons to be learned from the lawful sale of

34 Province of Ontario, *Report to Premiers — Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf>, 21 July 2002, 85–86.

35 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 8–2.

36 Australian Medical Association, *Submission G091*, 29 January 2002.

37 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

38 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

potentially harmful commodities, such as tobacco and prescription drugs. Consideration may even be given to legislating, as a public health measure, for the provision at the point of sale of appropriate information about the tests and the implications of the results obtained. Such consumer education would have the added benefit of ensuring the informed consent of the individual, an important element of information privacy principles.³⁹

Regulating home use genetic testing

5.42 The Inquiry considers that there are strong arguments for regulating the availability of home use genetic testing. Home use genetic testing raises problems of quality assurance, consent to testing, and a real possibility of harm where individuals are not provided with appropriate information about the interpretation and implications of genetic test results.

5.43 Two options for reform have been identified by the Inquiry and are discussed in more detail below. These involve implementing one or both of the following:

- Amending the *Therapeutic Goods Act 1989* (Cth) (*Therapeutic Goods Act*) and *Therapeutic Goods Regulations 1990* (Cth) (the Regulations) to ensure that the supply and advertising of home use genetic testing kits in Australia is prohibited, except where specifically approved by the Therapeutic Goods Administration (TGA);
- Making an appropriate body (such as the proposed Human Genetics Commission of Australia (HGCA))⁴⁰ responsible for developing Codes of Practice and other advice on home use genetic testing, including advice to the TGA on the regulation of home use genetic testing under its Act.

The Therapeutic Goods Act and Regulations

5.44 The *Therapeutic Goods Act* provides the legislative basis for a uniform national system of controls over therapeutic goods. This is primarily effected through regulation of the quality, safety, efficacy and timely availability of therapeutic goods; setting standards that the goods are required to comply with, and minimising any risk of misuse, inappropriate use, or unsafe use of the goods; and by regulating how the goods may be advertised. Unless specifically excluded or exempt, therapeutic goods may not be supplied to the Australian market, or exported, unless included in the Australian Register of Therapeutic Goods (ARTG).

³⁹ Ibid.

⁴⁰ See Ch 3.

5.45 The TGA is the Division of the Department of Health and Ageing with overall responsibility for administering the provisions of the *Therapeutic Goods Act*.

5.46 Therapeutic goods are defined in the Act as ‘goods that are represented ... for therapeutic use’.⁴¹ Therapeutic use means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.⁴²

5.47 Therapeutic goods can be divided broadly into two classes — medicines and therapeutic devices. Currently, the ARTG holds information on approximately 25,000 medicines and 30,000 therapeutic devices.

5.48 At the present time, therapeutic goods are classified as ‘registrable’ or ‘listable’ on a product-by-product basis. Registrable therapeutic goods are generally either higher risk products or products used to treat major medical conditions, and must undergo evaluation by the TGA prior to being included in the Register. Inclusion of goods in the Register means they may be lawfully imported into Australia, supplied in Australia, manufactured or exported from Australia by the sponsors of the goods. When determining whether registrable goods may be included in the Register, the advice and recommendations of ministerially-appointed evaluation committees established under the Regulations may be taken into account.

5.49 Part 3 of the *Therapeutic Goods Act* enables the TGA to impose conditions on the registration or listing of goods, including conditions relating to their use and supply.⁴³ In addition, Part 3 also provides for a range of offences including:

- the import, export, manufacture or supply of therapeutic goods that are not included in the Register;
- advertising therapeutic goods for indications other than those accepted in relation to the inclusion on the goods in the Register; and

⁴¹ *Therapeutic Goods Act 1989* (Cth) s 3.

⁴² *Ibid*, s 3. *Therapeutic Goods Act 1989* (Cth) s 3.

⁴³ *Ibid*, s 28.

- failure to notify adverse effects of registered goods.

5.50 Part 4 of the Act contains provisions relating to the manufacture of therapeutic goods. It is an offence to carry out any step in the manufacture of therapeutic goods without a licence, unless the goods, or the manufacturer, is exempted from the requirements under this Part.

5.51 Both the *Therapeutic Goods Act* and the Regulations currently contain measures that regulate the advertising of therapeutic goods. For example, Part 2 of the Regulations specifies that advertisements about certain therapeutic goods that are published in specified media (such as newspapers, journals, billboards, public areas of shopping centres, cinemas) must be approved before their publication, and must comply with the Therapeutic Goods Advertising Code. A range of sanctions may be applied to non-conforming advertisements.⁴⁴

5.52 The TGA is currently developing proposals for a new legislative framework for diagnostic tests, which may include products used in genetic testing.⁴⁵

Current regulation of goods used in genetic tests

5.53 Under the *Therapeutic Goods Act*, therapeutic devices are defined as:

goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means...⁴⁶

5.54 Therapeutic devices include 'diagnostic goods for in vitro use' (also called in vitro diagnostic devices, or IVDs). IVDs are defined in the Regulations as:

any therapeutic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for in vitro use), intended by the manufacturer to be used in vitro for the examination of specimens (including blood and tissue donations) derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state or a congenital abnormality or to determine safety and compatibility with a potential recipient.⁴⁷

⁴⁴ *Therapeutic Goods Regulations 1990* (Cth) reg 6, 7–8.

⁴⁵ Therapeutic Goods Administration, *Correspondence*, 19 July 2002. See Therapeutic Goods Administration, *Proposed Changes to In Vitro Diagnostic Tests Used to Test Human Blood and Tissues*, <<http://www.health.gov.au/tga/docs/html/ivdcons.htm>>, 24 July 2002.

⁴⁶ *Therapeutic Goods Act 1989* (Cth) s 3.

⁴⁷ *Therapeutic Goods Regulations 1990* (Cth) reg 2.

5.55 At the present time, a very limited number of IVDs are required to be included on the Register. In the context of genetic testing, products used to provide genetic information may or may not be considered IVDs, depending on their intended use as stated by the manufacturer.⁴⁸ For example, a buccal swab test kit containing implements for collecting and storing a buccal swab would be considered an IVD as it is being supplied with the intended use of examination of a human specimen, while a pair of tweezers would not be considered to be an IVD unless they were marketed for the specific purpose of genetic sample (hair) collection.⁴⁹

5.56 The situation is different in the case of goods used in DNA identification testing, including parentage testing. These goods do not fall within the definition of a therapeutic good (their intended purpose is not covered within the scope of therapeutic use), and therefore they are not regulated by the TGA.⁵⁰

Application to home use genetic IVDs

5.57 The *Therapeutic Goods Act* and Regulations also cover ‘goods for home use’,⁵¹ which include any therapeutic device intended for use outside a laboratory setting or to be carried out by a lay person — for example an over-the-counter pregnancy test kit. While it is likely that the new regulatory framework for IVDs will introduce a higher level of control for certain home use IVDs, the impact on home use genetic testing products is not clear.⁵²

5.58 The Inquiry believes that there may be good reasons (as discussed above) to introduce special controls for home use genetic testing. The TGA should be able to refuse approval where, for example, the goods are not safe for the purposes for which they are to be used, the presentation of the goods is unacceptable, the goods do not conform to applicable standards, or do not comply with prescribed quality or safety criteria.⁵³

5.59 Such special controls could include specific labelling requirements for home use genetic IVDs, or development of criteria that would be used to determine eligible IVDs for which home use versions could be approved. In the case of DNA identification testing, including parentage testing, this would require amendment of the *Therapeutic Goods Act* so as to include such genetic testing within the scope of ‘therapeutic use’.

48 Therapeutic Goods Administration, *Correspondence*, 19 July 2002.

49 Ibid.

50 Ibid.

51 *Therapeutic Goods Regulations 1990* (Cth) Sch 5, Item 7(b)(i). Tests for the screening and diagnosis of HIV and Hepatitis C are also not exempt from Part 3.

52 Therapeutic Goods Administration, *Correspondence*, 19 July 2002.

53 See *Therapeutic Goods Act 1989* (Cth) s 26.

Code of practice for home use genetic testing

5.60 Another mechanism to regulate the provision of home use genetic testing is through the development of a voluntary code of practice to provide minimum technical and ethical standards.

5.61 As mentioned above, in 1997 the United Kingdom Advisory Committee on Genetic Testing published a voluntary Code of Practice on genetic testing services supplied direct to the public in the United Kingdom. The Code of Practice prescribed minimum requirements in relation to testing laboratories, equipment and reagents, confidentiality and storage of samples and records, tests that may be supplied, who may be supplied tests, customer information, genetic consultation, and the involvement of general medical practitioners.⁵⁴

5.62 More recently, the United Kingdom's Department of Health has developed a voluntary code applying to organisations advertising and providing genetic paternity testing services directly to the public (see Chapter 31).⁵⁵

5.63 A similar approach could be taken in Australia for all home use genetic testing. The proposed HGCA (see Chapter 3) would be an appropriate body to develop such a code of practice in consultation with interested business and health consumer groups. In addition, if home use genetic testing were to be regulated by the TGA, the standing body could provide it with advice on whether certain categories of testing should be approved and, if so, on what terms.⁵⁶

Proposal 5–2. The *Therapeutic Goods Act 1989* (Cth) and *Therapeutic Goods Regulations 1990* (Cth) should be amended to enable the Therapeutic Goods Administration (TGA) to regulate home use genetic in vitro diagnostic devices (IVDs) and home use DNA identification test kits, including for parentage testing.

Proposal 5–3. The proposed HGCA should be responsible for developing codes of practice and other advice on home use genetic testing, including advice to the TGA on the regulation of genetic home use IVDs under the *Therapeutic Goods Act 1989* (Cth).

54 Advisory Committee on Genetic Testing, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public* (1997), Department of Health, London.

55 Group on Genetic Paternity Testing Services, *Code of Practice and Guidance on Genetic Paternity Testing Services*, (2001) Department of Health, <<http://www.doh.gov.uk/genetics/paternity.htm>>, 11 February 2002.

56 Therapeutic Goods Administration, *Consultation*, Canberra, 28 May 2002.

Regulating access to offshore testing

5.64 Individuals in Australia can access overseas genetic testing services with relative ease using the Internet and the postal service. The problems involved with regulating such access were referred to in a number of submissions.⁵⁷ For example, the Department of Health and Ageing observed that regulating non-consensual testing ‘raises difficulties because testing services are available internationally (often through internet marketing)’.⁵⁸ The Medical Practitioners Board of Victoria noted that, while there may be merit in restricting access to genetic testing to accredited laboratories, it was ‘not likely to be practical given the ease of access to many forms of testing for the general public’.⁵⁹ Similarly, the OFPC suggested that access to mail-order genetic testing means that genetic testing cannot be effectively and comprehensively regulated.⁶⁰

5.65 While it may be possible to regulate the supply and advertising of home use genetic testing in Australia through the *Therapeutic Goods Act* and Regulations, effective regulation of genetic testing services provided overseas by foreign companies and advertised through the Internet is more difficult.

5.66 There are significant practical difficulties in regulating the advertising of services on the Internet. Nevertheless, federal legislation has been enacted to restrict access to certain forms of Internet content such as offensive material and interactive gambling. If effective, these laws could serve as a model for regulating the advertising on the Internet of genetic testing services.

5.67 The objects of the *Broadcasting Services Act 1992* (Cth) include restricting access to Internet content that is likely to cause offence to a reasonable adult and protecting children from exposure to Internet content that is unsuitable for children.⁶¹ Schedule 5 of the *Broadcasting Services Act* establishes a system for regulating these aspects of the Internet industry. Under these provisions, a person may complain to the Australian Broadcasting Authority (ABA) about ‘prohibited content’ or ‘potential prohibited content’ on the Internet, and the ABA must investigate the complaint. If the ABA is satisfied that Internet content hosted in Australia is prohibited content, the ABA must give the relevant Internet content host a ‘take-down’ notice directing it not to host the prohibited content.

57 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; Medical Practitioners Board of Victoria, *Submission G155*, 10 April 2002; *Confidential Submission G022CON*, 3 December 2001; Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

58 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

59 Medical Practitioners Board of Victoria, *Submission G155*, 10 April 2002.

60 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

61 *Broadcasting Services Act 1992* (Cth) ss 3(1)(l)–(m).

5.68 If the Internet content is hosted outside Australia, the ABA must notify the content to Internet service providers so that the providers can deal with the content in accordance with procedures specified in an industry code or industry standard. These procedures might include filtering the prohibited content by technical means. In appropriate cases the ABA must also notify the police.

5.69 The *Interactive Gambling Act 2001* (Cth) reflects a similar attempt to regulate Internet content. The Act prohibits interactive gambling services from being provided to customers in Australia, prohibits the advertising of interactive gambling services, and establishes a complaints scheme by which individuals may complain to the ABA about interactive gambling services available on the Internet. If prohibited Internet gambling content is hosted outside Australia, the ABA must notify the content to Internet service providers under designated notification schemes set up under the Act or give each Internet service provider known to the ABA a written notice directing the provider to take all reasonable steps to prevent end-users from accessing the content.⁶²

5.70 Internet advertising of genetic testing services could be regulated in similar ways. For example, if home use genetic testing services were to be regulated under the *Therapeutic Goods Act*, the *Broadcasting Services Act* could be amended to incorporate a scheme similar to that applicable to offensive material. Under such a scheme the relevant prohibited content would refer to the advertising of home use genetic testing other than those approved by the TGA pursuant to the *Therapeutic Goods Act* and Regulations.

5.71 The Inquiry has no concluded view about the merits or otherwise of regulating the advertising of home use genetic testing kits on the Internet. The Inquiry invites further comment on this issue.

Question 5–3. Should legislation be enacted to prohibit Internet advertising of home use genetic testing unless approved by the TGA?

Taking and testing genetic samples without consent

5.72 Biomedical technology currently enables genetic testing to be performed on minute bodily samples. The polymerase chain reaction (PCR) method of genetic testing enables DNA from a single cell to be amplified many times to produce quantities of genetic material suitable for testing. Further, the development of automated ‘DNA chip’ technology makes it technically possible to obtain

⁶² *Interactive Gambling Act 2001* (Cth) s 24.

information about numerous genetic mutations simultaneously in a single test procedure.⁶³

5.73 Human genetic samples may be found nearly everywhere. Genetic information may be derived from easily accessible bodily samples such as hair follicles (humans shed hundreds of hairs every day), saliva left on a glass or cigarette, cheek cells left on a toothbrush, sloughed cells deposited on an item of clothing, or mucus in a tissue.

5.74 In combination, the power of biomedical technology and the ubiquity of human genetic samples leaves open the potential for bodily samples to be taken and tested without the knowledge or consent of the individual to whom they relate (non-consensual genetic testing).

5.75 The fear of ‘genetic trophy hunters’ has been cited as the reason former United States President Bill Clinton’s bodyguards collected a pint glass after he had drunk from it in a British pub, that is, to ensure that his DNA could not be obtained.⁶⁴

5.76 A link between ease of access to genetic testing and the potential for improper use of these services was made in a number of submissions. For example:

Genetic information might be collected surreptitiously (eg from a sample of skin, hair roots or saliva) for unauthorised purposes. The risk of this is increased by the availability of over-the-internet and over-the-counter genetic services. Although this conduct would generally breach the *Privacy Act* or the common law, there is an argument that criminal penalties should apply.⁶⁵

5.77 Similarly, the OFPC stated that it was concerned about:

the problems involved in a person’s obtaining genetic information about an individual for the wrong reasons without the individual’s knowledge or consent, whether by mail-order or through DIY testing. This issue raises, among others, proof of *bona fides*, proof of the identity of the person requesting the test and possible criminal sanctions for the unlawful use of genetic information without the knowledge and consent of the individual. The [Privacy Act] provides general protection in many of these circumstances but developments in this area should be monitored closely.⁶⁶

5.78 The Department of Health and Ageing agreed that ‘over-the-counter’ testing created the potential for genetic testing of an individual without the individual’s knowledge or consent.

63 Also known as ‘gene chips’, ‘biochips’ and ‘DNA microarrays’. See S Moore, ‘Making Chips to Probe Genes’, *IEEE Spectrum*, 1 March 2001, 54.

64 G Hinsliff, ‘Bid to Outlaw DNA Trophy Hunters’, *The Observer* (London), 3 March 2002.

65 K Liddell, *Submission G141*, 23 March 2002.

66 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

Current DNA profiling technologies enable accurate results from very small samples such as a hair and these can be easily obtained without a person being aware of it. Regulation of this practice raises difficulties because testing services are available internationally (often through internet marketing). Nonetheless, commercial and unaccredited laboratories exist in Australia and regulation of 'DNA theft' is an important issue which must be addressed.⁶⁷

The harm of non-consensual genetic testing

5.79 In determining whether the non-consensual collection and use of bodily samples for the purpose of genetic testing should be proscribed by law and, if so, how, it is necessary to closely examine the harm that may arise from this conduct.

5.80 The harm caused by non-consensual genetic testing may be categorised in various ways, depending on whether one looks at the collection of the genetic sample, the testing of the sample to derive genetic information from it, or the possible uses of the information so derived.

5.81 The collection of the sample may, in some circumstances, involve a physical harm or a trespass to the person (a battery). The collection may be intrusive of the physical space of the individual and, where it is known about, result in emotional harm. Emotional harm may result from situations where, from the perspective of the individual concerned, intimate bodily samples (such as menstrual blood or semen) are taken, or kinship relations or identity (for example, Aboriginality) is questioned.

5.82 The most obvious harm arising from the testing of the sample is the intrusion on basic human dignity and autonomy. The harm may be also characterised as involving a breach of information privacy.⁶⁸ As discussed in detail in Chapter 4, genetic testing may result in the disclosure of sensitive personal information of many kinds. Testing can reveal information about the present and future health of an individual; an individual's identity; and his or her parentage or kinship. The fact that harm may be caused by the non-consensual disclosure of these kinds of information is recognised by laws that proscribe disclosure in other contexts, including legal and statutory duties of confidentiality and information and health privacy legislation.

5.83 The possible uses of the information derived from non-consensual testing may also give rise to obvious harm, including harm caused:

- by the use of genetic information by employers, insurers and others for discriminatory purposes;

⁶⁷ Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

⁶⁸ As discussed in Ch 7, 'information privacy' can be defined as the right of an individual to control the collection, use and disclosure of information relating to them (personal information).

- to individuals who involuntarily learn about their long-term health prognosis and other physical and behavioural characteristics, in breach of their ‘right not to know’;⁶⁹
- by media publicity about an individual’s genetic characteristics, especially where that individual is a celebrity or otherwise newsworthy;
- by the use of genetic information by police in criminal proceedings or by litigants in civil proceedings; and
- by disruption to family relationships and harmony where parentage or other kinship information is disclosed.

Application of existing Australian law

5.84 Given that the conduct of non-consensual genetic testing gives rise to clear potential for harm, it is necessary to ask to what extent existing Australian law offers protection.

5.85 The position in the United Kingdom has recently been considered by the Human Genetics Commission (HGC). In its May 2002 report, the HGC concluded that there are scenarios where current legal remedies may not offer sufficient protection against breach of an individual’s genetic privacy. For example:

- a. X takes Y’s beer glass and obtains an analysis of his DNA. He or she then sells to a newspaper the information that Y has a particular genetic condition.
- b. X de-encrypts anonymised genetic information about Y from a research study for some wrongful purpose.
- c. X obtains a sample from Child A, for whom he has no parental responsibility, in order to ascertain whether he is the father of the child.⁷⁰

5.86 In Australia, legal protection against the non-consensual collection and use of bodily samples for the purpose of genetic testing is similarly limited. Some protection exists under the common law through the tort of trespass to the person. Any touching of a person’s body without consent may constitute a trespass. However, this would not apply to the collection of ‘discarded’ genetic material, such as hair from combs, saliva from a glass, cheek cells from a toothbrush, or mucus from a tissue. Nor is the taking of such genetic samples likely to constitute theft. Current law regards bodily samples as property only in the very limited sense

⁶⁹ The right not to know is discussed in Ch 7.

⁷⁰ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 60.

that hospitals and other organisations that have preserved them have a right of possession over those samples.⁷¹

5.87 The *Privacy Act 1988* (Cth) and similar state and territory legislation provide only limited protection against the collection and testing of genetic samples without consent in the kinds of circumstances identified by the HGC, for several reasons.

5.88 The first reason is that (except in New South Wales)⁷² information and health privacy legislation does not currently apply to genetic samples, as opposed to the genetic information derived from them. The collection of a genetic sample without consent (for example, from a beer glass) does not breach the federal *Privacy Act*.⁷³ Second, leaving aside the distinction between a genetic sample and genetic information derived from it, the coverage of the *Privacy Act* is limited because acts done, or practices engaged in, by individuals are exempt if done or engaged in 'other than in the course of a business carried on by the individual'.⁷⁴ Third, the National Privacy Principles (NPPs) do not apply to the collection, use or disclosure of personal information by an individual 'only for the purposes of, or in connection with, his or her personal, family or household affairs'.⁷⁵ Arguably, many of the circumstances in which genetic testing might take place surreptitiously have purposes that may relate to an individual's personal, family or household affairs. These might include purposes relating to family health, personal identity, or 'peace of mind' parentage testing.

5.89 In the circumstances identified by the HGC in the three examples above, the acts of person 'X' generally will not be regulated by the *Privacy Act*, unless done in the course of a business. Even then, if X is a journalist and the collection and testing of the sample is done in the course of journalism (for example, for the purpose of a news story relating to a celebrity paternity dispute), the acts may be exempt under other provisions of the *Privacy Act* dealing specifically with journalism.⁷⁶

5.90 In order to derive information from a genetic sample an individual ordinarily would need to submit the genetic sample to a laboratory for testing. It is relevant, therefore, to consider the obligations of the laboratory under privacy legislation. At least in the case of a private sector organisation, the collection, use and disclosure of personal information by the laboratory will be subject to the

71 See Ch 17.

72 *Privacy and Personal Information Protection Act 1998* (NSW) s 4.

73 The Inquiry proposes that the *Privacy Act* should be amended to define 'personal information' as including bodily samples from an individual whose identity is apparent or can reasonably be ascertained from the sample. See Ch 7.

74 *Privacy Act 1988* (Cth) s 7B(1).

75 *Ibid.*, s 16E.

76 *Ibid.*, s 7B(4).

NPPs. However, the laboratory may not know the identity of the individual from whom the sample was derived. If so, the laboratory will not be dealing with ‘personal information’ covered by the *Privacy Act*, even though the individual who submitted the sample for testing knows from whom it came.⁷⁷ Even assuming the laboratory, by analysing and reporting the results of testing, is collecting and disclosing personal information in terms of the *Privacy Act* and the NPPs, the legal protection extended to the individual from whom the sample was derived appears limited.⁷⁸

How should non-consensual genetic testing be penalised?

5.91 If unauthorised non-consensual genetic testing should be proscribed by law, how should the practice be penalised? In particular, should the relevant conduct be subject to criminal or civil remedies,⁷⁹ or both (as is the case, for example, with battery)?⁸⁰

5.92 Decisions about the form and level of penalty to be applied to proscribed conduct should depend on the purpose of the penalty, as well as the area of activity, the type of wrongdoer and the nature of the wrongdoing. The purposes of penalties may include punishment or retribution, social condemnation, deterrence, protection of third parties or the public at large, and payment of reparation or compensation.⁸¹

5.93 The main purposes of criminal law are traditionally considered to be deterrence and punishment. The aim of social condemnation, or stigma, traditionally applies more to criminal than civil penalties.⁸² Civil sanctions generally have the practical function of discouraging undesirable behaviour by imposing a financial cost on it.⁸³

77 Ibid, s 6(1). On the definition of ‘personal information’ see Ch7.

78 For example, for the purposes of NPP 1.1, the collection of personal information (by biochemical analysis) would be a necessary part of the functions of any testing laboratory. Further, it would be difficult to argue that it would be ‘reasonable and practicable’ for the laboratory to collect the information directly from the individual from whom the sample was derived in terms of NPP 1.4, particularly given, for example, that pathology samples are commonly submitted indirectly (that is, from medical practitioners). Finally, the disclosure of the test results to the individual who submitted the sample (and who contracted to receive the results) would appear to be a disclosure for ‘the primary purpose of collection’ in terms of NPP 2.1. Further, where the *Privacy Act* is breached, the enforcement mechanisms may be seen as providing an inadequate sanction against non-consensual genetic testing.

79 A ‘civil penalty’ is one imposed by courts applying civil rather than criminal court processes: Australian Law Reform Commission, *Securing Compliance: Civil and Administrative Penalties in Australian Federal Regulation*, Discussion Paper 65 (2002), ALRC, Sydney, para 2.44.

80 A battery may constitute both a tort, or civil wrong (trespass to the person) and a criminal offence (assault).

81 Australian Law Reform Commission, *Securing Compliance: Civil and Administrative Penalties in Australian Federal Regulation*, Discussion Paper 65 (2002), ALRC, Sydney, para 3.5.

82 Ibid, para 3.5–3.6.

83 See J Coffee, ‘Paradigms Lost: The Blurring of the Criminal and Civil Law Models — And What Can Be Done about It?’ (1992) 101 *Yale Law Journal* 1875.

5.94 The criminal law covers a vast array of activities and offences. These range from murder and assault to offensive language and jay-walking. In the federal sphere, criminal law includes customs infringements and breaches of consumer protection laws.⁸⁴ Criminal law is not only concerned with the most serious offences. There are, for example, scores of low-level record-keeping and information offences which are treated criminally in many regulatory regimes.⁸⁵ In the non-federal sphere, parking offences are criminal. In fact, outside areas of regulatory law it is relatively rare for the conduct of individuals to be made subject to non-criminal penalties.⁸⁶

5.95 One guide to the appropriateness, or otherwise, of subjecting non-consensual genetic testing to criminal penalty is the criminalisation of analogous conduct. While it is difficult to identify close analogies, existing crimes legislation (in addition to stealing offences) contains offences relating to:

- unauthorised supply of forensic material for a DNA database;⁸⁷
- unauthorised access to data held in computers;⁸⁸
- ‘peeping or prying’ near buildings;⁸⁹
- stalking or intimidation;⁹⁰ and
- interference with human remains.⁹¹

5.96 Analogous offences are also contained in other legislation. For example there are offences in the Human Tissue Acts concerning removing tissue from persons, living or dead, without consent or authority.⁹² The unauthorised disclosure of health information obtained by public sector health administrators and employees in the course of their employment is also subject to criminal penalty.⁹³

84 See D Brown and others, *Criminal Laws: Materials and Commentary on Criminal Laws and Process of New South Wales* (2001) The Federation Press, Sydney.

85 A Ashworth, ‘Is the Criminal Law a Lost Cause?’ (2000) 116 *Law Quarterly Review* 225, 243.

86 Regulatory law concerns the way that governments regulate private sector activity or otherwise intervene in the operation of different areas of society outside of traditional criminal law. Criminal regulatory offences include a number of traditional crimes such as fraud or obtaining benefits by deception, but also offences that are not so obviously criminal in their nature, such as failing to provide certain types of information or failing to meet a certain licensing standard: Australian Law Reform Commission, *Securing Compliance: Civil and Administrative Penalties in Australian Federal Regulation*, Discussion Paper 65 (2002), ALRC, Sydney, para 2.8.

87 *Crimes Act 1914* (Cth) s 23YDAD.

88 *Crimes Act 1900* (NSW) s 308H; *Summary Offences Act 1966* (Vic) s 9A.

89 *Crimes Act 1900* (NSW) s 547C.

90 *Ibid*, s 562AB; *Crimes Act 1958* (Vic) s 21A.

91 *Crimes Act 1900* (NSW) s 81C.

92 *Human Tissue Act 1983* (NSW) s 36; *Human Tissue Act 1982* (Vic) s 44.

93 *Health Administration Act 1982* (NSW) s 22; *Health Services Act 1988* (Vic) s 141.

5.97 Alternatively, new civil remedies might be created to deter non-consensual genetic testing. This approach could be taken instead of, or in addition to, the creation of any new criminal offence. One such approach would be to amend the *Privacy Act* to ensure that the conduct involved in non-consensual genetic testing constitutes an interference with privacy in a broader range of circumstances, enabling the individuals concerned to seek compensation under the Act. This could be backed up by legislation preventing the use of non-consensual genetic test results in court proceedings.⁹⁴

Do we need a new criminal offence?

5.98 The Inquiry has come to the preliminary view that, in light of the ready access by individuals to genetic testing services, there should be additional legal protection against the testing of genetic samples without the knowledge and consent of the individual concerned, or other lawful authority, and that this should take the form of a new criminal offence.

5.99 As discussed above, serious privacy and ethical concerns arise from non-consensual testing. The range of genetic information that can be derived from a bodily sample is wide and may have great importance for individuals, their families and their genetic relatives. Existing law does not provide adequate protection.

5.100 A number of proposals contained in this Discussion Paper address concerns about non-consensual testing. The proposals presented earlier in this chapter in relation to accreditation standards and the regulation of home use testing are also intended, in part, to address concerns about non-consensual testing. Chapter 31 focuses on the need to protect both adults and children from non-consensual parentage testing. However, these measures may not be sufficient.

5.101 The Inquiry is presently of the view that there are good arguments in favour of creating a new criminal offence. In particular, given the difficulties in regulating access to, and the conduct of, genetic testing laboratories overseas, the threat of criminal prosecution of individuals in Australia may be the only effective deterrent. In the Inquiry's view, criminalising some non-consensual genetic testing would not be disproportionate to the potential mischief to be avoided. Useful analogies may be drawn with other acts that are already subject to criminal sanction.

5.102 The Inquiry does not consider that the *Privacy Act* should be the primary vehicle by which non-consensual genetic testing should be prohibited. It is appropriate that, in some circumstances, the use and disclosure of genetic information derived from non-consensual genetic testing constitute an interference

94 L Skene, *Consultation*, Sydney, 27 June 2002.

with privacy under that Act. However, the focus of the *Privacy Act* is, and should remain, on regulating the practices of government and business rather than individuals in their private capacities. Further, where the *Privacy Act* is breached, the enforcement mechanisms may be seen as providing an inadequate sanction against non-consensual genetic testing.⁹⁵

The elements of the offence

5.103 The need for a new criminal offence was recently acknowledged by the HGC which recommended that:

consideration be given to the creation of a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes.⁹⁶

5.104 It is easier to propose the creation of such an offence in principle than to determine how it should be drafted and what exceptions should be recognised. These difficulties were noted by the HGC, which observed in respect of its recommendation that:

[t]here are a number of aspects that merit further close examination. For example, it will be important to ensure that any new offence does not interfere with appropriate and lawful non-consensual use of genetic material or genetic information by the police or courts. We would also not wish to see any new offence that might inhibit the use of genetic testing in medical and research settings.⁹⁷

5.105 The Inquiry has reached no concluded view as to the drafting of the proposed new criminal offence and invites comments on how such an offence might be framed. However, the Inquiry's preliminary views on the approach that should be taken are discussed below. The elements of the new criminal offence that need to be determined are: what constitutes the offending conduct, who are the potential offenders, what should be the required fault element of the offence, what exceptions should be recognised, and what penalties should apply?

⁹⁵ Enforcement of the Act is generally through resolution of individual complaints lodged with the Privacy Commissioner. When the Privacy Commissioner determines that a person's privacy has been interfered with, the Commissioner can impose a number of penalties, including a declaration that the organisation should not repeat or continue the offending conduct, a request that the organisation redress the loss or damage incurred, or a request that the organisation pay compensation for any loss or damage incurred. The decisions of the Privacy Commissioner are enforceable by the Federal Court or the Federal Magistrates Court. See *Privacy Act 1988* (Cth) Div 2–3.

⁹⁶ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 62.

⁹⁷ *Ibid.*, 62.

The offending conduct

5.106 The offending conduct (the *actus reus*) might encompass the taking of the sample or deceit in the taking of the sample, the submitting of the sample for testing, testing the sample, using or disclosing the results of testing, or a combination of these acts. The Inquiry's preliminary view is that the offence should focus on submitting the sample for testing and testing the sample. 'Genetic testing' will need to be defined for these purposes.

5.107 Criminalising the taking of the sample is inappropriate given the ubiquity of genetic samples. The harm is not in the simple taking of the sample (leaving aside situations where there is a battery). If an individual chooses to collect, for example, a lock of hair from another found on a hairdresser's floor, it is difficult to argue that any more harm is done to the individual than taking a photograph of them without their consent — which is not an offence unless followed by an unlawful use.⁹⁸

5.108 It has been suggested that the focus of regulation should be on the unauthorised uses of the information derived from testing, especially for financial advantage.⁹⁹ However, there would be significant difficulties involved in defining the unauthorised uses, given the range of information that may be derived from samples and the spectrum of possible uses. Some of these uses would, in any case, be proscribed by existing law, such as where the publication of genetic information is defamatory.

5.109 Further, the Inquiry considers that harm is done to individuals tested without their knowledge and consent even if the testing is done only to satisfy another individual's curiosity and there is no further use of it. Once the information comes into existence, the potential for improper use and disclosure will exist. By way of analogy, it is an offence to 'hack' into another person's computer, or to 'tap' their telephone, without lawful authority, even if no interesting information is obtained in the process.

The offenders

5.110 The primary targets of the criminal offence should be individuals or bodies corporate¹⁰⁰ that surreptitiously obtain and submit samples for testing (with the requisite fault element). It may also be desirable to target individuals or bodies corporate that conduct the testing, such as laboratories and their employees, agents or officers.

98 L Skene, *Consultation*, Sydney, 27 June 2002.

99 Ibid.

100 Where the offender is a body corporate, the physical elements of the offence will be attributed to the body corporate where committed by an employee, agent or officer acting within the actual or apparent scope of his or her employment, or within his or her actual or apparent authority: See *Criminal Code Act 1995* (Cth) ss 12.2, 12.1.

The fault element

5.111 The concept of criminality involves the notion of individual culpability and having a criminal intention for one's actions.¹⁰¹ Consistently with the approach taken to the drafting of other criminal offences such as stalking, the fault elements should be those of intention and knowledge.

5.112 In relation to individuals or bodies corporate that submit samples for testing, the Inquiry suggests that the fault elements of the offence should be that the offending individual or body corporate¹⁰² intends that the sample be tested and knows that the individual from whom the sample has been taken has not consented to testing or is reckless as to that fact,¹⁰³ and there is no lawful authority. In relation to laboratories, their employees, agents or officers, the fault elements also should be that the offending body corporate or individual knows that the individual from whom the sample has been taken has not consented to testing, or is reckless as to that fact (and there is no lawful authority).

5.113 In framing the offence, consideration also will need to be given to what constitutes consent, especially where the sample has been taken from a child. Consent for these purposes may need to be framed in terms of the proposals set out in Chapter 31, which deal with consent to the collection and testing of a child's genetic sample for the purpose of determining parentage.

Exceptions

5.114 Considerable care will need to be taken to ensure that appropriate forms of non-consensual genetic testing do not fall within the ambit of the new offence. For example, non-consensual testing in medical practice, medical research and law enforcement contexts should not constitute an offence under the new provision.

5.115 In this context, particular attention will be needed to ensure that a range of legitimate genetic testing practices are not caught by the new criminal offence. For example, these practices would include genetic testing:

- ordered by medical practitioners in order to assist in the treatment of patients (for example, relying on implied consent);

101 Australian Law Reform Commission, *Securing Compliance: Civil and Administrative Penalties in Australian Federal Regulation*, Discussion Paper 65 (2002), ALRC, Sydney, para 2.9.

102 Where the offender is a body corporate, the fault elements of the offence will be attributed to the body corporate where the body corporate 'expressly, tacitly or impliedly authorised or permitted the commission of the offence': *Criminal Code Act 1995* (Cth) s 12.3(1).

103 A person has knowledge of a circumstance or a result if he or she is aware that it exists or will exist in the ordinary course of events: *Ibid*, s 5.3.

- for medical research purposes, especially where a Human Research Ethics Committee, in granting ethical approval for a research proposal, has waived consent requirements (see Chapter 12); and
- for law enforcement purposes, including under regulatory frameworks for the forensic use of genetic samples and information (see Chapter 34).

5.116 Other legislation may provide a useful guide to the exceptions that may be required. For example, the Victorian anti-stalking provision does not apply to conduct engaged in by a person performing official duties for the purposes of the enforcement of the criminal law; the administration of any Act; the enforcement of a law imposing a pecuniary penalty; the execution of a warrant; or the protection of the public revenue.¹⁰⁴

5.117 Similarly, the use and disclosure principle in the *Privacy Act* (NPP 2) contains exceptions relating to use and disclosure for: research relevant to public health or public safety; serious threats to an individual's life, health or safety; serious threats to public health or public safety; use by law enforcement agencies in investigation, prosecution and court proceedings; and other uses and disclosures 'required or authorised by or under other law'.

The penalty

5.118 The Inquiry has no concluded view on the range or level of penalty most appropriate for breach of the proposed new criminal offence. However, the available penalties should reflect the wide spectrum of circumstances in which non-consensual genetic testing may take place. The penalty where a media organisation uses the test results for financial benefit should differ from that imposed on an individual who is concerned about the health of a relative. The penalties for testing for entirely prurient reasons should differ from those where there is some valid reason for wanting to obtain a genetic test result.

5.119 By way of comparison with broadly analogous offences in New South Wales, the maximum penalties for:

- unauthorised access to data held in computers is two years imprisonment;¹⁰⁵
- peeping or prying is three months imprisonment or a fine of two penalty units (currently \$220),¹⁰⁶ and

104 *Crimes Act 1958* (Vic) s 21A(4).

105 *Crimes Act 1900* (NSW) s 308H; *Summary Offences Act 1966* (Vic) s 9A.

106 *Crimes Act 1900* (NSW) s 547C.

- stalking or intimidation is five years or a fine of 50 penalty units (currently \$5500).¹⁰⁷

5.120 The Standing Committee of Attorneys-General would be the appropriate forum to initiate, through an appropriate committee,¹⁰⁸ the drafting of a model criminal offence relating to non-consensual genetic testing, intended for enactment into Commonwealth, state and territory law.

Proposal 5-4. The Standing Committee of Attorneys-General should initiate the development of a model criminal offence relating to non-consensual genetic testing, for enactment into Commonwealth, state and territory law.

Proposal 5-5. Criminal liability should attach to any individual or corporation that, without lawful authority, submits a sample for genetic testing, or conducts genetic testing on a sample, knowing (or recklessly indifferent to the fact) that the individual from whom the sample has been taken did not consent to such testing.

¹⁰⁷ Ibid s 562AB; *Crimes Act 1958* (Vic) s 21A.

¹⁰⁸ For example, the forensic procedures provisions of the Commonwealth Crimes Act (Part 1D) were developed for SCAG consideration by the Model Criminal Code Officers Committee: see Ch 34.

6. Coming to Terms with Genetic Information

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Introduction

6.1 In Chapter 2 of IP 26, the Inquiry provided a 'basic genetics primer',¹ which described the emerging understanding of genetic science in the wake of the Human Genome Project, as well as some of the underlying research and technology. Among other things, the chapter described the nature of DNA, RNA, genes and chromosomes and their role in human health, as well as the patterns of inheritance of (dominant and recessive) genetic traits. Largely for reasons of space, that material has not been reproduced in this Discussion Paper.²

6.2 This chapter is devoted to the implications that may be drawn from information about a person's genetic make-up. The terms of reference for the Inquiry focus on the handling of human genetic samples and information in practice, directing the Inquiry to provide policy advice about how best to protect personal privacy, guard against inappropriate discrimination, and promote high ethical standards.

¹ Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.54–2.110.

² However, it is still available on the ALRC's website: *Australian Law Reform Commission*, ALRC, <<http://www.alrc.gov.au>>, or AustLII, *Australian Law Reform Commission*, <<http://www.austlii.edu.au/au/other/alrc/publications/issues/26/>>, 23 July 2002.

6.3 As the Inquiry noted in IP 26:

Successfully fulfilling this brief not only involves providing adequate protections against the *unlawful* use of genetic information, but also putting into place measures aimed at ensuring that where such information may be used lawfully, it is used properly, fairly and intelligently.³

What is ‘genetic information’?

Apparent or inferential information

6.4 In one sense, almost all information about a person’s health and physical well being can be called ‘genetic information’. A casual glance reveals information about a person’s gender, race, height, weight, and other features that are related, in whole or in part, to that person’s genetic inheritance.

6.5 Doctors and insurers have been asking for, and using, general family medical histories for over 100 years to draw inferences about the present and future health of individuals. Medical and health practitioners were making clinical observations about genetic conditions long before the technology was developed to test directly for such conditions. Similarly, information that a person has high blood pressure, high cholesterol levels or diabetes, or that a person has had cancer, also may well provide information about that person’s genetic inheritance.

Genetic testing and information

6.6 In Chapter 4, the Inquiry noted that there are a number of types of scientific tests that may reveal genetic information. Most famously, these now include tests that amplify selected segments of a person’s DNA or RNA using polymerase chain reaction (PCR) technology, and then analyse the targeted gene sequences in search of ‘markers’ known to be associated with particular genetic traits, conditions or disorders.

6.7 However, other biochemical tests of non-genetic substances (for example, ordinary blood tests for cholesterol), as well as some medical imaging processes, also may provide strong indicators of particular genetic disorders, particularly in combination with other tests or clinical observations.

³ Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.20.

6.8 For the same reasons that the Inquiry is reluctant to adopt a hard and fast definition of ‘genetic test’,⁴ we are likewise reluctant to specify a precise or exhaustive definition of ‘genetic information’.⁵ Instead, the Inquiry’s strong preference is to consider the context, to determine whether the use or application of genetic-related information requires any special handling or protections.

6.9 Issues of genetic privacy and discrimination have become much more prominent and of greater public concern in recent years, with the advent of advanced DNA testing technology. It is no coincidence that there are now reviews and inquiries similar to this operating in many other countries, where there was very little activity going back more than a decade.

The primacy of context

6.10 As such technology continues to progress, and DNA testing becomes cheaper, quicker, more accurate and much more prevalent, there inevitably will be even more pressure placed upon those institutional and individual safeguards that are meant to protect privacy, prevent discrimination and uphold ethical best practice. Consequently, many or most of the proposals made by the Inquiry in this Discussion Paper will relate to ‘genetic information’ gained from DNA (or related) testing, or tissue samples which may be subject to such testing.

6.11 However, this is not invariably the case, and the ambit of the Inquiry’s coverage must vary according to the circumstances — especially in accordance with the potential mischief that is being addressed.

6.12 For example, the relatively inexpensive Guthrie heel prick tests — performed on virtually all newborns in Australia — involves the measurement of proteins in the blood spots collected to detect such genetic-linked disorders as phenylketonuria (PKU), galactosemia, congenital hypothyroidism, cystic fibrosis and a number of rare metabolic disorders. Guthrie tests do not involve DNA analysis; nevertheless there are some important issues for this Inquiry related to consent to such testing. Even more importantly, Guthrie cards contain blood samples from which genetic information later may be drawn, and the mass testing program over the last 30 years potentially has resulted in a very large, if disorganised, national genetic database.⁶

6.13 Similarly, nuchal translucency is an imaging procedure that is sometimes performed on a human foetus in utero, to determine the likelihood that the baby will have the genetic condition of Down syndrome. Although nuchal translucency

4 See Ch 4.

5 The UK Human Genetics Commission also prefers this approach. See Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 33.

6 See Pt E.

does not involve any DNA testing or analysis, the procedure does provide important genetic information — which must be presented to the parents accompanied by appropriate genetic counselling and support.⁷

6.14 In the context of risk-rating for insurance purposes, an insurer may wish to collect and use ‘old-fashioned’ genetic information, in the form of family history, as well as information drawn from DNA tests. Sound policy and practice must be developed in relation to both sources.⁸ Employers may be most interested in whether a worker has a predisposition to a genetic-linked disease or disorder that may be triggered by agents (for example, chemicals or dusts) found in the workplace.⁹

6.15 Law enforcement officials are mainly concerned to secure a ‘DNA profile’ — a genetic ‘fingerprint’ — for use in identifying an individual.¹⁰ The use of DNA for personal identification is also at the centre of parentage testing.¹¹ By way of contrast, scientific researchers generally work with de-identified (or anonymised) samples, since they are seeking trends and correlations across broader populations, rather than conclusions about known individuals.¹² Similarly, epidemiologists and public health officials are concerned with detecting broad trends and have little use for individual details.

6.16 Even in the context of the clinical medical usages, the degree of concern about the sensitivities surrounding genetic testing and information can vary greatly with the circumstances.¹³ For example, genetic information can relate to a condition that is *clinically apparent* — such as when a genetic test is performed to confirm a diagnosis with respect to someone who already has exhibited signs or symptoms of a particular disorder.

6.17 In these circumstances, genetic tests are not distinctly different in nature from other forms of clinical diagnostic testing (such as blood tests, MRI or CAT-scans), but may be more accurate and far less invasive (involving a buccal swab or a drop of blood). For example, it may be preferable to use a genetic test to diagnose cystic fibrosis in an infant rather than by a less accurate sweat test. Similarly, a genetic test for haemochromatosis is far less difficult and painful for the patient than a liver biopsy.¹⁴

7 Pt F. See also G Parasivam, *Submission G140*, 19 March 2002; Australian Federation of Right to Life Association, *Submission G082*, 17 January 2002.

8 Pt G.

9 Pt H.

10 Pt J.

11 Pt I.

12 Pt D.

13 Pt F.

14 See Human Genetics Society of Australasia, *Submission 6 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-Discrimination Bill 1998* 11 May 1998.

6.18 Genetic information also can relate to a condition that is *latent* — such as when a genetic test is done on someone who is apparently free of a disorder at present, in order to predict the likelihood that he or she will, or may, develop the disorder in the future, or may be a carrier for the disease or disorder. As noted in Chapter 4, such ‘predictive testing’ is called ‘presymptomatic testing’ where an individual’s family medical history suggests that he or she may have the genetic disorder, but the symptoms have not yet become manifest.

6.19 Predictive tests obviously raise greater ethical and social concerns¹⁵ than testing conducted for immediate clinical reasons, requiring among other things:

- careful thought about whether testing ought to be performed where no treatment is available, or where the patient is a child;
- much more care in interpretation, both by health professionals and the individuals concerned;
- considerably more attention devoted to collateral uses, and privacy and discrimination concerns; and
- the provision of adequate pre- and post-test counselling and support services.

Genetic difference: genotype and phenotype

6.20 Genes may come in different versions, known as *alleles*. These alleles arise when there is a change in the ordering of the bases described above — in effect, a ‘typographical error’ in the code, involving the change of a single letter, the inversion of two letters, the deletion or insertion of a phrase (a ‘codon’), or the repetition of a phrase. This change in the sequence may cause no harm (a ‘polymorphism’), or it may make the gene faulty (a ‘mutation’) in the way it directs (‘expresses’) the production of protein.

6.21 All humans have the same basic set of about 32,000–35,000 genes, according to the latest best estimates.¹⁶ This is far lower than the initial estimate of 100,000, and very similar to the mouse — and, at least for some people, uncomfortably close to the figure for the round worm (19,000), the fruit fly (13,000) and mustard cress (25,000). As has been widely reported, the human

15 C Jamieson, *Genetic Testing for Late Onset Diseases: In-depth Thematic Analysis of Policy and Jurisdictional Issues*, Health Canada, <<http://www.hc-sc.gc.ca/iacb-dgiac/arad-draa/english/rmdd/wpapers/thematic.pdf>>, 28 July 2002.

16 E Lander, ‘Genomic Information: Driving a Revolution in Bio-Medicine’ (Paper presented at Seventh International Conference of the Human Genome Organisation, Shanghai, 14 April 2002).

genome is more than 98% identical to that of chimpanzees, and 97% identical to that of gorillas.¹⁷

6.22 However, these findings also explode the old notion that ‘one gene codes for one protein’ — human genes clearly are much more complex than their counterparts in other species.

6.23 Although any two human beings will be 99.9% identical genetically, the precise DNA sequence of about 6.2 billion letters (3.1 billion base pairs) differs in each person’s ‘genetic code’.¹⁸ The remaining 0.1 percent of difference is thought to comprise more than 10 million common single-letter genetic variations (and a larger number of rare variants). The rate of variation is very low in humans (one single nucleotide polymorphism per 1300 bases) compared with other species, including other primates — suggesting a small species with a small ‘starter population’.¹⁹

6.24 These facts explain both the striking similarities among all people that are the result of our common inheritance, and the many individual differences found even within a nuclear family.

6.25 Some genetic variations make little or no difference to health, for example, hair colour. However, some mutations do affect basic functioning:

Mutations are permanent and inheritable changes in the ability of a gene to encode its protein. Much like typographical errors, which can change the meaning of a word, or even render a sentence as gibberish, such changes in gene structure can have severe effects on the ability of a gene to encode its protein. Some mutations prevent any

17 The principal genetic difference is that the other primates have 24 pairs of chromosomes, rather than the 23 pairs that characterise human beings. This appears to be the result of the fusion of two medium-sized ape chromosomes to become human chromosome 2, the second largest of the human chromosomes. Human chromosome 2 is not only the same size as the two ape chromosomes put together, but it also contains the same pattern of bands. M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 24.

18 The letters, A, T, C, and G (representing the chemical substances, or ‘nucleotides’, Adenine, Thymine, Cytosine, and Guanine) are arranged base pairs. These nucleotides link together to form long polynucleotide chains. A DNA molecule consists of two of these chains, linked together by hydrogen bonds, running in opposite directions. Linkage of the chains follows a strict rule of ‘complementary base pairing’: the base A can only pair with the base T, and vice versa; and the base G can only pair with the base C, and vice versa. These two chains link together in a ladder-like shape, twisted into the now famous DNA ‘double helix’, with sugars and phosphates forming the sides or backbone of the ladder and the base pairs forming the rungs. See Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.54–2.58.

19 E Lander, ‘Genomic Information: Driving a Revolution in Bio-Medicine’ (Paper presented at Seventh International Conference of the Human Genome Organisation, Shanghai, 14 April 2002).

protein from being produced, some produce a non-functional or only partially functional protein, and some produce a faulty or poisonous version of the protein.²⁰

6.26 The unique combination of alleles found in a particular individual's genetic make-up is said to constitute that person's *genotype*. The observable physical characteristics of this genotype, as determined by the interaction of both genetic makeup and environmental factors, is said to constitute that person's *phenotype*. This would include such features as eye colour and hair colour, determined genetically, as well as height and weight — determined by genetic factors as well as by diet and other environmental influences.

The influence of environment

6.27 For much of the latter part of the last century, the prevailing orthodoxy was that 'nurture' (environment) is far more important than 'nature' (genes) in influencing human development,²¹ at least outside of the basic inherited physical traits. The pace and weight of genetic research in recent times, however, appears to have tipped common wisdom in the other direction — perhaps too far in the direction of genetic exceptionalism and determinism (see below).

6.28 In fact, the picture is far more complex. A person is not the sum of a column of traits and behaviours determined by individual genes; instead, it is better to think of a person as comprising *all of*:

- the product of his or her genes;
- the intricate interaction of those genes; and
- the elaborate interaction between that genetic legacy and environmental factors.

6.29 Even a simple reference to 'the environment' understates the dynamic and multifaceted nature of this relationship. At the most simple level, the quality of the 'environment' — a nutritious diet, access to good health care, opportunities for exercise — will allow the full expression of genetically inherited traits, such as height. Over a lifetime, other aspects of the physical environment also will shape human health and development — for example, air and water pollution, endemic

20 R Hawley and C Mori, *The Human Genome: A User's Guide* (1999) Harcourt Academic Press, Burlington, 6. eg, Huntington's disease (HD) is caused by a mutation to a gene that lies on chromosome 4, in which the triplet CAG repeats an abnormally large number of times. Most people have 10–15 repeats; 39 or more repeats mean that the person will develop HD at some time, with the larger the number of repeats the earlier and more severe the onset. The complete lack of this triplet causes another rare but serious disease, Wolf-Hirschhorn syndrome: see M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 55.

21 See S Rose, L Kamin and R Lewontin, *Not in Our Genes: Biology, Ideology and Human Nature* (1985) Pantheon.

disease, workplace safety, drought and war. Choice and chance also play an important role — smoking and skydiving pose dangers to health unrelated to genetic inheritance, and a high speed, head-on car accident will always trump good genes.

6.30 As Ridley has put it:

You had better get used to such indeterminacy. The more we delve into the genome the less fatalistic it will seem. Grey indeterminacy, variable causality and vague predisposition are the hallmarks of the system ... because simplicity piled upon simplicity creates complexity. The genome is as complicated and indeterminate as ordinary life, because it is ordinary life. This should come as a relief. Simple determinism, whether of the genetic or environmental kind, is a depressing prospect for those with a fondness for free will.²²

6.31 The 'environment' is also full of social constructs that affect our well-being and the opportunities to reach our full potential. If a community prohibits women from receiving higher education, or bars from employment (expressly, or through direct or indirect discrimination) members of certain racial or ethnic groups or persons with a physical disability, then inherent intellectual ability will count for little. Similarly, if a community is pre-occupied with idealised (and atypical) body images, then this may contribute to severe eating disorders and ill health in otherwise healthy young women, notwithstanding genes that code for good health.

6.32 Alzheimer's disease is an example of a disease that may be partly genetic and partly environmental:

The predisposition to develop Alzheimer's disease is determined by the genes you inherit from your parents, but whether you get it or not when you're in your 70s, your 80s, your 90s obviously depends upon the stimulation that you receive from your environment.²³

Medical genetics

Genes and human health

6.33 Ridley has pointed out that the tendency to identify a specific gene as the cause of disease obscures the vital role of genes in human health:

Open any catalogue of the human genome and you will be confronted not with a list of human potentialities, but a list of diseases, mostly named after pairs of obscure central-European doctors. ... The impression given is that genes are there to cause diseases. ...

22 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 75.

23 Prof Bob Williamson: The Science Show, *Huntington's Disease Study*, Radio National, <<http://www.abc.net.au/rn/science/ss/stories/s117687.htm>>, 9 October 2001.

Yet to define genes by the diseases they cause is about as absurd as defining organs of the body by the diseases they get: livers are there to cause cirrhosis, hearts to cause heart attacks and brains to cause strokes. It is a measure, not of our knowledge but of our ignorance, that this is the way the genome catalogues read. It is literally true that the only thing we know about some genes is that their malfunction causes a particular disease. This is a pitifully small thing to know about a gene, and a terribly misleading one. It leads to the dangerous shorthand that runs as follows: 'X has got the Wolf-Hirschhorn gene'. Wrong. We all have the Wolf-Hirschhorn gene, except, ironically, people who have Wolf-Hirschhorn syndrome. Their sickness is caused by the fact that the gene is missing altogether. In the rest of us the gene is a positive, not a negative force. The sufferers have the mutation, not the gene.²⁴

6.34 Medical conditions or diseases linked to genes can be classified in a number of ways, including:²⁵

- single-gene (or 'monogenic');
- polygenic;
- multifactorial;
- chromosomal (such as Down syndrome);²⁶ and
- somatic cell.²⁷

Monogenic disorders

6.35 A monogenic disorder is one in which a mutation in one or both alleles of just one gene causes a genetic disease. Much of our early understanding about genetic influences on health is derived from observation and study of monogenic disorders, such as Huntington's disease. However, such diseases are relatively rare:

Huntington's disease is at the far end of the spectrum of genetics. It is pure fatalism, undiluted by environmental variability. Good living, good medicine, healthy food, loving families or great riches can do nothing about [it]. Your fate is in your genes.²⁸

6.36 However:

Unless you are unlucky enough to have a rare and serious genetic condition, and most of us do not, the impact of genes upon our lives is a gradual, partial, blended sort of thing. You are not tall or a dwarf, like Mendel's pea plants, you are somewhere in

24 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 54–55.

25 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 37.

26 Ibid, 69–70.

27 The 'spontaneous gene mutations occurring during life' referred to above, are typically associated with ageing, auto-immune disease and congenital malformations: Ibid, 210–211.

28 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 64.

between. You are not wrinkled or smooth, but somewhere in between. This comes as no great surprise, because just as we know it is unhelpful to think of water as a lot of little billiard balls called atoms, so it is unhelpful to think of our bodies as the products of single, discrete genes.²⁹

Polygenic disorders and haplotyping

6.37 We are increasingly aware that the vast majority of medical conditions with some genetic link involve either the complex interaction of a number of genes (polygenic) or the complex interaction between genes and the environment (multifactorial disorders).³⁰

6.38 According to the Human Genome Database,³¹ as of 7 October 2001, 10,832 genes have been mapped to individual chromosomes, of which 1,610 have been identified as being involved in a genetic disorder. It may be that most of the simple linkages already have been made, since the rate of discovery has slowed dramatically despite better technology: of the last 3,783 genes to have been mapped, only 17 have been identified with a genetic disorder.

6.39 Following the success of the Human Genome Project (HGP), the 'next big thing', according to Dr Francis Collins, director of the United States National Human Genome Research Institute, is to produce a Human Haplotype Map — 'haplotypes' (or 'haplotype blocks') amounting to a number of closely-linked alleles along a region of a chromosome that tend to be inherited together.³²

6.40 According to the US National Human Genome Research Institute:

The elucidation of the entire human genome has made possible our current effort to develop a haplotype map of the genome. The haplotype map, or 'HapMap', will be a reference work that catalogs the genetic variations of most importance to health and disease.

29 Ibid, 66.

30 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 55, 211.

31 An international collaboration in support of the Human Genome Project. See the excellent website hosted by the Hospital for Sick Children in Toronto, Canada, which contains regularly updated tables containing details of 'Genetic Disorders by Chromosome', as well as a 'Display Map' to view genetic disorders mapped to a chromosome: see Hospital for Sick Children, *Reports and Statistics*, <<http://www.gdb.org/gdb/report.html>>, 5 October 2001.

32 According to the National Human Genome Research Institute, 'Haplotype and allele frequencies are affected by cellular-level processes such as mutation, recombination, and gene conversion, as well as by population-level processes such as natural selection against alleles that contribute to disease. ... Haplotype and allele frequencies are also affected by population history factors such as population size, bottlenecks or expansions of population size, founder effects, isolation of a population or admixture between populations, and patterns of mate choice': National Human Genome Research Institute, *Developing a Haplotype Map of the Human Genome for Finding Genes Related to Health and Disease*, <<http://www.genome.gov/page.cfm?pageID=10001665>>, 23 July 2002.

The DNA sequence of any two people is some 99.9 percent identical. The variations, however, may greatly affect an individual's disease risk. Sites in the DNA sequence where individuals differ at a single DNA base are called single nucleotide polymorphisms (SNPs). Sets of nearby SNPs on the same chromosome are inherited in blocks. This pattern of SNPs on a block is a haplotype. Blocks may contain a large number of SNPs, but a relatively few SNPs can be enough to uniquely identify a haplotype. The HapMap is a map of these haplotype blocks, including the specific SNPs that identify the haplotypes.

The HapMap will enable researchers to quickly compare a patient's genetic patterns with known patterns, and thus determine if that patient is at risk for particular diseases. In addition, people with the same disease may respond differently to the same drug treatments; the HapMap will enable researchers to examine drug efficacy in specific diseases with genetic patterns. Finally, haplotype mapping will reveal the role of variation in individual responses to environmental factors.³³

6.41 In theory, there could be large numbers of haplotypes in a chromosome region; however, recent research suggests that there are a smaller number of common haplotypes — perhaps as few as four or five common patterns across all populations — which would permit researchers to shortcut their work dramatically by testing for genetic predispositions for such complex diseases as cancer, diabetes, hypertension, and Alzheimer's block-by-block, rather than letter-by-letter.³⁴ Researchers involved in the work supporting this 'common variant hypothesis' have drawn three important conclusions:

First, the human genome can be objectively parsed into simple haplotype blocks each averaging 11,000 to 22,000 DNA letters but only four or five different variations in the letters. Second, the blocks are similar across individuals from Africa, Europe, and Asia, suggesting that a map of haplotypes will have broad utility for most people. Third, the haplotype blocks appear to capture about 90 percent of genetic variation in a region of the human genome.³⁵

6.42 According to Mark Daly, one of the authors:

This study is a significant step toward developing a more powerful statistical approach to studying complex human disease. Genetics has not made tremendous inroads in complex disease, even though great effort has been put in during the last 10 to 15 years. As a community, we've come to understand that complex diseases are not caused by single high-penetrance genes, but from more modest risk factors common in populations.

33 See the National Human Genome Research Institute website: Ibid.

34 See S Gabriel and others, 'The Structure of Haplotype Blocks in the Human Genome' (2002) 296 *Science* 2225; discussed in C Morton, *The Next Big Thing in Mining the Genome: A Simpler Tool for Finding Disease Genes and Spotting Genetic Variation*, Harvard University Focus, <http://focus.hms.harvard.edu/2002/June7_2002/genomics.html>, 21 July 2002.

35 C Morton, *The Next Big Thing in Mining the Genome: A Simpler Tool for Finding Disease Genes and Spotting Genetic Variation*, Harvard University Focus, <http://focus.hms.harvard.edu/2002/June7_2002/genomics.html>, 21 July 2002. However, for a contrary view of the promise of haplotype research, see J Couzin, 'New Mapping Project Splits the Community' (2002) 296 *Science* 1391.

This study provides a great deal of hard data scientists can use to go back and refine and improve models of population biology and molecular evolution. For once, genetics worked out to be easier than it could have been. But now we have to do the disease studies, which will not be simple.³⁶

6.43 For example, researchers at the Massachusetts Institute of Technology's Whitehead Center for Genome Research and Massachusetts General Hospital (affiliated with Harvard Medical School) have found:

Strong evidence that a common single-letter variation in the gene *PPAR-gamma* plays a role in the risk of type 2 diabetes in the general population. Carried by 85 percent of the general population, the variant increases the risk of disease by 30 percent. These results have now been confirmed by other researchers and in multiple populations. A growing list of examples supports the hypothesis, including ApoE4 in Alzheimer's disease, Factor V Leiden in deep vein thrombosis, and CCR5 in protection against HIV.³⁷

Multifactorial disorders

6.44 In the case of multifactorial disorders, inheriting a mutated allele for particular conditions means that the person is susceptible or predisposed to develop the condition. Other factors such as diet or exposure to certain environmental factors are necessary to ensure the expression of the trait or condition. Most of the important and common medical problems in humans are multifactorial, including heart disease, hypertension, psychiatric illness (such as schizophrenia), dementia, diabetes, and cancers.

Is genetic information special?

6.45 One of the central matters for the Inquiry is whether genetic information is so fundamentally different (qualitatively or quantitatively) from other forms of personal health information that it requires special regimes (for example, with respect to consent, privacy and discrimination) to regulate its collection, use and disclosure.

The ubiquity dimension

6.46 Substantial information about a person's identity and genetic make-up can be gathered for analysis from 'the tiny bits of genetic material we scatter around us without much thought', such as 'the cells mixed in our saliva and the

36 C Morton, *The Next Big Thing in Mining the Genome: A Simpler Tool for Finding Disease Genes and Spotting Genetic Variation*, Harvard University Focus, <http://focus.hms.harvard.edu/2002/June7_2002/genomics.html>, 21 July 2002.

37 Ibid.

bulbs at the base of the hairs we continuously shed³⁸ — which is also what makes it a potent force for police investigations, where ‘the saliva on a licked postage stamp can help solve a major crime’.³⁹

6.47 Every cell in a person’s body, with the exception of sex cells, contains all of his or her genetic code. Unlike other forms of personal health data, a person’s genetic code is not transitory — genetic information lasts for life. Therefore, the testing of any biological sample any time can reveal the full complement of a person’s genetic information.

6.48 There is also potential for stored genetic samples to be re-tested as new tests and techniques are developed, or our understanding of genetic conditions is advanced. Thus, genetic information is unusual to the extent that, as a technical matter, it may be obtained by testing material that is readily available — indeed, virtually ubiquitous — without the knowledge or consent of the person in question.

6.49 While there appears to be a community consensus in favour of the use of genetic material for identification in the law enforcement context, there would be no such comfort in the thought that hairs, or saliva taken from a glass, or mucous or drops of blood from a discarded handkerchief, might be taken and subjected to DNA analysis by an employer, an insurer, a government official, a journalist or a medical researcher, without that person’s knowledge or consent (or some other lawful authority).

6.50 The bulk of this Discussion Paper considers whether, and to what extent, protective mechanisms (whether formal law or ethical oversight or industry practice) need to be put into place in each of the various relevant contexts to control the use and avoid the misuse of genetic information. Parts of this Discussion Paper also address specific concerns about taking and submitting another person’s tissue samples for DNA analysis, without that person’s consent or some other lawful authority.⁴⁰

The familial dimension

6.51 While each person’s genetic information is unique,⁴¹ it also can reveal information about and, therefore, have implications for that person’s blood relatives, including those in succeeding and preceding generations. Thus, genetic information can be said to flow from ‘before the cradle to after the grave’.

38 T Murray, ‘Genetic Exceptionalism and “Future Diaries”’: Is Genetic Information Different From Other Medical Information?’ in M Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven, 60.

39 Ibid, 60.

40 See eg Ch 5, Ch 31.

41 Even ‘identical twins’ have minute differences in their genetic code.

6.52 Sometimes these implications may even extend beyond the family to larger groups of closely-linked people with common ancestry (for example, indigenous, ethnic or ethno-religious communities).

6.53 Moving in the other direction, it may be possible to draw general inferences about the genetic information of an individual who belongs to a family or a group, if information is already known about other members of the family or group. Similarly, genetic information is capable of revealing 'family secrets', including information about parentage (for example, non-paternity or misattributed parentage), adoption, or the use of artificial reproductive technology.

6.54 Demonstrating that an individual is a carrier of a mutated allele for cystic fibrosis (CF) means that one of that person's biological parents is also a carrier, and that his or her siblings may be affected or also may be carriers.⁴² Tay-Sachs disease is primarily (but not exclusively) found in persons of Eastern European ('Ashkenazi') Jewish descent; sickle cell anaemia primarily affects persons of black African descent; and haemochromatosis is common in persons of northern European descent.⁴³

6.55 The familial nature of genetic information poses certain ethical questions and challenges, both for individuals and families, as well as for those persons and institutions that handle this information, such as medical practitioners, scientific researchers, hospitals, family cancer registers, and others. For example, as sensitive health information, the instinctive reaction is to provide a high level of privacy protection for genetic information.

6.56 However, to the extent that genetic information has a familial dimension, it can be argued that it is 'shared' information, with other family members having rights — or at least interests — in information that may have implications for their own health.⁴⁴ Precisely because genetic information is familial in nature, much of it will come as no surprise; indeed, it can often provide great relief to those who receive the data. It is relatively rare that individuals learn of a risk through genetic testing that they did not already anticipate.

6.57 At the same time, some family members may wish to assert a right *not* to know about the results of a test taken by a family member to determine the presence or absence of a serious genetic disorder, such as Huntington's disease, preferring to organise their lives without the shadow of such information.

42 Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.75–2.86 regarding patterns of inheritance.

43 Ibid, para 2.117.

44 Disclosure to genetic relatives is discussed at length in Ch 18.

6.58 As with so many of the issues considered in this Paper, resolving such tensions is not easy, and it is not a matter of simply vindicating individual rights — since the core of the problem is that while each individual's position may be perfectly understandable and defensible, the competing and conflicting positions ultimately must be subject to some sort of test which carefully balances individual, familial and societal interests.

The predictive dimension

6.59 Other questions for this Inquiry arise from the fact that, until now, individuals and society have not had to deal with predictive information of such quantity, and there is no considered community view about access to and use of predictive genetic information by family members and people or organisations outside the family.

6.60 Information generated by DNA testing and analysis can be very precise — indicating whether a particular allele or mutation is or is not present.⁴⁵ However, this precision often will prove unhelpful when it comes to predicting future health.

6.61 Genetic information tends to be about possibilities rather than certainties, because only a proportion of those people with a particular disease-related mutation or other variant will go on to develop the disorder. Also, in some cases, genetic testing may fail to find a mutation, even though the clinical evidence is to the contrary.

6.62 'Penetrance' is the term used to describe the degree of likelihood (based on clinical studies) that an individual carrying a particular genetic trait that could cause a disorder will actually develop it.⁴⁶ This can vary from very low to very high, but it is not always a straightforward calculation.⁴⁷ For instance, it is possible to speak of the penetrance for each particular mutation (or combination of mutations) causing cystic fibrosis (CF). For the mutation known as 'DF508', the penetrance is high — about 99% (but not 100%). For other alleles, the penetrance is lower, but this also depends upon the definition of the disease.⁴⁸ The severity of the disease also may vary with the mutation — some individuals have mild CF, while others have severe CF.

6.63 The so-called 'breast cancer gene', BRCA1 and BRCA2, is found in about 1% of the female population, and its presence is said to increase the risk of developing breast cancer by a factor of five. However, only 60–85% of women

45 Assuming that scientific research already has confirmed the particular 'markers' that are being tested for.

46 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 47.

47 Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, Table 2–1, lists the known penetrance rates for a variety of genetic conditions.

48 In the case of cystic fibrosis, for example, clinicians must consider whether male infertility in the absence of any other clinical signs is a 'condition', or a 'disease', or nothing of significance.

with the BRCA1 or BRCA2 mutation will develop breast cancer during their lifetimes (that is, 60–85% penetrance). In other words, 15–40% will not do so. It is important to note that *everyone* has the BRCA1 and BRCA2 genes — which, in their correct form, have a role in suppressing the growth of tumours in breast and ovarian tissue. Increased risk of breast cancer is due to inheriting the mutated alleles of these genes (including from the father), which removes their preventive capacity.

6.64 Huntington's disease is an example of a condition with a very high penetrance, approaching 100%. Those who test positive for the HD mutation will almost always develop the disease if they live long enough.⁴⁹ However, even for HD, some people may develop the disease very late in life (in their 80s) — if they have not already died of something else. Some studies indicate different progress in identical twins, with one twin developing symptoms of HD much later than the other.⁵⁰

6.65 There are greater pressures to discover, gain access to and use genetic information than is the case for traditional health information. Its predictive nature makes it of particular interest in situations where information about a person's future, even though imprecise, could be incorporated into decision making by the individual or by others (such as employers, insurance companies or public health authorities).

6.66 On the one hand, genetic information has the potential to empower people to make better choices about health and medical care for themselves and their families, in association with other forms of health information.⁵¹ On the other hand, however, there are growing concerns that predictive genetic information and its implications — absent a strong technical and educational foundation, as well as appropriate genetic counselling and support — may be misunderstood or mistakenly applied by others who are permitted access to the information, resulting in adverse consequences for the person concerned.

6.67 This may be true even within the context of health care. Genetic support groups, for example, have related instances to the Inquiry in which genetic test information or the nature of a particular genetic condition is poorly understood or

49 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 58. See also M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 55–66.

50 There is on-going research to determine the extent to which an enriched environment (mental stimulation, physical activity etc) may delay the onset of HD and other degenerative diseases. See A van Dellen and others, 'Environmental Effects on Huntington's Disease in Transgenic Mice' (2000) 404 *Nature* 721, 721–722, discussed on the ABC Radio program 'The Science Show', 15 April 2000: The Science Show, *Huntington's Disease Study*, Radio National, <<http://www.abc.net.au/rn/science/ss/stories/s117687.htm>>, 9 October 2001.

51 See G Parasivam, *Submission G140*, 19 March 2002.

poorly communicated by medical practitioners. Similarly, the Commonwealth Department of Health and Ageing submitted that:

There is ... an identified need for general practitioners to be better educated about specific issues relating to genetic testing and the handling of genetic information. A needs assessment among Victorian general practitioners ... has identified that current knowledge of genetics among general practitioners is poor and that education and training is needed in technical, clinical and counselling aspects of genetic testing as well as ethical and privacy of information issues.⁵²

6.68 In the way of the modern world, people take the name of the genetic condition they believe they may have (based on family history, or a genetic test result, or perhaps even a self-assessment based upon apparent symptoms), type this into a powerful Internet search engine, download a great deal of technical information — and probably scare themselves witless.

6.69 A fascinating literature has emerged in recent years suggesting very clearly that:

Even among highly educated [people], the ability to solve basic numeracy problems is, on average, relatively poor.⁵³

6.70 Many classic research studies demonstrate that even well-educated people have considerable difficulty in understanding or weighing risk or opportunity when presented with figures about relative probability. For example, participants strongly tend to choose a 9-in-100 chance (that is, 9%) of winning a gamble over a 1-in-10 chance (10%).⁵⁴ Similarly, participants rated cancer as riskier when it was described as 'kills 1,286 out of 10,000 people' (that is, 12.86% risk of mortality) than as 'kills 24.14 out of 100 people' (24.14%).⁵⁵ It appears that people intuitively react to the larger raw numbers (for example 1,286), rather than the relative percentages (24.14% to 12.86%), and this even extends to the consideration of visual cues:

People assess quantity or probability by using the numerosity of the stimulus object as a judgmental clue. In their size-estimation task, a circle was judged as bigger when it was displayed as an array of numerous pieces in a pizza-slice shape.⁵⁶

52 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002, 13.

53 I Lipkus, G Samsa and B Rimer, 'General Performance on a Numeracy Scale among Highly Educated Samples' (2001) 21 *Medical Decision Making* 37, 37–44.

54 V Denes-Raj and S Epstein, 'Conflict between Intuitive and Rational Processing: When People Behave against Their Better Judgment' (1994) 66 *Journal of Personality and Social Psychology* 819, 819–829.

55 K Yamagishi, 'When a 12.86% Mortality is More Dangerous than 24.14%: Implications for Risk Communication' (1997) 11 *Applied Cognitive Psychology* 495, 495–506.

56 Ibid, 504. Other studies agree that 'The traditional use of proportions to express risk in genetic counselling lacks scientific basis. Rates were easier to understand than proportions, regardless of respondents' age, language and education': D Grimes and G Snively, 'Patients' Understanding of Medical Risks: Implications for Genetic Counseling' (1999) 93 *Obstetrics & Gynecology* 910, 910.

6.71 Community and professional education and the ready availability of information when needed can minimise misunderstanding of, over-reaction to, and misuse of, genetic information. This will require further research and clear thinking about how best to communicate information about risk and probability in clinical settings and genetic counselling,⁵⁷ as well as in other contexts in which use might be permitted in certain circumstances, such as insurance and employment.⁵⁸

6.72 Melzer and Zimmern have noted that:

genetic tests for markers that may not result in symptoms for half a century or more could be new examples of a process of premature medicalisation of attaching the 'disease' label before it has been established that prevention or treatment is clearly beneficial.⁵⁹

6.73 The worst result for Australia would be to allow genetic information to be used in such a way as to stereotype people about their future ability to function and the probability that disease will occur, rather than relying on evidence of actual disease and ability⁶⁰ — and thus creating the *real* risk of establishing a new 'genetic underclass' of people who are fit and able, but are locked out of securing insurance, employment or access to other goods, services and entitlements.

6.74 The Commonwealth Department of Health and Ageing has submitted that:

Instances of discrimination based on an individual's genetic information are known to have occurred. To some degree, such discrimination appears to be due to a significant overestimation of the reliability and predictive capacity of genetic information and to limited knowledge about the interaction between genetic and other environmental factors. These issues need to be actively addressed.⁶¹

6.75 In respect of insurance, the Anti-Discrimination Board of New South Wales submitted that:

57 See D Grimes and G Snively, 'Patients' Understanding of Medical Risks: Implications for Genetic Counseling' (1999) 93 *Obstetrics & Gynecology* 910, 910-914; I Lipkus and others, 'Relationships among Breast Cancer Perceived Absolute Risk, Comparative Risk, and Worries' (2000) 9 *Cancer Epidemiology, Biomarkers & Prevention* 973, 973-975; B Biesecker and J Garber, 'Testing and Counseling Adults for Heritable Cancer Risk' (1995) 17 *Journal of the National Cancer Institute Monographs* 115, 115-118; and A Edwards and others, 'Presenting Risk Information — A Review of the Effects of "Framing" and Other Manipulations on Patient Outcomes' (2001) 6 *Journal of Health Communications* 61, 61-82 (which contains an extensive review of the literature on risk framing in the clinical setting).

58 See Parts G, H.

59 D Melzer and R Zimmern, 'Genetics and Medicalisation' (2002) 324 *British Medical Journal* 863.

60 E Draper, 'The Screening of America: The Social and Legal Framework of Employers' Use of Genetic Information' (1999) 20 *Berkeley Journal of Employment & Labour Law* 286, 290-291.

61 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002, 3.

Assessing the degree of risk on the basis of genetic information is by no means clear cut. The nature of the information varies significantly depending upon factors such as whether the information indicates a predisposition to a disorder that is dominant or recessive and the fact that the degree of symptom expression and time of onset will vary between individuals. These factors will influence the relevance of predictive genetic information when applied to risk rating for insurance purposes.⁶²

6.76 In respect of employment, the Australian Council of Trade Unions submitted that:

If genetic testing was allowed, it is certain that it would be misused. First, it would be used to screen out employees who might have only a slightly higher predisposition to acquire a condition than the general population. Many employers would not distinguish between a predisposition and a certainty, while the possibility of false negatives and positives would not necessarily be taken into account.⁶³

6.77 Similarly, the Inquiry was urged to caution against using genetic predisposition, without great care, to determine the eligibility of athletes to participate in sport.⁶⁴

6.78 Yamagishi also has pointed out that the inability to make proper risk assessments is not merely a problem for individual patients, their families and health care professionals — there is also an important broader social dimension. Public officials and policy-makers often make judgments about spending priorities and the systemic use of resources to meet certain risks — while failing to give proper regard to evidence that deploying scarce resources to meet other, far more probable, risks would be more effective and efficient in terms of reducing harm (for example, illness or accident) overall.⁶⁵

Is genetic information truly ‘exceptional’?

Competing philosophies

6.79 The literature about public policy-making in respect of genetic information, especially in the United States, has tended to feature two polarised schools of thought. Those who favour ‘genetic exceptionalism’ view genetic information as uniquely powerful and posing special threats to privacy and discrimination that mandate dedicated and higher levels of legal protection. By way of contrast, the ‘genetic inclusivists’ argue that genetic information is just one of a number of sources of personal health and medical information, and there is no need for any higher or special protections.

62 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002, 32. See also M Otlowski, *Submission G159*, 24 April 2002.

63 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

64 A Miah, *Submission G139*, 15 March 2002.

65 K Yamagishi, ‘When a 12.86% Mortality is More Dangerous than 24.14%: Implications for Risk Communication’ (1997) 11 *Applied Cognitive Psychology* 495, 495–496, 505.

6.80 Professors Annas, Glantz and Roche of the Boston University School of Public Health, the authors of the influential US Model Genetic Privacy Act,⁶⁶ have been the main proponents of ‘genetic exceptionalism’, arguing that genetic information is so unique and so much more powerful than other forms of health information that it requires dedicated protective measures:

To the extent that we accord special status to our genes and what they reveal, genetic information is uniquely powerful and uniquely personal, and thus merits unique privacy protection.⁶⁷

6.81 Annas, Glantz and Roche offer three justifications for this view, along the lines of the matters discussed above. First, that a person’s DNA ‘can predict an individual’s likely medical future for a variety of conditions’—indeed, they argue that one’s DNA is a:

Coded probabilistic future diary because it describes an important part of a person’s unique future and, as such, can affect and undermine an individual’s view of his/her life’s possibilities. Unlike ordinary diaries that are created by the writer, the information contained in one’s DNA, which is stable and can be stored for long periods of time, is in code and is largely unknown to the person. Most of the code cannot now be broken, but parts are being deciphered almost daily.⁶⁸

6.82 Second, that genetic information about an individual also ‘divulges personal information about one’s parents, siblings, and children’.⁶⁹ Third, that there is a legitimate worry about the possibilities of genetic discrimination, since there is a history of genetics being used to stigmatise and victimise.

6.83 However, there also are some strong arguments that genetic information is not fundamentally different from other sorts of health and medical information, and therefore does not invariably merit special treatment. Dr Thomas Murray⁷⁰ has suggested that much of the drive behind genetic exceptionalism is based upon a

66 This Model Bill strongly influenced the Genetic Privacy and Non-discrimination Bill 1998, introduced into the Australian Parliament by Australian Democrats Senator (now leader) Natasha Stott Despoja in March 1998. See Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 2.27–2.29 for a discussion of this Bill, and its consideration by a Senate committee. For the committee report, see Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, 1. The Bill was restored to the Senate *Notice Paper* on 14 May 2002: see <<http://www.aph.gov.au/parlinfo/billsnet/bills1st.pdf>>.

67 G Annas, L Glantz and P Roche, ‘Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations’ (1995) 23(4) *The Journal of Law, Medicine and Ethics* 360, 365.

68 Ibid, 360.

69 Ibid.

70 President of the Hastings Center for Bioethics, in New York; formerly Chair of the Human Genome Project’s ELSI Task Force on Genetic Information and Insurance.

generalised image of genetic information as ‘a mysterious, powerful and inexorable force that will dominate and control our futures’.⁷¹

6.84 Another leading American expert in this area, Professor Lawrence Gostin,⁷² once argued that there are ‘compelling justifications’ for special privacy protection for genetic information, grounded in:

the sheer breadth of information discoverable; the potential to unlock secrets that are currently unknown about the person; the unique quality of the information enabling certain identification of the individual; the stability of DNA rendering distant future applications possible; and the generalizability of the data to families, genetically related communities, and ethnic and racial populations.⁷³

6.85 However, Gostin has since come to the conclusion that:

Genetic exceptionalism is flawed for two reasons: (1) strict protections of autonomy, privacy and equal treatment of persons with genetic conditions threaten the accomplishment of public goods; and (2) there is no clear demarcation separating genetic data from other health data; other health data deserve protections in a national health information infrastructure.⁷⁴

6.86 On this view, genetic information is neither distinctive nor unique in its ability to predict an individual’s future health, but indicates only a rough range of probabilities. Information about lifestyle (smoker or non-smoker, skydiver or race car driver, miner or office worker) and non-genetic test results (for example, for hepatitis, HIV/AIDS or cholesterol) also provide important clues to present and future health. Murray notes that many other factors and forms of health information ‘afford equally interesting predictions’ and ‘have implications for future health that are every bit as cogent and sensitive as genetic predispositions’.⁷⁵

6.87 Similarly, other non-genetic test results will contain very sensitive personal information, with the potential for causing distress, discrimination and stigma — such as a positive result for HIV/AIDS, tuberculosis, Hepatitis B or C, or a sexually transmitted disease. Murray notes here that:

Again, genetics is not alone. Institutions and individuals can and have used all sorts of information, both visible and occult, as the basis for discrimination. ... Perhaps what really frightens and galls us about discrimination on the basis of genetic information

71 T Murray, ‘Genetic Exceptionalism and “Future Diaries”: Is Genetic Information Different From Other Medical Information?’ in M Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven, 60, 64.

72 Professor of Law, Georgetown University and Professor of Public Health, Johns Hopkins University.

73 L Gostin, ‘Genetic Privacy’ (1995) 23(4) *The Journal of Law, Medicine and Ethics* 320, 326.

74 L Gostin and J Hodge, ‘Genetic Privacy and the Law: An End to Genetics Exceptionalism’ (1999) 40 *Jurimetrics: The Journal of Law, Science, and Technology* 21.

75 T Murray, ‘Genetic Exceptionalism and “Future Diaries”: Is Genetic Information Different From Other Medical Information?’ in M Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven, 60, 64.

is its reliance on information about us over which we have no control and may not even know ourselves. Here again it is the hidden and mysterious nature of genetic information, joined with its aura of power and ubiquity, lurking close beneath the surface of our discomfort.⁷⁶

6.88 Acceptance of genetic exceptionalism, Murray argues, would in practice require health systems to adopt a ‘two bucket theory of disease’, categorising and tossing every disease and risk factor into either the ‘genetic’ or the ‘non-genetic’ bucket — whereas ‘many diseases and risks don’t fit neatly into either bucket’.⁷⁷

6.89 In abandoning genetic exceptionalism, Murray writes that his Task Force on genetics and insurance ultimately concluded that:

There was no good moral justification for treating genetic information, genetic diseases, or genetic risk factors as categorically different from other medical information, diseases or risk factors. ... Our need for health care in most cases will be the product of a complex mix of factors, genetic and non-genetic, both within the scope of our responsibility and outside of that scope. The distinction between genetic and non-genetic factors is not the crucial one.⁷⁸

6.90 As a general matter, the consultations and submissions supported this view. The Commonwealth Department of Health and Ageing understood genetic information as part of a continuum of personal and health information, which would be difficult to ‘quarantine’ and subject to a different set of rules in the health sector.⁷⁹

6.91 Similarly, health law expert Dr Roger Magnusson submitted:

Genetic information is likely to become, in future, an integral part of each patient’s individualised health care program. In my view, it is reasonable to assume that, over time, genetic information will become ‘smeared across’ — so to speak — the individual’s clinical record, since it will be a relevant component of health status in many areas. Whether or not this information is or should be regarded as especially sensitive will depend, just like non-genetic information, on what it is.

The future role of genetic information within clinical care provides an important and pragmatic argument against genetic exceptionalism. Ultimately, there will be little point in seeking to compartmentalise and quarantine genetic health information behind additional privacy or security barriers. A generic solution to the privacy challenges of genetic health information is preferable.⁸⁰

76 Ibid, 60.

77 Ibid, 67.

78 Ibid, 71.

79 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002, 3.

80 R Magnusson, *Submission G039*, 10 January 2002; Queensland Government, *Submission G161*, 16 May 2002.

6.92 The Office of the Federal Privacy Commissioner also emphasised the need to approach privacy protection in relation to genetic information according to the context in which it is used:

In the interests of simplicity and ‘workability’, the privacy protection to be afforded to genetic information should be based primarily on the regulation of the *activities* — the acceptable uses and the misuses — involving that information.⁸¹

6.93 The Centre for Law and Genetics did not consider that, in any general sense, genetic information should be treated uniquely or separately from other forms of health information; however, the Centre noted that ‘there are particular issues associated with genetic information, particularly in the context of privacy and discrimination, that warrant special consideration’.⁸²

6.94 The NSW Nurses’ Association submitted that genetic information:

is more powerful than other forms of health information. As such it requires special legal protection and other exceptional measures ... Our position is based upon a clear potential for abuse by significant decision makers — employers, insurers and public authorities.⁸³

Towards a contextual approach

6.95 The University of Michigan’s Life Sciences, Values and Society Program has noted that:

Throughout the early 1990s many state legislatures pursued an exceptionalist approach, however as the nation moved into the 21st century state legislatures nationwide seemed to be moving towards the middle ground.⁸⁴

6.96 This trend is also reflected in the Inquiry’s emerging approach to the issues before us. There is little value in having to choose between opposing schools to define our own philosophy about the nature of genetic information.

6.97 The Inquiry accepts enough of the inclusivist or anti-exceptionalist argument to believe that it would be a mistake to attempt to deal in isolation with the issues surrounding genetic information through a new, dedicated ‘Big Law’ — for example, a Genetic Privacy, Discrimination and Research Act. To do so would unfairly privilege genetic information as against all other forms of relevant health and medical information — so that if, for example, a person suffers from a clearly

81 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002, 13.

82 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

83 New South Wales Nurses’ Association, *Submission G090*, 21 January 2002, 2.

84 Life Sciences Values and Society Program (University of Michigan), *Genetic Testing*, <<http://www.lifesciences.umich.edu/pdf/GeneTest.pdf>>, 21 July 2002.

genetic-linked disease like CF they are 'in', but someone suffering from tuberculosis is 'out'.

6.98 Equally importantly, such an approach would divorce genetic information from the principles, processes and institutions that have been developed over time to provide ethical oversight of research, ensure best practice in clinical medicine, protect personal privacy, and prohibit unlawful discrimination. Of course, some of those laws, principles and practices may be inadequate to protect *other* forms of health information.⁸⁵ However, the solution for this requires a general remedy, rather than singling out the handling of genetic information for improvement.

6.99 The Inquiry certainly does accept that there are some special features and issues attaching to genetic information, as discussed above, so that it is necessary to engage in a thorough inspection of existing principles, practices and safeguards, and of the legal, ethical and regulatory landscape, to ensure that all of these are adequate to the task.

6.100 Magnusson suggests that there actually may be less of an exceptionalist case for dealing with genetic information than for HIV/AIDS:

Genetic exceptionalism has a prominent precedent in HIV/AIDS, a life-threatening infection that emerged in an environment of widespread ignorance and prejudice. Gradually, over a period of about 10 years, Australian legislatures enacted a body of AIDS-specific laws in most jurisdictions.⁸⁶ On the other hand, unlike information relating to HIV/AIDS status, there is nothing discrete or self-contained about genetic information as a form of health information. As clinical genetics continues to develop, any attempt to compartmentalise genetic health data from other forms of health information will likely become unworkable. This is because — as the clinical implications of the genetic determinants of disease come to be better understood — genetic testing, and the volume of clinical genetic information, will both increase. Genetics-specific privacy laws will only contribute yet another layer of legal complexity (and health privacy law is already bewilderingly complex), while constituting a major irritant to health providers themselves.⁸⁷

6.101 The Centre for Law and Genetics also recommended that the Inquiry:

pursue the 'integrated' approach for the following reasons:

- the issues raised in the protection of human genetic information cover a wide range of activities from research to establish medical practice;
- regulation in this range of areas has traditionally centred on professional codes of ethical practice;

⁸⁵ C Roberts, *Submission G072*, 13 January 2002.

⁸⁶ R Magnusson, 'Australian HIV/AIDS Legislation: A Review for Doctors' (1996) 26 *Australian and New Zealand Journal of Medicine* 396; J Godwin and others, *Australian HIV/AIDS Legal Guide* (2nd ed, 1993).

⁸⁷ R Magnusson, *Submission G039*, 10 January 2002.

- many genetic tests produce results that do not differ to any great extent from other categories of private health information; and
- in the next decade genetics will become a less unique and more commonplace tool in diagnosis, treatment, and healthcare generally.⁸⁸

6.102 Similarly, Privacy NSW submitted that:

On one view the kind of information derived from DNA samples is so utterly unlike other kinds of personal information that it needs to be the subject of separate regulation. Arguments in favour of the separate regulation of genetic information are particularly appealing in the current regulatory environment where information privacy protection varies widely across and within jurisdictions.

On another view, the social implications of genetic information are so broad that a specific regulatory framework, just for genetics, would be unlikely to pick up all of them. Separate genetic regulation may risk engendering an overly deterministic approach to health care and privacy which fails to adapt to changing issues and technology. Integrating genetic safeguards in mainstream privacy legislation may ensure a more consistent and open process of adaptation to new social values and needs. In some specific areas such as insurance and employment, however, the exceptional features of genetic information may justify special treatment.⁸⁹

6.103 The bulk of this lengthy Discussion Paper examines the use of genetic information in a host of different contexts.⁹⁰ Where existing laws or processes are inadequate or inappropriate, the Inquiry has developed proposals for their reform. Where there are major gaps, the Inquiry has proposed a number of new, targeted laws and processes.

6.104 In recognition of the fact that genetic science and technology are moving very rapidly, the Inquiry also has proposed that a new standing body — a Human Genetics Commission of Australia — be established to provide on-going advice and scrutiny in this area long after our final report has been delivered to government.⁹¹

88 Centre for Law and Genetics, *Submission G048*, 14 January 2002. See also Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; Life Sciences Network, *Submission G129*, 19 March 2002.

89 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

90 The Queensland Government also has urged a contextual approach, noting that 'it would appear that a single new enactment may not be sufficient to overcome situations where there may be a threat of discrimination, in for eg insurance or employment, or threat to privacy and confidentiality': Queensland Government, *Submission G161*, 16 May 2002.

91 See Ch 3.

The dangers of 'genetic essentialism'

6.105 Aldous Huxley's *Brave New World* was perhaps the first cultural response to the fascination with eugenics in the 1920s and 1930s as a modernist principle for using science to improve society and social organisation.⁹² In light of recent scientific advances, popular culture is again beginning to consider the chilling vision of a society organised around genetic determinism ('a society that worships total predictability and perfection'), in films such as 'GATTACA' (1997).⁹³

6.106 'Genetic essentialism' is a reductionist view of human beings as essentially consisting of their genes,⁹⁴ with human worth describable in the language of genetics. It is closely associated with 'genetic determinism' — the belief that human health and behaviour are basically predetermined by, and co-extensive with, a person's genetic make-up. That is:

personal traits are predictable and permanent, determined at conception, 'hard-wired' into the human constitution ... [T]his ideology minimizes the importance of social context.⁹⁵

6.107 One of the discoverers of the DNA double helix, Nobel Prize winner Dr James Watson, famously has said that '[w]e used to think our future was in the stars. Now we know it is in our genes'. The widespread use of genetic information to identify individuals or groups at risk for disease or harm from a work environment, or to guide provision of any social benefits or services, or in any way to classify people, may change or challenge the way we think about what it means to be human.

6.108 As a society, will we come to measure the worth of a person by his or her genetic makeup? Will we come to regard all illness and even behaviour and preferences (political, sexual, cultural, aesthetic) as genetically predetermined? Will we come to view some gene-linked behavioural traits (obesity, smoking, drug and alcohol dependence) with more sympathy, in the same way that we now avoid attributing fault to, and stigmatising, persons with other genetic disorders?⁹⁶ If so, will this challenge the fundamental ideas upon which our civil society and legal

92 A Huxley, *Brave New World* (1932) Penguin Modern Classics, London.

93 See Ch 2. 'GATTACA' is taken from the four-letter building blocks for DNA. The film's website is found at Sony Pictures, *Welcome to Gattaca*, <<http://www.gattaca.com>>, 23 July 2002.

94 Or 'Genes 'R' Us', as one submission put it: I Barns, *Submission G056*, 8 January 2002.

95 R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 316-321.

96 M Segal, 'Autonomy and the Family in the Testing of Adolescents for Behavioural Traits' (Paper presented at Seventh International Conference of the Human Genome Organisation, 17 April 2002).

system are built, which emphasise free will, autonomy, individual moral and criminal responsibility,⁹⁷ and social responsibility?⁹⁸

6.109 The Office of the Federal Privacy Commissioner submitted that advances in genetic science:

should not override the fact that, as human beings, we have the unique capacity to make rational decisions about our lives. This means that the greatest human right is the freedom to choose. Even if our understanding of the interaction of the determining factors were to improve enormously, except where social considerations require it (for example, the lawful prevention of harms to others), the existence of a free society presumes that the individual is free to choose.

Especially where that choice involves our own bodies and destinies, the voluntary nature of our decision-making excludes reliance on the concept that our lives and well-being are pre-determined genetically. To hold otherwise is to render an exercise of an individual's free will in a democratic society as a meaningless practice. With that freedom to choose, there comes the social recognition of the need for people to take responsibility for their decisions, which could otherwise be evaded by pleading genetic pre-determinism. The consequences of the latter, for example, in the criminal justice system, are unthinkable.⁹⁹

6.110 Murray has warned that:

genetic risks may come to be seen as *the* explanation for complex multifactorial diseases. They may also be seen as fundamental, defining characteristics of the persons who have such risks, essentially reducing those persons to their genetic propensities. ... we do not have to pretend that genes are unimportant to avoid determinism or reductionism. We should give genes their due, but no more than that.¹⁰⁰

97 For an interesting discussion of how genetics might impact upon traditional notions of criminal responsibility, see C Wells, 'I Blame the Parents': Fitting New Genes in Old Criminal Laws' (1998) 61(5) *The Modern Law Review* 724. One submission argues that in the 20th century, the criminal law moved to recognise that intellectual disability, mental illness and other permanent or temporary mental impairments could have the effect of diminishing, or even excluding, criminal responsibility. Similarly, as genetic science develops and comes to be better understood, criminal law also will adapt to concepts of genetic determinism, and move towards a more pragmatic approach to 'imprisonment or institutionalization of the minority who perform unacceptable behaviours ... as a regrettable but expedient action for the harmonious function of society. It would be seen to have a protective and rehabilitative function and would neither involve imputation of guilt, nor be regarded as retribution': *Confidential Submission G063CON*, 14 January 2002.

98 See L. Andrews, *Future Perfect: Confronting Decisions About Genetics* (2001) Columbia University Press, New York; M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, Ch 22; D Hamer and P Copeland, *Living with Our Genes* (1998) Anchor Books, New York. See also N Tonti-Filippini, *Submission G014*, 16 November 2001.

99 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002. See also S Raeburn, *Submission G033*, 2 January 2002.

100 T Murray, 'Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different From Other Medical Information?' in M Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven, 60, 70.

... there is a vicious circularity in insisting that genetic information is different and must be given special treatment. The more we repeat that genetic information is fundamentally unlike other kinds of medical information, the more support we implicitly provide for genetic determinism, for the notion that genetics exerts special power over our lives.¹⁰¹

6.111 Ridley has cautioned against adopting a crude dichotomy that equates genetic influences with ‘determinism’, and environmental influences with ‘freedom’:

There has been a long tradition among a certain kind of science writer to say that the world of biology is divided into people who believe in genetic determinism and people who believe in freedom. Yet these same writers have rejected genetic determinism only by establishing other forms of biological determinism in its place — the determinism of parental influence or social conditioning. It is odd that so many writers who defend human dignity against the tyranny of our genes seem happy to accept the tyranny of our surroundings. ... The crude distinction between genes as implacable programmers of a Calvinist predestination and the environment as the home of liberal free will is a fallacy.¹⁰²

6.112 A number of serious concerns may be raised about the social consequences of adopting or internalising the tenets of genetic essentialism, even where this is borne of optimism for the benefits of medical and scientific advances.

6.113 For example, an over-concentration of research into genes and their health implications could lead to neglect of the effects on human health of other factors, such as the physical, social, spiritual and economic environments in which people live.¹⁰³

6.114 Many communities in Australia have close family and cultural links and are aware of their origins and heritage. Nelkin and Lindee have cautioned against supplanting human identity and relationships with molecular biology:

As the science of genetics has moved from the laboratory to mass culture, from professional journals to the television screen, the gene has been transformed. Instead of a piece of hereditary information, it has become the key to human relationships and the basis of family cohesion. Instead of a string of purines and pyrimidines, it has become the essence of identity and the source of social difference. Instead of an important molecule, it has become the secular equivalent of the human soul.¹⁰⁴

101 Ibid, 71.

102 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 302–303.

103 See R Lewontin, *The Triple Helix: Gene, Organism and Environment* (2000) Harvard University Press, Cambridge. See also S Raeburn, *Submission G033*, 2 January 2002. Regarding the spiritual dimension in health, see Christian Science Committee on Publication, *Submission G127*, 19 March 2002.

104 D Nelkin and S Lindee, *The DNA Mystique: The Gene as a Cultural Icon* (1995) W Freeman, New York, 198.

6.115 In Chapter 32, the Inquiry notes that there already have been disputes in some Aboriginal communities, and calls for the utilisation of genetic testing to confirm or deny kinship relations — and thus to determine Aboriginality (for example, for the purpose of voting in ATSIC elections, or being a party to a native title claim, or obtaining certain benefits targeted for indigenous people).

6.116 Current attitudes of social solidarity also could be threatened by genetic essentialism. For example, an expectation could develop that those with genetic susceptibilities, or at risk of having children with a genetic disorder, increasingly should take financial responsibility for their own and their affected children's health care.¹⁰⁵

6.117 As discussed above, and elsewhere in this Discussion Paper,¹⁰⁶ there is a clear need for much more public and professional education about genetics, and the sensible application of genetic information within a range of important contexts.

6.118 The submission from Queensland Advocacy Inc summarises very well the social forces and tensions involved:

Genetic determinism is not necessarily a belief in a causal world in which only genes have a determining effect on human health and behaviour. It could rather be the belief that the world is best served through emphasising the role of genes and seeking to order life accordingly. It is conceptually possible to be a genetic determinist and also believe that genes are a myth. It is important to distinguish causal determinism from ideological determinism. The problem at issue is an ideology of genetic determinism: the seeking for an account of life and its major events in terms of genes in order to use that account in the shaping of society. It makes sense that even very disempowered people could perceive the benefits in adopting such a view, particularly if it promises to open up access to significant resources. Genetic determinism is potentially a strong contender for the status of 'most promoted scientific myth' of the era. It could also be the most insidious. ...

The most important response to the state of affairs in which this does occur, is to create opportunities for greater public involvement in the cycles of construction, deconstruction and reconstruction of genetic information. Human genetic information is ultimately, not about genes; it is about people. The information, because it originates in language and social practices, can be used in two ways. Either it can be regarded as private, which centres power in professions and individuals, or it can be regarded as public, which places power back into the community. The responsibilities created by either response are enormous. On either side lie distinctly undesirable prospects — enormous professional and corporate power or overwhelming public apathy — and the future may be charted through one of these factors ensuring that the other occurs. The task of ethics, including this inquiry, is to work against either occurring.¹⁰⁷

105 Australian Federation of Right to Life Association, *Submission G082*, 17 January 2002.

106 See Ch 20.

107 Queensland Advocacy Inc, *Submission G088*, 4 February 2002.

6.119 The challenge for our society is to maintain its moral and ethical compass, supporting those aspects of genetic science (including the subtle and complex interplay between genes and environment) which reduce pain and suffering and increase quality of life, whilst firmly resisting the lazy or perverse use of this knowledge in such a way that tends to diminish personal freedom and personal responsibility, and creates new opportunities for unfair discrimination.

Part C. Regulatory Framework

7. Information and Health Privacy Law

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Introduction

7.1 The terms of reference require the Inquiry to report on whether, and to what extent, a regulatory framework is required to protect the privacy of human genetic samples and information. Privacy is a concept capable of many meanings.

Privacy has been variously described as the right to be let alone, the right to personal space or autonomy, the right of people to exercise control over their personal information or the degree of interference with their personal life, a popular reaction to the spread of new technologies or, more recently, simply fair information practices.¹

¹ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

7.2 It is worth remarking that there are increasingly few zones of privacy to be found in modern life. High density urbanisation means people have less space of their own. Surveillance cameras in public areas, shops and even in the workplace are increasingly common for security reasons. Computers can track every movement and transaction and facilitate cross-matching of information from disparate databases, and can directly monitor the activity of users (through ‘cookies’ and other means). Popular culture, especially as portrayed on television and on the Internet, is full of so-called ‘reality programming’ based upon intensive video surveillance of the sort that was first suggested — with horror, rather than fascination — in George Orwell’s classic novel *1984*.

7.3 There is actually a very low rate of genetic variation among humans — 99.9% of the human genome is identical. So when we talk about ‘genetic privacy’ we are referring to only that very tiny part of the human genome which is unique to each individual, the single nucleotide polymorphisms (SNPs) that occur once in roughly 1,300 bases in each individual’s genetic code. It is interesting that, in what has arguably become — with little public resistance in some areas, and strong encouragement in others — a ‘surveillance society’, there is genuine community concern about protecting the privacy of genetic information in particular.

7.4 Most importantly for the purposes of this Inquiry, the privacy of human genetic information is one aspect of the broader concept of information privacy. Information privacy can be defined as the right of individuals to control the collection, use and disclosure of information relating to them (personal information).

7.5 The High Court has confirmed that there is no enforceable general right to privacy in Australian common law and, in particular, there is no tort of invasion of privacy. With certain exceptions, such as where duties of confidentiality are breached, enforcement of rights to privacy must be based on statute,² including information and health privacy legislation.

Information and health privacy legislation

7.6 This chapter briefly summarises the existing legislative framework for the protection of information and health privacy based on the *Privacy Act 1988* (Cth) (the *Privacy Act*) and similar state and territory legislation and its application to the privacy of genetic samples and information.

7.7 The Inquiry has sought to assess the adequacy of existing privacy legislation as a framework for protecting the privacy of genetic samples and information and has made reform proposals to better protect genetic privacy. There

2 *Australian Broadcasting Corp v Lenah Game Meats Pty Ltd* (2001) 185 ALR 1.

are other mechanisms through which privacy protection of genetic samples could be pursued. These include recognising new property rights in genetic material or amending the Human Tissue Acts to regulate the collection, storage, use of, and access to, genetic samples.³ These options are examined further in Chapter 17.

7.8 At present, national regulation of information privacy is provided by a complex, fragmented and overlapping set of federal, state and territory legislation. The chapter discusses whether there is a need for uniformity or greater harmonisation of laws concerning the privacy protection of human genetic information and, if so, on what basis.

7.9 The Inquiry is of the view that while some inadequacies in the existing legislative privacy framework can be identified these are best remedied through changes to general information and health privacy laws (including the *Privacy Act*), rather than through developing a new regulatory framework for the protection of genetic samples and information specifically. This chapter examines the reasons for this conclusion.

7.10 On the assumption that the *Privacy Act* (amended as proposed in this Discussion Paper) will continue to form the legislative underpinning for the privacy protection of genetic information, this chapter examines a range of issues relating to the coverage of the *Privacy Act* — including the key issue of whether the *Privacy Act* should cover genetic samples, as well as the genetic information derived from them.

7.11 Finally, the chapter discusses some issues that arise in the practical application of the *Privacy Act* and privacy principles to genetic samples and information and, in particular, the implications of the shared or familial nature of genetic information and the so-called right not to know.

The Privacy Act

7.12 There is much existing federal, state and territory regulation of information privacy. At the federal level, information privacy is regulated by the *Privacy Act*. While the *Privacy Act* is the major focus of consideration in this chapter, state and territory legislation is also discussed in the context of the need for greater harmonisation across Australian jurisdictions.

3 *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

7.13 The *Privacy Act* is intended to protect the personal information of individuals and to give them control over how that information is collected, used and disclosed. The legislation sets out certain safeguards that government, private sector organisations and individuals must observe in collecting, storing, using and disclosing personal information. It also gives individuals rights to access and correct their own personal information.

7.14 The *Privacy Act* contains privacy safeguards set out in a number of Information Privacy Principles (IPPs) and National Privacy Principles (NPPs), which have the force of law.⁴

7.15 The IPPs cover collection, storage and security, use, disclosure and access to ‘personal information’, which is in a ‘record’ held by an ‘agency’, as those terms are defined in the *Privacy Act*. With limited exceptions, agencies include only Commonwealth public sector entities.

7.16 Most private sector organisations are covered by the new private sector provisions of the *Privacy Act*.⁵ The organisations covered include all health services holding health information as defined by the *Privacy Act*. The Act extends privacy protection to genetic information collected, used and disclosed by private sector entities such as private hospitals, health practitioners and insurance companies.⁶

7.17 Private sector organisations must comply with the NPPs. The NPPs set out how organisations should collect, use and disclose personal information, maintain data quality, keep personal information secure, maintain openness, allow for access and correction of personal information, use identifiers, allow anonymity, conduct transborder data flows and collect sensitive information. Some of these principles are similar to the IPPs. However, among other differences, the NPPs contain special provisions for ‘sensitive information’ and ‘health information’ (as discussed below, health information is a subset of sensitive information).

7.18 It is difficult to summarise the possible application of the IPPs and NPPs to the many circumstances in which questions about the privacy protection of genetic information may arise. IP 26 mapped some of the key protections provided

⁴ *Privacy Act 1988* (Cth) s 14 (IPPs), Sch 3 (NPPs).

⁵ The *Privacy Amendment (Private Sector) Act 2000* (Cth) came into operation on 21 December 2001 and extended the coverage of the *Privacy Act* to much of the private sector. The new private sector provisions of the *Privacy Act* apply to ‘organisations’, which include partnerships, unincorporated associations and bodies corporate. An individual who is self-employed or a sole trader is considered an organisation for the purposes of the *Privacy Act*. Organisations are generally responsible for the actions of their employees, contractors and subcontractors, all of which are covered by the *Privacy Act*: ss 6C, 8.

⁶ To the extent that genetic information comprises ‘personal information’ and/or ‘health information’ as those terms are defined in the Act: *Privacy Act 1988* (Cth) s 6.

to genetic information by the *Privacy Act*, with a focus on the application of the NPPs regarding collection, use and disclosure and access.⁷

State and territory legislation

7.19 As discussed in IP 26,⁸ most state and territory government bodies and local governments are not covered by the *Privacy Act*.⁹ In particular, public hospitals and other state, territory or local government health service providers are not subject to the *Privacy Act*.¹⁰ Further, private sector health service providers working under contract for a state, territory or local government agency are not covered by the *Privacy Act*.

7.20 State and territory government agencies and private sector organisations working for them may be covered by state or territory information or health privacy legislation.¹¹ This legislation applies privacy principles similar to those in the *Privacy Act* to ‘personal information’, ‘health information’ or ‘personal health information’ as those terms are variously defined in the legislation.

7.21 States and territories also have other legislation relating to the administration of public health services that may contain provisions to protect the confidentiality of health information obtained by public sector health administrators and health service providers in the course of their employment.¹²

Harmonisation of health privacy law

7.22 While the *Privacy Act* creates a framework for national regulation of health information in the private sector, as well as protecting privacy in the Commonwealth public sector, there is no comprehensive framework for consistent national regulation of health information across public and private sectors, state and federal.

7 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.32–4.82.

8 Ibid, para 4.23.

9 However, state or territory bodies that are incorporated companies, societies or associations are deemed to be organisations for the purposes of the *Privacy Act* and will be subject to the legislation. There is a provision in the legislation for these bodies to be prescribed out of the coverage of the *Privacy Act*: *Privacy Act 1988* (Cth) s 6C.

10 Although some Commonwealth services provided within state or territory public hospitals and those provided under contract to the Commonwealth, such as clinical services for the Department of Veterans’ Affairs may be covered by the *Privacy Act*: Ibid s 8.

11 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Information Privacy Act 2000* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT). Other states and territories are actively considering new information or health privacy legislation: eg Exposure Draft Health Records and Information Privacy Bill 2001 (NSW). The coverage of relevant state and territory legislation was summarised in the Issues Paper: Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.109–4.118.

12 Eg *Health Administration Act 1982* (NSW); *Private Hospitals Regulations 1996* (NSW); *Nursing Homes Regulation 1996* (NSW); *Day Procedure Centres Regulation 1996* (NSW); *Health Services Act 1988* (Vic); *South Australian Health Commission Act 1976* (SA).

7.23 Instead, national regulation of information and health privacy is provided by complex, fragmented and overlapping federal, state and territory legislation. Health information is subject to different protection depending on whether it is held by a Commonwealth agency, state agency or private sector organisation. The situation is complicated by the fact that many different organisations may be responsible for delivery of health services to any one individual. Therefore, different legal regimes and privacy protection may apply to different parts of the health information relating to a single individual.

7.24 Problems that arise from the lack of uniformity are discussed in specific contexts elsewhere in this Discussion Paper¹³ and were highlighted in submissions. For example, the Centre for Law and Genetics noted that:

Public hospitals and universities are generally considered to be State and Territory government agencies and therefore come within the ambit of State and Territory privacy laws. The privacy legislation within the various States and Territories is incomplete and lacking in uniformity. In Tasmania, for example, there is no privacy legislation. Where privacy legislation does exist, it is not necessarily compatible with either the public sector or private sector provisions in the federal Act.¹⁴

7.25 The Commonwealth Attorney-General's Department observed that, as with most other areas of regulation, practical difficulties arise when organisations are required to comply with a number of similar or conflicting laws:

It leads to greater expense when they have to seek professional advice regarding their legal obligations and implement different procedures for compliance. Where relevant it can also lead to forum shopping by consumers in relation to complaint-handling. This is an unsatisfactory situation and should be avoided by having national standards where possible.¹⁵

7.26 Particular complexity arises where States and Territories have health privacy legislation purporting to cover the private sector, as is the case in the ACT and Victoria, and as is proposed in New South Wales.¹⁶ Various aspects of this state and territory legislation may be inconsistent with the *Privacy Act* and may create confusion and uncertainty for those organisations and individuals needing to comply with both sets of regulation.¹⁷

7.27 Differing submissions were made to the Inquiry regarding the relationship between federal privacy laws, on the one hand, and state and territory privacy laws, on the other. The *Privacy Act* provides that it is not to affect the

13 See eg the coverage of genetic samples (below); regulation of human genetic research databases (Ch 15); genetic registers (Ch 19).

14 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

15 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

16 *Health Records (Privacy and Access) Act 1997* (ACT); *Health Records Act 2001* (Vic); Exposure Draft Health Records and Information Privacy Bill 2001 (NSW).

17 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

operation of a law of a State or of a Territory that makes provision with respect to the collection, holding, use, correction, disclosure or transfer of personal information capable of operating concurrently with the Act.¹⁸ The Commonwealth Attorney-General's Department stated that this provision is not intended to enable state and territory law to regulate the same types of personal information and organisations that are regulated by the *Privacy Act*.¹⁹ In contrast, Privacy NSW submitted that the States should be free to 'enhance the Commonwealth's minimum standards in State legislation that provides for more stringent genetic privacy protection'. This might require a savings clause in the *Privacy Act*, similar to those in other federal human rights legislation.²⁰

7.28 IP 26 asked whether there should be uniformity or greater harmonisation of federal, state and territory laws concerning the privacy protection of human genetic information.²¹ This proposition met with general approval.²² Privacy NSW summarised the desirability of a uniform approach in the following terms:

A uniform approach to genetic information privacy is essential to ensure that all persons have equal protection regardless of where they live and who handles their genetic information. Widely differing standards of protection not only undermine human rights, they also undermine public confidence in the way that institutions handle their personal information, especially in an increasingly networked information environment. Lack of uniformity can also add to confusion for those responsible for handling personal information, as well as obstruct cross-border flows of information.²³

7.29 The means by which uniformity or greater harmonisation of health privacy law should be pursued is problematic. As discussed below, possible approaches to harmonisation include the development of a National Health Privacy Code, new federal, state and territory health privacy legislation, or the development of a regulatory framework specifically for genetic information.

18 *Privacy Act 1988* (Cth) s 3.

19 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

20 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

21 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 4–6.

22 See Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Nurses' Association, *Submission G090*, 21 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; Sydney IVF Limited, *Submission G062*, 14 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002; Queensland University of Technology, *Submission G109*, 14 March 2002; Disability Discrimination Legal Service, *Submission G146*, 28 March 2002; Australian Academy of Science, *Submission G097*, 21 January 2002; Australian Privacy Charter Council, *Submission G120*, 18 March 2002; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

23 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

A National Health Privacy Code

7.30 As detailed in IP 26, the Australian Health Ministers' Advisory Council (AHMAC) has formed a joint Commonwealth, State and Territory Health Information Privacy Working Group to work towards the establishment of a nationally consistent regime for the protection of health information, which applies to both the public and private sectors. The first step in this process is the development of a National Health Privacy Code, which was expected to be circulated for public comment in the first part of 2002.²⁴

7.31 The National Health Privacy Code is intended to comprise a nationally consistent set of rules for the handling of personal health information. While the mechanism for implementing the Code is still under consideration, it is currently expected to operate as a code under Part IIIAA of the *Privacy Act*.²⁵

7.32 Part IIIAA provides for a process by which organisations may agree to be bound by a privacy code, approved by the Privacy Commissioner, which includes levels of privacy protection at least equivalent to the NPPs.²⁶ For the purposes of the *Privacy Act*, the term 'organisation' covers only private sector organisations. However, on the request of the government of a State or Territory, regulations may prescribe an instrumentality of a State or Territory as an organisation for the purposes of the Act.²⁷ This provides a mechanism by which the operation of an approved code might be extended to state and territory public sector health service providers.

7.33 The Inquiry considers it unlikely that the AHMAC process will lead to uniformity or greater harmonisation of health privacy law in the short term. Several States and Territories have recently enacted, or propose to enact, their own health privacy legislation. Depending on the content of these new laws, this may be seen as running counter to the proposal to develop a National Health Privacy Code to provide consistency across all jurisdictions.²⁸

Federal health privacy legislation

7.34 Other means of pursuing uniformity or greater harmonisation of health privacy law might include enacting new federal health privacy legislation to regulate the handling of health information in both the Commonwealth public

24 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

25 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

26 *Privacy Act 1988* (Cth) s 18BB.

27 *Ibid* s 6C.

28 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

sector and private sector,²⁹ and to serve as a model for similar state and territory legislation.

7.35 Differing views have been expressed on whether federal health privacy legislation is desirable. The Office of the Federal Privacy Commissioner (OFPC) opposed the idea and submitted that:

[a]dditional legislation of that nature will create problems of compatibility with the existing privacy framework. It would prejudice attempts to realise a consistent national standard for the protection of health information privacy. The introduction of a separate scheme to protect health information privacy, or even genetic information privacy, intended to co-exist with existing forms of regulation, would be likely to encourage forum-shopping or 'regulatory arbitrage'. In the interests of achieving a single uniform scheme of privacy regulation for health information, it would be preferable to concentrate on improving existing legislation within the current regulatory framework. Any special legislative protections for health information generally or genetic information in particular should be effected within this framework.³⁰

7.36 Some submissions suggested that there should be separate federal health privacy legislation.³¹ For example, the Centre for Law and Genetics considered that deficiencies identified in the privacy protection of genetic information should be addressed through new health privacy legislation:

Within the framework of privacy legislation specific to health, provisions could be included giving special recognition to the protection of genetic information to address perceived deficiencies in this area, as indeed could be done for other areas of health where there may be a need for particular protection. After all, genetic information is clearly health information and is best dealt with within this context, with the addition of specific provisions as appropriate. This would ensure a coherent approach is taken to the issue, in a manner consistent within a general health privacy framework.³²

7.37 While the House of Representatives Standing Committee on Legal and Constitutional Affairs ultimately recommended that health information be included in the Privacy Amendment (Private Sector) Bill 2000 (Cth),³³ the Centre for Law and Genetics observed that

29 At present, the handling of personal information (including health information) in the Commonwealth public sector is governed by the IPPs and in the private sector by the NPPs.

30 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

31 Centre for Law and Genetics, *Submission G048*, 14 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002. The Australian Medical Association suggested that, because the *Privacy Act* is not health specific, it does not deal adequately with the privacy of electronic health records or genetic privacy issues.

32 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

33 Standing Committee on Legal and Constitutional Affairs, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000* (2000), House of Representatives, Parliament of the Commonwealth of Australia, Canberra, ch 6–7, rec 14–15.

the only reason that the committee ultimately decided to recommend that health information should remain part of the Bill, was because it thought it unlikely that a consensus could be achieved in the near future that would lead to the development of a separate legislative or regulatory code governing health services. Its recommendations were, instead, directed towards achieving such reforms in the future and therefore retaining the legislation's coverage of health information, at least on an interim basis, to ensure an acceptable level of privacy and access rights throughout Australia.³⁴

7.38 Other submissions suggested that existing privacy legislation is adequate to protect human genetic information³⁵ or that the reform priority should be on selective changes to the existing regulatory framework.³⁶ For example Privacy NSW favoured an approach that

identifies the weaknesses in the way existing privacy rules are expressed and which expands their scope to make them more responsive to the challenge proposed by genetic privacy issues.³⁷

Genetic privacy legislation

7.39 A third approach to harmonisation would involve the development of a regulatory framework specifically for genetic information. At the federal level, such an approach was taken in the Genetic Privacy and Non-discrimination Bill 1998 (Cth), introduced by Democrat Senator Natasha Stott Despoja.³⁸

7.40 The Bill, which was last debated on 5 October 2000 in the Senate, was restored to the Notice Paper for the Senate on 14 May 2002. As discussed in IP 26, the Bill addresses genetic information and deals with information privacy, consent and genetic discrimination.³⁹

³⁴ Centre for Law and Genetics, *Submission G048*, 14 January 2002.

³⁵ Life Sciences Network, *Submission G129*, 19 March 2002.

³⁶ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

³⁷ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

³⁸ The Genetic Privacy and Non-discrimination Bill 1998 (Cth) pre-dated the enactment of the *Privacy Amendment (Private Sector) Act 2000* (Cth). Senator Stott Despoja noted that there would have been no need for the former to deal with privacy if an effective legislated scheme for privacy protection had already been implemented. Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, additional comments by Senator Natasha Stott Despoja, 34.

³⁹ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.124–4.131.

7.41 There has been no significant support in consultations or in submissions to this Inquiry for new legislation dealing specifically with genetic privacy. Most submissions that considered the issue opposed such an approach.⁴⁰

The Inquiry's views

7.42 Given the plethora of existing regulations relating to the privacy protection of genetic information, it seems more appropriate to amend existing legislation to ensure that issues of genetic privacy are adequately covered rather than to add another layer of complexity by enacting genetic privacy legislation.

7.43 In particular, there would be considerable practical difficulty in defining the respective coverage of genetic privacy legislation and other information and health privacy legislation. Genetic information already forms part of ordinary clinical health information. It can be expected that genetic information will become increasingly important in the prevention, diagnosis and treatment of disease. As this occurs it will become increasingly difficult, if not meaningless, to distinguish between genetic information and other health information located, for example, in medical records held by health service providers.⁴¹

7.44 While genetic information has some special characteristics that distinguish it from most other forms of personal information,⁴² the Inquiry is currently of the view that, to a large extent, genetic privacy issues and reform options are similar to those applicable to information privacy generally and, in particular, to the privacy of medical records and other health information.

7.45 The terms of reference require the Inquiry, in reporting on the regulatory framework required to protect the privacy of human genetic samples and information, to have regard to existing or proposed Commonwealth legislation and legislation in other jurisdictions.

40 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; K Liddell, *Submission G141*, 23 March 2002; R Magnusson, *Submission G039*, 10 January 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; N Saunders and P Komesaroff, *Submission G084*, 9 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002; Queensland University of Technology, *Submission G109*, 14 March 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002; Australian Society for Medical Research, *Submission G124*, 18 March 2002. The NSW Nurses' Association and the Genetic Support Council Western Australia suggested that specific genetic privacy legislation might be desirable: New South Wales Nurses' Association, *Submission G090*, 21 January 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

41 R Magnusson, *Submission G039*, 10 January 2002. Australian Society for Medical Research, *Submission G124*, 18 March 2002. The Society stated that 'specific, all encompassing genetic legislation would provide considerable burden and limited benefits'.

42 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.10–4.14.

7.46 Deficiencies in the existing regulatory framework for information and health privacy are a focus of the Inquiry only to the extent that they concern the protection of genetic samples and information specifically. The terms of reference do not anticipate that the Inquiry will review the adequacy of health information privacy laws more generally. Nor do they require that the Inquiry reach a concluded view on whether privacy protection is best provided within the framework of the *Privacy Act* or in new information or health privacy legislation.

7.47 However, consultations and submissions have emphasised the importance of greater harmonisation in information and health privacy law, both within the federal sphere and between federal, state and territory laws. Effective protection of genetic samples and information requires that efforts continue to be made to achieve a harmonised approach.

7.48 While the Inquiry expresses no view on the exact mechanism by which such harmonisation should be pursued, it considers that Commonwealth, state and territory governments should give priority to this policy aim. In this context, the AHMAC process is one obvious starting point for harmonisation initiatives.

7.49 The overarching need for greater harmonisation has implications for how the reform proposals presented in this Discussion Paper should be approached by Commonwealth, state and territory governments.

Proposal 7-1. As a matter of high priority, Commonwealth, state and territory governments should pursue the harmonisation of information and health privacy legislation as it relates to human genetic information. This would be achieved most effectively by developing nationally consistent rules for handling all health information.

The Privacy Act and genetic samples

7.50 A key term that defines the coverage of the *Privacy Act* is ‘personal information’. The IPPs and NPPs apply when government, private sector organisations and individuals collect, store, use and disclose personal information. Under s 6(1) of the *Privacy Act* ‘personal information’ is defined as follows:

personal information means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

7.51 The definition of a ‘record’ is also important to the coverage of the Act. In general, the *Privacy Act* applies only to the handling of personal information in a record.⁴³ Under s 6(1) of the *Privacy Act* a ‘record’ is relevantly defined as follows:

record means:

- (a) a document; or
- (b) a database (however kept); or
- (c) a photograph or other pictorial representation of a person; ...

7.52 The terms of reference of the Inquiry refer to the privacy of ‘human genetic samples and information’. These words distinguish genetic ‘samples’ from information that may be derived from them. Any human biological sample can reveal an individual’s genetic information. The Inquiry must, therefore, consider the privacy of all human biological samples that may be identified with a living individual.

7.53 The extent to which the *Privacy Act* covers a particular genetic sample depends on whether the genetic sample may be considered to be ‘information’ in a ‘record’ and, if so, whether the information is about an identifiable individual, within the definition of personal information quoted above.

Is a genetic sample ‘information’?

7.54 One interpretation is that the *Privacy Act* does not cover genetic samples, even where they are identifiable (for example, where they have a name or other identifier attached), because samples are not personal information.

7.55 This interpretation is taken by the OFPC. The OFPC’s submission to the Inquiry assumes that an amendment to the definition of personal information would be required in order to extend the coverage of the *Privacy Act* to include bodily samples or other sources of genetic information.

7.56 Consistently with this interpretation, the OFPC’s *Guidelines on Privacy in the Private Health Sector* state that ‘health information’, which is a particular subset of personal information, includes ‘*information about* physical or biological samples, where it can be linked to an individual’.⁴⁴ This approach maintains the distinction between information and its source. The *Privacy Act* definition of health information includes, among other things, ‘personal information collected in connection with the donation, or intended donation, by the individual of his or her

⁴³ See *Privacy Act 1988* (Cth) s 16B.

⁴⁴ Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, para A.3.2 (emphasis added).

body parts, organs or body substances'.⁴⁵ This definition clearly distinguishes between information and the donated body substance.

7.57 Common law principles of statutory interpretation require that where general words are used, they should be given their plain and ordinary meaning, unless the contrary is shown.⁴⁶ The plain and ordinary meaning of the word information may not extend to a genetic sample, as opposed to the information that is derived by sequencing the DNA that it contains.⁴⁷

Should identifiable genetic samples be considered 'information'?

7.58 The discussion of privacy issues contained in IP 26 focussed primarily on genetic information, rather than genetic samples.⁴⁸ The Attorney-General's Department observed that in some contexts IP 26 appeared to assume that, for privacy purposes, genetic samples should be treated as if they are genetic information:

The Department is of the view that the inquiry would benefit from an examination of the issue of the privacy of genetic samples and whether it is appropriate to regard references to genetic samples as synonymous with, or as a part of, genetic information. Alternatively the inquiry may consider whether genetic samples are purely physical material from which, with appropriate equipment and expertise, genetic information can be derived. Further, the inquiry may wish to consider the implications of either view, particularly with regard to security of, and access to, genetic samples.⁴⁹

7.59 Genetic samples are widely seen as closely analogous to information. DNA is often popularly referred to as a 'genetic code' and the genome as a 'book'. The four bases of DNA (A-G-C-T)⁵⁰ are sometimes called the 'genetic alphabet'. Genetic science itself is replete with the language of information and information technology — for example, there are bases, codons, messenger RNA, transcription and translation.⁵¹

⁴⁵ *Privacy Act 1988* (Cth) s 6.

⁴⁶ See D Pearce and R Geddes, *Statutory Interpretation in Australia* (5th ed, 2001) Butterworths, Sydney, 35–36.

⁴⁷ In a related vein, it has been suggested that a bodily sample, such as a Guthrie card, is not a 'document' for the purposes of the *Freedom of Information Act 1982* (Vic) s 5(1). Therefore, there is no right of access to the card: L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 140.

⁴⁸ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Ch 7.

⁴⁹ Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

⁵⁰ Adenine; guanine; thymine; cytosine.

⁵¹ See the basic genetics primer in Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.54–2.61.

The idea of the genome as a book is not, strictly speaking, even a metaphor. It is literally true. A book is a piece of digital information, written in linear, one-dimensional and one-directional form and defined by a code that transliterates a small alphabet of signs into a large lexicon of meanings through the order of their groupings. So is a genome.⁵²

7.60 If, as suggested above, the *Privacy Act* as presently drafted does not cover genetic samples themselves, the question is whether it should be amended to explicitly define personal information and health information to include bodily samples.

7.61 Different approaches have been taken to this question in state and territory legislation regarding information and health privacy. The *Privacy and Personal Information Protection Act 1998* (NSW) defines personal information to include 'such things as an individual's fingerprints, retina prints, body samples or genetic characteristics'.⁵³ Individually identifiable genetic samples are therefore covered by the New South Wales legislation.

7.62 Other state and territory legislation contains definitions of personal information and health information which, in relevant respects, more closely follow the wording contained in the *Privacy Act*. Genetic samples themselves may not be covered by such legislation.⁵⁴

7.63 The OFPC has noted that the current legislative framework for privacy protection protects informational privacy and not bodily or physical privacy. The OFPC submitted, in respect of the coverage of genetic samples, that:

[i]n the interests of consistent and coherent regulation of information privacy, the abuses or misuses of that information need to be regulated, rather than the sources of that information. For these reasons, I would be reluctant to support a further amendment to the definition of either 'personal information' or 'health information' to include bodily samples or other sources of genetic information. However, this may well be a matter for an Australian Human Genetics Advisory Commission to consider in some detail.⁵⁵

7.64 This view draws a sharp distinction between information and the sources of information. One basis for this distinction is that, unlike a book or other written information, technology must intervene to create genetic information from a DNA sample.

52 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 7–8.

53 *Privacy and Personal Information Protection Act 1998* (NSW) s 4. Draft NSW legislation adopts the same wording in its definition of personal information: Exposure Draft Health Records and Information Privacy Bill 2001 (NSW) s 5.

54 See *Health Records Act 2001* (Vic) s 3 'health information'; 'personal information'; *Information Privacy Act 2000* (Vic) s 3 'personal information'; *Health Records (Privacy and Access) Act 1997* (ACT) s 4 'personal health information'; 'personal information'.

55 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

7.65 In response it may be observed that if the book exists in electronic form, technology will also be required to intervene. Computerised information, whether on a hard drive, a CD or some other format, requires technological intervention before information may be derived from the bytes recorded.

7.66 In relation to information privacy protection there may sometimes be no logical or practical reason to distinguish between information and its immediate sources. In this context it is worth noting the distinction between 'data' and 'information'.⁵⁶ The term data has been said to refer to 'inert symbols, signs or measures' while 'information' implies 'the use of data by humans to extract meaning'.⁵⁷

The distinction between information and data could be equated with that between a raw material and the manufactured product. Information can be derived from data when those data are interpreted to produce meaning and therefore the interpreter must possess the skills necessary to undertake that task ... the context here could involve words and mathematical notation; it could be graphic — involving colours, figures, shapes; or audiovisual — sound, motion, words and graphic symbols.⁵⁸

7.67 There is no question that personal data on an encrypted CD-ROM is considered to be 'information' in a 'record' for the purposes of the *Privacy Act*, yet in some circumstances personal information may be as easily derived from a genetic sample as from such data. Modern genetic sequencing technology may make genetic samples as immediate a source of information as, for example, a computer disk or database.

Extending the Privacy Act to cover genetic samples

7.68 There may be advantages in extending the *Privacy Act* to cover identifiable genetic samples. The IPPs and NPPs provide important protections throughout the 'information cycle' and these principles may be capable of providing similar protection for genetic samples.

56 While the *Privacy Act* and other Australian privacy legislation tend to use the term personal information rather than personal data, legislation of this kind may be described, as it is in the United Kingdom and in Europe, as 'data protection' legislation: *Data Protection Act 1998* (UK). The UK legislation makes distinctions between 'data' and 'information' for various purposes: *Data Protection Act 1998* (UK) s 1; s 2. See also *Directive on the Protection of Individuals With Regard to the Processing of Personal Data and on the Free Movement of Such Data 1995* (European Parliament and of the Council of the European Union). The *Privacy Act* gave effect to Australia's agreement to implement OECD guidelines governing 'the protection of privacy and transborder flows of personal data': Organisation for Economic Co-operation and Development, *Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data* (1980). Perhaps due to this history, the heading to NPP 9 refers to 'Transborder data flows' but the text refers only to personal information.

57 R Clarke, *Introduction to Dataveillance and Information Privacy, and Definitions of Terms*, <<http://www.anu.edu.au/people/Roger.Clarke/DV/Intro.html>>, 6 June 2002.

58 S Saxby, *The Age of Information* (1990) Macmillan, London, 11.

7.69 There would be important consequences for the Inquiry in *not* making such a proposal. As genetic samples are not currently covered by the *Privacy Act*, even where identifiable, there is a major gap in the framework for protecting the privacy of the individuals from whom genetic samples are taken. Some other regime may have to be developed to fill the gap.

7.70 Consider this example. A pathology laboratory possesses a collection of test tubes of blood taken from individuals for clinical purposes and labelled with the name of the patient from whom the blood has been taken. So long as no associated personal information is disclosed with it, a labelled test tube may be given to any other individual or organisation — for example, to a prospective employer or insurer of the individual concerned, or to a journalist. While there may be professional, regulatory, contractual or other consequences for the pathology laboratory,⁵⁹ individual privacy rights in respect of the samples may not be asserted by the individual from whom the blood was taken. While the laboratory is prohibited from disclosing health information derived from the genetic sample without the individual's consent, other than for the primary purpose of collection,⁶⁰ no similar privacy protection attaches to the sample itself.

7.71 The drafters of the *Privacy Act* may not have had genetic samples in mind, but the IPPs and NPPs are drafted as high level principles capable of flexible interpretation in a myriad of circumstances. The IPPs and NPPs do not prescribe exactly what an organisation must do to comply with them. Rather, they apply broad standards — for example, based on whether an organisation has taken 'reasonable steps' to do something, whether certain possible actions are 'reasonable and practicable' or 'impracticable' and whether information is 'necessary' for certain purposes.⁶¹

7.72 It has been stated that one strength of the principles is that they are 'technology neutral'.⁶² That is, the principles of fair information handling can be applied evenly, no matter the form in which information is held or stored:

The result is that the NPPs apply equally to conventional, electronic and digital environments. This neutrality also aims to ensure that the legislation will not date and will work in practice now and for many years to come.⁶³

59 Depending on the circumstances, these consequences could include liability for breach of a contractual undertaking or fiduciary duty, loss of National Association of Testing Authorities Australia (NATA) accreditation and eligibility to obtain Medicare fees for medical services, penalties for sale of human tissue under the Human Tissue Acts, and disciplinary action by health registration authorities.

60 *Privacy Act 1988* (Cth) NPP 2.1.

61 See eg *Ibid* NPP 1.

62 See Attorney-General's Department, *Submission to Australian Senate Select Committee on Information Technologies Inquiry into E-Privacy* 1 August 2000.

63 Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), OFPC, Sydney, 2.

7.73 Given the close analogies between genetic samples and forms of data or information, the NPPs may be sufficiently flexible to extend sensible and balanced privacy protection to genetic samples.

7.74 Some problems of interpretation will inevitably arise. For example, if the information in question is a genetic sample, what would it mean for an individual to have a right to 'access' or 'correct' personal information, or for an organisation to 'disclose' such information.⁶⁴

7.75 However, it is possible to apply these concepts in a sensible way to genetic samples. For example, a right of access does not imply a right to require that a sample be re-analysed, de-identified or destroyed.⁶⁵ The obvious mechanism by which to access genetic information, such as that contained in a medical record, is by providing a copy of the information. While it may not be practicable to make a copy of a genetic sample,⁶⁶ a portion of the sample may be able to be provided to the individual concerned.

7.76 It may not appear obviously sensible to talk about a right to 'correct' a genetic sample. However, a wrongly identified sample may be held by an organisation, for example, because of a chain of custody problem. There seems no reason why a right of correction should not come into play in those circumstances.

7.77 Personal information may be disclosed by giving someone a document or a computer disk containing information about an identifiable individual. Similarly, if an organisation were to give a labelled genetic sample to another organisation this can easily be described as a 'disclosure'. The right of the individual concerned to exercise some control of the kinds of disclosure that may occur is not necessarily inconsistent with the right of the organisation to 'own' that sample.⁶⁷

7.78 The Inquiry recognises the possibility that the inclusion of genetic samples in the definition of personal information may lead to unforeseen consequences for the regulation of some existing practices concerning the handling of genetic and other bodily samples. Concerns about the application of privacy legislation to genetic samples have been raised in submissions. For example, the Human Genetics Society of Australasia asked:

64 *Privacy Act 1988* (Cth) NPP 6, NPP 2.

65 See L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 40.

66 Although DNA may be 'copied' using a technological process known as polymerase chain reaction (PCR), a process also called DNA amplification (see Ch 4).

67 Ownership of genetic samples is discussed in Ch 17.

Is consent required for the storage of tissue samples after the primary purpose for their collection has been achieved? Is implied consent adequate for certain secondary uses of stored samples eg. re-testing in the light of new knowledge, quality assurance, research using anonymous samples, and is express consent required for other uses eg. research that may generate information relevant to the health of research subjects?⁶⁸

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7.79 These are important questions but it is not clear that applying the principles contained in the *Privacy Act* and similar information and health privacy legislation would necessarily lead to undesirable results, or even dictate practices that differ significantly from those used presently.

7.80 It is not the intention of this proposal to reform existing laws that deal with the protection of the individual's person and their body parts. These include laws dealing with physical violence and assault, the ownership or theft of body parts,⁶⁹ and controls over the transplantation of organs or the donation of human tissue. The focus remains on information privacy and on protecting genetic samples as an immediate source of personal information.

7.81 The Inquiry notes that, to date, submissions and consultations have not clearly identified circumstances in which applying the *Privacy Act* to genetic samples would lead to adverse consequences. If such consequences did arise, the federal Privacy Commissioner would be able to issue a Public Interest Determination to remedy the problem.⁷⁰

7.82 In this context, it may be observed that the New South Wales legislation has been in operation since 1 July 2000.⁷¹ Despite the fact that the information privacy principles contained in the *Privacy and Personal Information Protection Act 1998* (NSW) must be adhered to by public hospitals and other state government health service providers, the Act's coverage of bodily samples has not led to noticeable controversy. On the other hand, the absence of controversy may suggest the adequacy of existing constraints on the handling of bodily samples and the protection of information derived from them.⁷²

Conclusion

7.83 The Inquiry proposes that the *Privacy Act* be amended to cover genetic samples for the following reasons. First, there is a gap in the existing framework for protecting the privacy of genetic samples. Second, genetic samples are closely

68 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

69 The possible use of property rights in genetic material as a means of protecting genetic privacy is discussed (and rejected) in Ch 17.

70 A Public Interest Determination (PID) may be issued by the Privacy Commissioner, on the application of an interested person, where an act or practice may breach the NPPs but the public interest in doing the act, or engaging in the practice, substantially outweighs the public interest in adhering to NPPs: See *Privacy Act 1988* (Cth) Part VI.

71 *Privacy and Personal Information Protection Act 1998* (NSW).

72 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

analogous to genetic information and the IPPs and NPPs appear capable of extending appropriate privacy protection to genetic samples. Finally, no circumstances have yet been identified in which applying the *Privacy Act* to genetic samples would lead to adverse consequences.

7.84 However, the proposal requires further detailed consideration. It would represent a fundamental change to the coverage of the *Privacy Act*, extending it beyond information privacy as currently conceived. It has been suggested that problems may arise from this blurring of distinctions between ‘information privacy’ and ‘bodily privacy’, to the detriment of regulatory efficacy and public understanding of genetics.

This indicates that much further thought needs to be given to whether these apparently incompatible concepts of regulation can exist side by side, with any degree of efficacy, within the same definitional scheme or explanatory mechanism.⁷³

7.85 This change in coverage may, at the least, require review of the audit, investigation, complaints handling and enforcement provisions of the Act to determine whether they continue to be appropriate where the protection of genetic samples is at issue. A more fundamental re-writing of the *Privacy Act* than encompassed by the proposal might be necessary to regulate effectively the handling of genetic samples. Further, the resource and policy implications for the OPFC, as the regulator of a future regime that covers samples, will also require more detailed consideration.

7.86 The Inquiry recognises that this proposal will have to be further tested to determine to what extent it conflicts with, or duplicates, existing legal provisions for the protection of the human body and its individual parts⁷⁴ including, but not limited to, the Human Tissue Acts (discussed below.)

Proposal 7–2. The *Privacy Act 1988* (Cth) should be amended expressly to: (a) define personal information to include bodily samples from an individual whose identity is apparent or can reasonably be ascertained from the sample; and (b) define a ‘record’ to include a bodily sample.

Question 7–1. Does the *Privacy and Personal Information Protection Act 1998* (NSW) provide an appropriate model for amending the *Privacy Act* to include bodily samples within the definition of personal information?

⁷³ Ibid.

⁷⁴ Ibid.

Question 7–2. What are the implications of Proposal 7–2 for the operation of the existing audit, investigation, complaints handling and enforcement provisions of the *Privacy Act*?

Privacy and the Human Tissue Acts

7.87 The donation of human tissues is regulated in all States and Territories by human tissue legislation (the Human Tissue Acts).⁷⁵ It has been suggested that, if the *Privacy Act* or other information or health privacy legislation applies to bodily samples, problems may arise in the relationship between privacy laws and the Human Tissue Acts.⁷⁶

7.88 Dr Roger Magnusson suggested that the existing relationship between legal controls on human tissue, and legal controls on information derived from human tissue, may be unclear. He submitted that the law should clarify the relationship between the Human Tissue Acts and privacy legislation.⁷⁷

The better view is that as soon as any genetic information is generated from a tissue sample and linked to an individual, this would trigger the application of relevant privacy laws. In the meantime, and indeed subsequently, human tissue legislation would continue to apply to the tissue samples themselves.⁷⁸

7.89 Others have suggested that the Human Tissue Acts may be the appropriate legislation to protect the privacy of human genetic information by regulating the collection, storage, use of and access to genetic samples.⁷⁹ This option represents an alternative to using the *Privacy Act* to achieve these same ends and is discussed in more detail in Chapter 17. In this context, Dr Magnusson observed that:

If tissue samples embody an individual's genomic complement, one could argue that all tissue samples are inherently 'personal information'. If this argument were adopted, it would suggest that human tissue legislation should be strengthened to better protect human tissue samples even prior to the 'extraction' of any genetic information from them. This is probably unnecessary, however, since as soon as

75 *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT). The Human Tissue Acts and reform options related to these Acts are discussed in more detail in Ch 16.

76 Advisory Committee members, *Advisory Committee meeting*, 31 May 2002.

77 R Magnusson, *Submission G039*, 10 January 2002.

78 Ibid.

79 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

genetic information — or identifying health information of any kind — is generated, privacy controls would operate in any event.⁸⁰

7.90 These comments are consistent with the Inquiry's earlier conclusion that genetic samples are so closely analogous to personal information that they should receive information privacy protection.

7.91 The Inquiry is interested in further comments on the relationship between the *Privacy Act* or similar information or health privacy legislation and the Human Tissue Acts, particularly in the light of the proposal above.

Question 7-3. If the *Privacy Act* were amended to cover genetic samples, what problems, if any, might arise in the relationship between that Act and other laws relating to bodily samples, such as the Human Tissue Acts?

When is a genetic sample about an identifiable individual?

7.92 As noted above, the *Privacy Act* does not apply to information (or a bodily sample) unless it is 'about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion'.⁸¹ The IPPs and NPPs do not apply to the collection, use or disclosure of information that is de-identified in such a way as to fall outside this definition.

7.93 The concept of de-identification arises in different ways under the NPPs. Under NPP 10.3, an organisation may collect health information about an individual for research purposes without consent only where the research cannot be conducted by collecting 'information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained'.

7.94 In relation to the conduct of research involving humans (see Part D), the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement) also makes distinctions between identified, potentially identifiable and de-identified personal information or material.⁸² Under the National Statement, information or material is 'de-identified' only if the process of de-identification is irreversible — for example

⁸⁰ R Magnusson, *Submission G039*, 10 January 2002.

⁸¹ From the definition of personal information in *Privacy Act 1988* (Cth) s 6(1). Relevant state and territory privacy legislation contains similar definitions.

⁸² National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9.

because the identifiers have been removed permanently or because the data have never been identified.⁸³

7.95 Some submissions questioned whether it can ever be said that a genetic sample is truly de-identified,⁸⁴ at least as long as the individual from whom the sample was taken, or their body, still exists. As collections of genetic samples and information proliferate, the chances that any given genetic sample may be able to be re-identified by matching it with samples on human genetic databases increases. In this context, Dr Nicholas Tonti-Filippini stated that:

It is simply impractical now to consider that human tissue or individual genomic information can be de-identified. The capacity of bioinformatics and the cross-linking of data bases makes the concept impractical.⁸⁵

7.96 Similarly, the Centre for Law and Genetics submitted that:

In relation to the issue of de-identification, there are particular problems with the de-identification of genetic information in tissue samples. Because a sample can be re-identified, the only way to permanently de-identify a sample is to physically destroy it. There may be some justification for requiring this to be done once the relevant genetic information has been extracted.⁸⁶

7.97 This touches on broader issues concerning de-identification and the coverage of privacy legislation. Canadian academics, Trudo Lemmens and Lisa Austin, have written that there are serious questions

regarding the extent to which genetic information can be collected or used in a non-identifiable form. Genetic information, unlike other health information, is inherently linked to a particular individual. This fact, in combination with computer technology, makes the linkage of genetic information to an identifiable individual always a possibility ... Given these concerns, it is not advisable to completely exempt 'anonymous' genetic information from data protection regimes.⁸⁷

7.98 On the other hand, the Commonwealth Attorney-General's Department observed, in relation to the argument that genetic information by its nature is always identifiable, that

83 The National Statement states that 'It should be recognised that the term "de-identified" is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain "potentially identifiable"': Ibid, 9.

84 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

85 N Tonti-Filippini, *Correspondence*, 17 May 2002.

86 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

87 T Lemmens and L Austin, 'The Challenges of Regulating the Use of Genetic Information' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 26, 33–34.

the same could be said of fingerprints, dental records or any other uniquely identifying features of an individual. It appears that to be identifiable, the information must usually be accompanied by other identifying information.⁸⁸

7.99 The *Privacy Act* applies only to information about an individual whose identity is apparent, or can reasonably be ascertained.⁸⁹ Such a standard, based on reasonableness, means that in some cases it will not be clear whether particular information is identifiable and, therefore, whether or not the IPPs and NPPs apply to how it is handled.⁹⁰

7.100 The Inquiry does not believe that genetic samples should be considered as inherently identifiable for the purposes of the *Privacy Act*. Whether they are reasonably identifiable or not will depend on the surrounding context. In most circumstances, an unlabelled and uncoded sample may still be considered as de-identified, despite a theoretical possibility of re-identification. On this view, the coverage of genetic samples under the *Privacy Act* would not adversely affect the conduct of human genetic research, quality assurance and other activities using anonymised samples.

Import and export of genetic samples

7.101 There may be a need for regulation to ensure that genetic samples derived from Australia cannot be exported to jurisdictions where equivalent privacy and other protections do not exist. Similarly, it may be argued that research in Australia should be conducted only on genetic samples that have been collected elsewhere in accordance with appropriate privacy and other ethical standards. Bringing genetic samples within the framework of the *Privacy Act* might provide one mechanism to implement such regulation, at least in relation to the export of genetic samples.

7.102 NPP 9 prohibits ‘transborder data flows’ of personal information by an organisation to foreign countries unless:

- the recipient of the information is subject to a law, binding scheme or contract that effectively upholds principles substantially similar to the NPPs;
- the individual consents to the transfer;

88 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

89 From the definition of personal information in the *Privacy Act: Privacy Act 1988* (Cth) s 6(1). Relevant state and territory privacy legislation contains similar definitions.

90 Another issue involves the extent to which coded data can be considered to be de-identified. For example, where an independent person holds the code and it is not possible for the researchers themselves to ascertain the identity of the individual concerned (without the assistance of the independent person), is information de-identified so that it is not governed by the *Privacy Act*?

- the transfer is necessary for the performance of a contract between the individual and the organisation or in the interest of the individual;
- the transfer is for the benefit of the individual, it is impractical to obtain consent and in any case the individual would be likely to give it; or
- the organisation has taken reasonable steps to ensure that the information which it has transferred will not be dealt with inconsistently with the NPPs.

7.103 There seems no reason why these restrictions should not apply to genetic samples as much as to genetic information derived from them. The Inquiry understands that it is common for Australian pharmaceutical companies to send bodily samples overseas for analysis in the conduct of clinical trials.

7.104 In consultations, Human Research Ethics Committee chairs and officers observed that while research protocols may provide that exported tissue will only be used for the specified purpose of collection, once the samples leave the jurisdiction there may be no effective control over possible future uses.⁹¹ NPP 9 would permit the export of genetic samples to continue, but subject to the safeguards mentioned above.

7.105 Issues relating to the use of genetic samples collected overseas and then transferred to Australia are adequately covered by existing regulation of ethical conduct in human research and protection of privacy, based on the National Statement and *Privacy Act* respectively (as modified by the Inquiry's other proposals).

Question 7-4. Should genetic samples obtained in Australia be exported only to jurisdictions whose laws provide protections equivalent to that of the *Privacy Act* and the NHMRC's National Statement on Ethical Conduct in Research Involving Humans?

Question 7-5. Is NPP 9 of the *Privacy Act* an appropriate model for regulating the export of genetic samples?

Deceased persons

7.106 The *Privacy Act* regulates the handling of personal information about individuals. Section 6 of the Act defines an individual as 'a natural person'. The *Privacy Act* does not cover genetic samples taken from, or genetic information

91 HREC Chairs and Officers, *Consultation*, Sydney, 20 June 2002.

about, deceased persons. An individual may only make a complaint under the *Privacy Act* in relation to an interference to their own privacy.

7.107 However, the Commonwealth Attorney-General's Department noted that:

It may be possible that a blood relative of a deceased person could complain about the collection or use of genetic information to the extent that the genetic information would contain information about them and from which their identity could be reasonably ascertained.⁹²

7.108 This is one implication of the shared or familial nature of genetic information. Clearly, an individual's genetic information is information about that individual. However, to a greater or lesser degree it is also 'about' the individual's immediate family, other genetic relatives, ethnic subgroup, racial group, and ultimately humanity itself.

7.109 The Inquiry has been informed about situations in which individuals have been denied optimal medical care because of difficulty in obtaining access to the medical records of deceased relatives. The following example illustrates the problem:

The client is a 24 year old individual whose mother died at age 40 of bowel cancer and polyps. The father subsequently remarried and there was falling out between the children and the father so they have lost contact with him. They present for genetic advice. It is essential to know whether there were a few polyps or a condition known as Familial Adenomatous Polyposis was present. The histopathology would state this. The offspring are genetically related and therefore have a greater need for the information than the spouse who has 'moved on'. In both the ACT and Queensland there is now a blanket rule in medical records departments to prohibit access without the executor's permission. In the current case [the client] was not aware of who that was and now does not know whether annual colonoscopy or 3-5 yearly colonoscopy is necessary.⁹³

7.110 The high level principles for fair information handling codified in the *Privacy Act* may provide a flexible basis for dealing with this issue, without further amendment. For example, if the matter were tested, it may well be that, for example, the Privacy Commissioner or a court might find that a person has a right of access to genetic information about his or her deceased parents or siblings (on the grounds that the information is also information 'about' the person seeking access), but not to the same information about a deceased second cousin.

92 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

93 K Barlow-Stewart, *Correspondence*, 18 July 2002.

Question 7–6. Does the *Privacy Act* adequately deal with issues that may arise in relation to the genetic samples and information of deceased individuals?

Genetic information and health information

7.111 The *Privacy Act* applies privacy protection to an individual's 'personal information'. The Act recognises that a subset of personal information is 'sensitive information', which due to its nature attracts some higher standards of privacy protection. 'Health information' is one of the types of 'sensitive information'.

7.112 Genetic information is not specifically referred to in the Act. The Explanatory Memorandum to the Privacy Amendment (Private Sector) Bill 2000 stated that its definition of 'health information' covered genetic information, while at the same time noting that the NPPs were not designed to address the unique privacy issues associated with the handling of genetic information.⁹⁴

7.113 In the *Privacy Act* 'health information' is separately defined as

- (a) information or an opinion about:
 - (i) the health or a disability (at any time) of an individual; or
 - (ii) an individual's expressed wishes about the future provision of health services to him or her; or
 - (iii) a health service provided, or to be provided, to an individual;that is also personal information; or
- (b) other personal information collected to provide, or in providing, a health service;
- or
- (c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances.

7.114 There are differences in the way the *Privacy Act* treats personal information, health information and other sensitive information. Health and other sensitive information are provided higher levels of protection than ordinary

⁹⁴ In the Senate, the Bill was amended to define 'genetic information' and to insert genetic information into the definition of health information. This amendment and other Senate amendments relating specifically to genetic information were not accepted by the House of Representatives. The reasons of the House for disagreeing to the amendments of the Senate included that it would be premature to accept the amendments proposed until the government had the benefit of the report of the present Inquiry: Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 5 December 2000, 1965 (Reasons of the House of Representatives for Disagreeing to the Amendments of the Senate presented by the Hon Darryl Williams Attorney-General). See also Senate Legal and Constitutional Legislation Committee, *Provisions of the Privacy Amendment (Private Sector) Bill* (2000), The Parliament of Australia, Canberra, 26–27.

personal information.⁹⁵ Generally, genetic information will receive the special protection afforded to sensitive information under the *Privacy Act* if it can be defined as health information or some other element of sensitive information, for example, if it constitutes information or an opinion about an individual's racial or ethnic origin, their sexual preferences or their criminal record.

7.115 IP 26 noted that there are circumstances in which genetic information may not be health information, as defined in the *Privacy Act*. This may occur either because the information is not about health, disability or the provision of a health service (as in the case of parentage or forensic testing) or because it is not about the health or disability of an existing individual (as may sometimes be the case with genetic carrier testing — where the information is primarily about the health of future children).⁹⁶ The Inquiry notes that some genetic information collected for criminal forensic purposes may fall within the definition of sensitive information if it is information about an individual's criminal record but that a range of genetic information will remain outside the definitions of sensitive information and health information.

7.116 The Attorney-General's Department noted that the consequences of this gap include that commercial laboratories that currently offer parentage testing may be able to use genetic information for direct marketing purposes.⁹⁷

7.117 Submissions indicated general support for amending the *Privacy Act* to ensure that genetic information is treated as health information under the Act.⁹⁸ Some submissions referred to the definition used in the *Health Records Act 2001* (Vic) and the Exposure draft Health Records and Information Privacy Bill 2001 (NSW) as appropriate models.⁹⁹ The Victorian legislation defines health information to include

95 Subject to some limited exceptions, NPP 10 requires consent for the collection of sensitive information: compare *Privacy Act 1988* (Cth), NPP 1, which requires only that the individual be informed about various matters such as their access rights, the purposes of collection and to whom the organisation usually discloses information of that kind. The use and disclosure of sensitive information other than for the primary purpose of collection is more constrained than is the case with ordinary personal information — the secondary purpose must be directly related to the primary purpose: *Privacy Act 1988* (Cth) NPP 2.1(a).

96 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.75–4.79.

97 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002. Direct marketing is a permissible secondary use of personal information but not health information: *Privacy Act 1988* (Cth) NPP 2.1(c).

98 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; The Royal College of Pathologists of Australasia, *Submission G144*, 25 March 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; UnitingCare NSW & ACT, *Submission G052*, 14 January 2002; Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

99 The Royal College of Pathologists of Australasia, *Submission G144*, 25 March 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Genetics Service Advisory

other personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.¹⁰⁰

7.118 The proposed New South Wales legislation defines health information to include

other personal information that is genetic information about an individual arising from a health service provided to the individual in a form that is or could be predictive of the health (at any time) of the individual or of any sibling, relative or descendant of the individual.

7.119 Both of these definitions would be broad enough to encompass genetic carrier testing. It is unclear whether the Victorian definition covers parentage, research or forensic testing information.¹⁰¹ The New South Wales definition clearly would not cover such information because of the required connection with the provision of a health service.

7.120 Privacy NSW submitted that genetic information should be separately and comprehensively defined in the *Privacy Act*.

Such a definition should recognise the individual and relational nature of genetic information. It should not be linked only to the provision of a 'health service', but rather apply to all circumstances where genetic information may be collected, used or disclosed, including for research or commercial purposes.¹⁰²

7.121 The Inquiry is of the view that genetic information should receive the special protection afforded to health and other sensitive information under the *Privacy Act*. The existing definitions of sensitive information and health information do not provide that level of protection for all genetic information. The Inquiry therefore proposes that the definition of health information in the *Privacy Act* be amended to make clear that it includes genetic information, whether or not the information is collected in relation to the health of, or the provision of a health service to, the individual.

Proposal 7-3. The *Privacy Act* should be amended to clarify that 'health information' includes genetic information, whether or not the information is collected in relation to the health of, or the provision of a health service to, an individual.

Committee, *Submission G094*, 25 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002 (expressing the views of the AHMAC Privacy Working Group).

100 *Health Records Act 2001* (Vic) s 3(1)(d). The Act came into effect from 1 July 2002.

101 The Victorian definition refers to information in a form which 'is or could be' predictive of health. It may not require that the information be obtained for health-related purposes.

102 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

Small business exemption

7.122 Under the small business exemption, some small business operators are excluded from the definition of ‘organisation’ and are therefore entirely exempt from the operation of the *Privacy Act*.¹⁰³ Certain organisations cannot qualify for this exemption — for example if they provide ‘a health service to another individual and hold any health information except in an employee record’.¹⁰⁴

7.123 In his Second Reading Speech on the Privacy Amendment (Private Sector) Bill 2000, the Attorney-General explained the basis of the small business exemption as follows:

The exemption for small business is based on the premise that not all private sector organisations pose the same risk to privacy. Many small businesses do not have significant holdings of personal information. They may have customer records that they use for their own business purposes; however, they do not sell or otherwise deal with customer information in a way that poses a high risk to the privacy interests of those customers. However, the government recognises that there are some small businesses, or acts and practices of small businesses, that pose a higher risk to privacy than others and should be caught by the privacy obligations set out in the bill. The bill makes it very clear that not all businesses with an annual turnover of \$3 million or less can take advantage of the exemption. Small businesses that provide health services and hold health information are one example of this special category. Small businesses that trade in personal information are another. It is for this reason that small business operators that provide health services and hold health information, that trade in personal information or that are contracted to provide a service to the Commonwealth will be covered by the legislation.¹⁰⁵

7.124 Dr Tim Smyth has observed:

While health service providers who hold health information are subject to the Act, irrespective of their turnover, a small business that is not a health service provider can remain exempt from the Act even though it might hold health information. A business that simply stores genetic samples or acts as a data repository, providing no health service, may not be subject to the Commonwealth Act.¹⁰⁶

103 In summary, to qualify for the small business operator exemption, an entity (i) must have an annual turnover of \$3 m or less; (ii) cannot be related to a business with an annual turnover of greater than \$3m; (iii) must not provide a health service and hold health records; (iv) must not disclose personal information about an individual for a benefit, service or advantage; (v) must not provide a benefit, service or advantage to collect personal information; (vi) cannot be a contracted service provider for a Commonwealth contract (even if the entity is not a party to the contract). See *Privacy Act 1988* (Cth) s 6C–6E.

104 Ibid s 6D(4)(b).s

105 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 12 April 2000, 15749 (The Hon Daryl Williams QC AC MP (Attorney-General)).

106 T Smyth, ‘Protecting Human Genetic Information and Its Use’ (2002) 10(6) *Health Law Bulletin* 64, 66.

7.125 It has also been suggested that research undertaken by a genomics company may fall outside the definition of a health service.¹⁰⁷ These may not be the only examples of small businesses that hold genetic information but are not covered by the Act.

7.126 The Inquiry has formed the preliminary view that the acts and practices of small business operators that hold genetic information pose a potential risk to the privacy of both the individual concerned and his or her genetic relatives. For this reason, the Inquiry is of the view that small business operators that hold genetic information should be subject to the provisions of the *Privacy Act*, whether or not they provide a health service.

Proposal 7-4. The *Privacy Act* should be amended to ensure that all small business operators that hold genetic information are subject to the provisions of the Act.

Applying the Privacy Act to genetic information

7.127 IP 26 asked about potential privacy problems that arise in the practical application of the *Privacy Act* and the NPPs to genetic samples and information.¹⁰⁸ It noted that special issues may be raised by the familial nature of genetic information and by its predictive power, especially in relation to an individual's right not to know about their long-term health prognosis.¹⁰⁹

7.128 A wide range of relevant comment was received in submissions to the Inquiry. Many of these concerns are examined in more detail elsewhere in this Discussion Paper.

7.129 The Human Genetics Society of Australasia referred to possible problems in applying the NPPs in relation to consent requirements in the collection of genetic samples, the collection of clinical family history information, the disclosure of genetic information to genetic relatives of a patient or to genetic registers and the de-identification of genetic samples and information.¹¹⁰

107 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

108 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 4-3.

109 Ibid, para 4.83-4.102.

110 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

7.130 Privacy NSW expressed a general concern that the NPPs are too widely drawn for the purposes of genetic information privacy. It also expressed specific concerns about consent to the use of genetic information in research.¹¹¹

7.131 Similarly, the Australian Privacy Charter Council submitted generally that the NPPs contain too many exemptions and exceptions. The Council also raised specific concerns about the definition of health information, the exceptions in relation to collection and use and disclosure principles and the application of the access principles to familial genetic information.¹¹²

The familial nature of genetic information

7.132 Submissions confirmed that the familial or collective nature of genetic information is a characteristic that needs to be given special attention in considering the application of the NPPs to genetic samples and information.¹¹³ For example, Dr Graeme Suthers noted that privacy conflicts in the clinical use of genetic information

usually have to do with the familial nature of the disorder or information rather than its 'genetic' nature *per se*. It is not the DNA basis of the diagnosis that is of concern. Similar conflicts could arise in relation to familial disorders that are diagnosed by non-DNA means. In a society that places such a premium on individual autonomy, the fact that we are irrevocably linked to other people can cause difficulties.¹¹⁴

7.133 The Royal College of Pathologists of Australasia observed that privacy principles that apply to individuals present practical difficulties to health service providers who deal with genetic information that is, by its nature, shared.¹¹⁵

7.134 IP 26 noted that it has been suggested that, rather than adopting regulatory approaches like the *Privacy Act*, which focus on protecting an individual's right to privacy, a 'medical model' of regulation should apply to genetic testing.¹¹⁶ This model is said to be based primarily on what doctors consider to be best practice in providing medical care for patients and their families.¹¹⁷ Control of genetic samples and information would be 'shared' among genetic relatives.

111 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

112 Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

113 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Australian Privacy Charter Council, *Submission G120*, 18 March 2002; Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002; I Turnbull, *Submission G059*, 14 January 2002; G Suthers, *Submission G026*, 30 November 2001; The Royal College of Pathologists of Australasia, *Submission G144*, 25 March 2002.

114 G Suthers, *Submission G026*, 30 November 2001.

115 The Royal College of Pathologists of Australasia, *Submission G144*, 25 March 2002.

116 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.87–4.93.

117 L Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6 *Medical Law Review* 1, 24.

On this model, people would not have the ultimate right to 'control' their information and the use of their tissue taken for genetic testing (though the nature and use of the information and tissue will be fully discussed at the outset before testing is undertaken); and doctors will have a special role in providing and imparting genetic information that may appear contrary to their traditional obligation to maintain patient confidentiality.¹¹⁸

7.135 The OFPC responded that, while this approach had merit, it failed to take into account a number of other relevant factors, including the fundamental nature of an individual's right to maintain a degree of control over the handling of their health information, the need for individual rights to be balanced with the legitimate interests of third parties and of the community in general and the rights of individuals not to know.¹¹⁹

7.136 One view is that genetic information is of two kinds — familial and personal. The familial aspect is that a mutation exists in a family. This will sometimes be known by family members in any event because earlier members will have died or suffered from the mutation. However, mutations can occur spontaneously so it is possible that a person might be the first in the family to have a familial mutation which could still be inherited. The personal aspect is the person's own genetic status, that is, positive or negative for the mutation.¹²⁰ On this basis it can be argued that the fact that a mutation is in a family is not personal to an individual and all genetic relatives should be entitled to know. The second type of information, an individual's own genetic status, should remain confidential.

7.137 The familial nature of genetic information is also discussed in the context of the Inquiry's proposals concerning how health professionals collect and deal with genetic information about genetic relatives (Chapters 18–19).

The right not to know

7.138 The right not to know has been stated as the right people should have to be protected from information that their own bodies can yield, based on the ethical principle of autonomy. This principle may be seen as having particular application to genetic testing because of the predictive power, or perceived predictive power,

118 Ibid, 24. A contrary view is expressed in D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130. See also L Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162.

119 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

120 See L Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6 *Medical Law Review* 1.

of genetic information in relation to a person's long-term health prognosis and other physical and behavioural characteristics.¹²¹

7.139 The right not to know was a common topic in submissions that considered the application of the NPPs to genetic samples and information.¹²² The Centre for Law and Genetics submitted that the right not to know should be recognised under privacy legislation. They submitted that, at present

[n]ot only is there no specific recognition or protection of the right not to know, there are provisions contained in the Act (in particular, NPP 1.5) which may encourage information to be inappropriately disclosed to the individual about whom it is collected in an over zealous attempt to comply with the requirements of the legislation.¹²³

7.140 Under the *Privacy Act* the 'right not to know' is protected to some extent by the requirement that, in most circumstances, genetic testing will not be permitted without the consent of the individual concerned, given after appropriate information has been provided to them.¹²⁴

7.141 The specific concern raised by the Centre for Law and Genetics related to NPP 1.5, which provides that if an organisation collects personal information about an individual from someone else, it must take reasonable steps to ensure that the person is or has been made aware of the collection. The concern is that if genetic information is collected from one individual then, in some circumstances, there may be an obligation to notify genetic relatives about this information — thereby revealing information about their own genetic status.

7.142 As discussed in Chapter 18, a Temporary Public Interest Determination (the Temporary PID) has been issued by the federal Privacy Commissioner to ensure that organisations can continue to collect family health information without breaching the NPPs.¹²⁵ At least where a health service is being provided, the Temporary PID may be sufficient to ease concerns that information will be inappropriately disclosed as part of a notification under NPP 1.5.

121 Privacy Commissioner of Canada, *Genetic Testing and Privacy* (1992), Privacy Commissioner of Canada, Ottawa, 30–31. The right not to know is supported in a number of international instruments: *Universal Declaration of the Human Genome and Human Rights*, UNESCO, <<http://www.unesco.org/ibc/en/genome/projet/>>, 29 July 2002 art 5; *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*, Council of Europe, (entered into force on 1 December 1999), art 10.

122 *Confidential Submission G051CON*, 14 January 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

123 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

124 In the research context, the National Statement also requires that research participants be asked, at the time of giving consent, whether or not they wish to receive the results of the tests that relate to them as individuals: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.10; 16.15–16.16.

125 See Office of the Federal Privacy Commissioner, *Temporary Public Interest Determination No. 2001–1*, <http://www.privacy.gov.au/act/public_interest/index.html#2>, 22 July 2002.

7.143 The right not to know is examined in the context of the Inquiry's proposals concerning the disclosure by health professionals of genetic information to genetic relatives without the consent of their patient (see Chapter 18).

8. Anti-Discrimination Law

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Introduction

Officially they are called 'In-valids'. ... They are the 'healthy ill'. They don't actually have anything yet — they may never have. But since few of the pre-conditions can be cured or reversed, it is easier to treat them as if they were already sick.¹

8.1 Many submissions received by the Inquiry included statements about the undesirable effects of inappropriate and discriminatory use of genetic information. The NSW Anti-Discrimination Board stated:

Rather than acting as an impediment to the development and application of genetic technology, effective anti-discrimination and privacy legislation are critical to realising the public health benefits of genetic information. Conversely, if we fail to provide such protection, discrimination and privacy concerns will act as disincentives to testing and research participation and have negative consequences for individual and public health outcomes.²

8.2 The Human Genetics Society of Australasia provided a topical example:

One concern is that people will avoid having potentially important tests that may help in their clinical management for fear of discrimination. For example, a test for factor 5 Leiden would enable a person to know if they were at increased risk of developing a deep vein thrombosis when on a long flight. However, fear of not being allowed to fly or not obtaining insurance may prevent them taking the test.³

8.3 Recognising these dangers, the Inquiry's terms of reference asked whether a regulatory framework is required to provide protection from inappropriate discriminatory use of human genetic samples and information.

8.4 In some circumstances, discrimination on the ground of a person's genetic status may already be unlawful under existing race, sex, or disability anti-discrimination laws. This chapter explores possible deficiencies in this protection, particularly in relation to disability discrimination. The chapter also looks at whether these deficiencies should be addressed through new legislation dealing specifically with genetic discrimination or within the existing legal framework.

8.5 Australia has anti-discrimination legislation at the federal level as well as legislation in all the States and Territories.⁴ This chapter focuses on the federal legislation but reference is made to the state and territory legislation in the context

1 A Niccol, *GATTACA* (1997), Columbia Pictures.

2 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

3 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

4 *Racial Discrimination Act 1975* (Cth); *Sex Discrimination Act 1984* (Cth); *Disability Discrimination Act 1992* (Cth); *Human Rights and Equal Opportunity Commission Act 1986* (Cth); *Anti-Discrimination Act 1977* (NSW); *Equal Opportunity Act 1995* (Vic); *Anti-Discrimination Act 1991* (Qld); *Equal Opportunity Act 1984* (WA); *Equal Opportunity Act 1984* (SA); *Anti-Discrimination Act 1998* (Tas); *Discrimination Act 1991* (ACT); *Anti-Discrimination Act 1992* (NT).

of discussing the need for greater harmonisation across Australian jurisdictions and examining alternative models for consideration.

8.6 The primary pieces of federal anti-discrimination legislation are the:

- *Sex Discrimination Act 1984* (Cth) (SDA);
- *Racial Discrimination Act 1975* (Cth) (RDA);
- *Disability Discrimination Act 1992* (Cth) (DDA); and
- *Human Rights and Equal Opportunity Commission Act 1986* (Cth) (HREOC Act).

8.7 In addition, the *Workplace Relations Act 1996* (Cth) (WRA) contains provisions that prohibit discrimination on a range of grounds in terminating employment. The WRA is discussed in more detail in Chapter 27.

Constitutional issues

Commonwealth constitutional powers

8.8 The federal Parliament's power to legislate is set out in, and limited by, the Commonwealth Constitution. The relevant provisions do not expressly refer to 'human rights' or 'discrimination' and the Commonwealth's legislation in this area is principally based on the 'external affairs' power in s 51(xxix). The High Court has interpreted this provision to mean that the Commonwealth may enact laws to implement its international legal obligations,⁵ subject to certain implied and express constitutional limitations, and provided the laws are reasonably appropriate and adapted to implement the obligations.⁶

8.9 In addition, the DDA and the SDA expressly identify a number of other heads of constitutional power that support the legislation. The intention of these provisions is to extend the reach of the legislation as far as possible, given the absence of an express power to enact laws with respect to discrimination. For example, under s 12 of the DDA, the Act extends to:

- matters covered by specified international conventions;
- matters external to Australia or of international concern;

⁵ *Commonwealth v Tasmania* (1983) 158 CLR 1 (The Tasmanian Dam Case).

⁶ *Richardson v Forestry Commission* (1988) 164 CLR 261.

- discrimination by foreign, trading or financial corporations;
- discrimination in the course of carrying on the business of insurance or banking;
- discrimination in the course of interstate or international trade and commerce; and
- discrimination against Commonwealth employees in connection with their employment.

State and Territory laws

8.10 The States and Territories do not have similar constitutional limitations and do not need to base their legislation on Australia's international human rights obligations. Each jurisdiction has enacted anti-discrimination legislation and, while the Acts are not identical, there are considerable similarities between them. In many situations involving claims of discrimination, state and territory anti-discrimination legislation will overlap with federal laws. Where this occurs, an individual may have a choice of legislation under which to seek redress.

8.11 Under s 109 of the Constitution, in the event of an inconsistency between federal and state laws, the federal law prevails and the state law is inoperative to the extent of the inconsistency.⁷ This caused problems in the early days of anti-discrimination legislation in Australia. All federal anti-discrimination Acts now contain provisions expressly indicating that the federal Act is not to be taken to exclude or limit the operation of any state or territory law capable of operating concurrently with the federal Act. Some problems of articulation between federal and state laws still remain, for example in the field of insurance.⁸

8.12 IP 26 asked whether there should be uniformity or greater harmonisation of federal, state and territory laws concerning discrimination in relation to human genetic information. Submissions received by the Inquiry expressed strong support for greater harmonisation across jurisdictions.

8.13 The Human Genetics Society of Australasia⁹ noted that family members affected by genetic disorders may live in a number of States and Territories and the Australian Society for Medical Research¹⁰ expressed the view that greater national

⁷ *Dao v Australian Postal Commission* (1987) 162 CLR 317.

⁸ The High Court has held that provisions of the *Life Insurance Act 1945* (Cth) (allowing life insurers to classify risks according to actuarial evidence) are inconsistent with provisions of the *Anti-Discrimination Act 1977* (NSW) (precluding insurers from discriminating against insurance applicants in respect of disability). See *Australian Mutual Provident Society v Goulden* (1986) 160 CLR 330.

⁹ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

¹⁰ Australian Society for Medical Research, *Submission G124*, 18 March 2002.

uniformity would benefit the public as well as the scientific community. The Australian Institute of Actuaries¹¹ noted that companies often operate across state borders and that it was confusing for such companies to be subject to different regimes in each jurisdiction. The Inquiry considers that such inconsistencies may provide a disincentive for organisations to develop policies and programs that comply with anti-discrimination legislation because the rules that apply are unclear and may differ from one jurisdiction to another.

8.14 The NSW Anti-Discrimination Board summarised the issue as follows:

Uniformity or, at a minimum, greater harmonisation of federal, State and Territory anti-discrimination legislation is crucial to an effective legislative regime to provide protection against genetic discrimination. It would ensure that people are afforded equal protection under the Australian law, regardless of [in] which State or Territory people reside and where the conduct occurs within Australia. Uniformity would reduce the complexity of jurisdictional decisions about whether to proceed under State/Territory or federal legislation for the would be complainants. It also supports greater certainty about people's rights and responsibilities under anti-discrimination law, rather than such understanding being undermined by uncertainty which arises when there are inconsistencies between different federal, State and Territory laws. Uniformity of anti-discrimination legislation would enhance certainty by increasing the likelihood that case law from one jurisdiction is applicable in another and for precedent to be applied.¹²

8.15 Although one submission expressed the view that it was important to balance the ability of States and Territories to act independently and perhaps add new progressive grounds,¹³ the Inquiry is of the view that greater harmonisation across jurisdictions, for example, in relation to the definition of disability or impairment, would be beneficial. Harmonisation is not intended to stifle the role of the States in innovation and experimentation, but to ensure that similar means are adopted where similar goals exist. The proposals in this chapter reflect this position.

International context

8.16 Australia's federal anti-discrimination legislation makes reference to a wide range of international instruments as well as 'matters external to Australia' (in the case of the DDA and SDA) and 'matters of international concern' (in relation to the DDA).¹⁴ These instruments do not specifically address discrimination on the basis of genetic status. However, as noted in Chapter 2, the international community has, in recent years, been turning its attention to this

11 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

12 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

13 Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

14 These references were included to help ensure the widest possible constitutional basis for this legislation following the reasoning of the High Court in *Koowarta v Bjelke-Petersen* (1982) 39 ALR 417.

matter in some detail. The *UNESCO Declaration of Human Rights and the Human Genome 1997* recognises that

research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but ... that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics.¹⁵

8.17 The Declaration is not a binding legal instrument but is evidence of growing international concern and an indication of the general approach of the international community in this area. Article 2 of the Declaration states that:

Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics. That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

8.18 Article 6 goes on to declare that:

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

8.19 The Council of Europe's *Convention on Human Rights and Biomedicine 1997*, which is a legally binding instrument and has been signed and ratified by 13 countries to date, gives a clear indication of the approach adopted in Europe in relation to this issue. Article 11 states that:

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

8.20 It is against this background that the Inquiry has been asked to consider whether the protection offered by existing legislation in Australia is adequate.

Australian anti-discrimination law framework

8.21 Despite the differences of detail between Australian jurisdictions, all legislation dealing with discrimination embodies the same paradigm or framework for identifying unlawful discrimination. Generally, for discrimination to be unlawful, an act or omission must:

- be based on one of the grounds or attributes set out in the legislation, such as race, sex or disability;

15 *Universal Declaration of the Human Genome and Human Rights*, UNESCO, <<http://www.unesco.org/ibc/en/genome/projet/>>, 29 July 2002.

- fall within an area of activity set out in the legislation, such as employment, education, or the provision of goods or services;
- result in some harm or less favourable treatment, whether by direct or indirect discrimination; and
- not fall within an exception, exemption or defence.

Specified ground or attribute

8.22 In order to be unlawful, the discrimination must be based on one of the grounds or attributes set out in the legislation. This means that the statutory definitions of these grounds are crucial to the operation of the legislation. In Australia, these grounds vary from jurisdiction to jurisdiction and include race, sex, sexuality, pregnancy, marital status, parental status, age, disability, religion, political belief or activity, and trade union activity. If a person is discriminated against on the basis of an attribute that is not listed in the legislation, for example, simply because the discriminator does not like them personally, the victim has no remedy under anti-discrimination law.

8.23 Discrimination based on characteristics imputed to, or presumed to be held by, people who fall within one of the grounds is also unlawful, even if the assumption is incorrect either generally or with respect to a specific individual.

8.24 Potentially, any of the grounds or attributes listed in Australian anti-discrimination law may be relevant to discrimination on the basis of genetic status. The relevance of these grounds will depend upon our expanding understanding of genetics, and of the way in which genes may influence attributes such as race, sexuality and so on. Currently, the most obviously relevant ground, however, is disability or impairment and this is discussed in detail below.

Specified area of activity

8.25 In order to be unlawful, discrimination must occur in a field of activity set out in the legislation. The areas specified in Australian anti-discrimination legislation vary from jurisdiction to jurisdiction and include employment, education, the provision of goods and services, superannuation, insurance, accommodation, the disposition of land, membership of clubs, and the administration of laws and government programs. This coverage is wide, but does not generally include acts done in the private sphere, reflecting the public/private distinction that runs through much of Australian anti-discrimination law.

8.26 Some legislation has adopted a slightly different approach. The RDA refers to areas,¹⁶ but also contains a more general provision, based on the language of the *International Convention on the Elimination of all Forms of Racial Discrimination 1966*. Section 9(1) of the RDA states that:

9(1) It is unlawful for a person to do any act involving a distinction, exclusion, restriction or preference based on race ... which has the purpose or effect of nullifying or impairing the recognition ... of any human right ... in any field of public life.¹⁷

8.27 The Genetic Privacy and Non-discrimination Bill 1998 (Cth), which is discussed below, also adopted this approach. Clause 17 of the Bill was in the same terms as s 9 of the RDA, with the substitution of 'genetic information' for 'race'.

Direct and indirect discrimination

8.28 Australian law recognises two ways in which discrimination may occur. These are direct discrimination and indirect discrimination.

8.29 Direct discrimination occurs when a person is treated less favourably than another person who does not share the first person's attribute. For example, refusing admission to a cinema to anyone other than Caucasians will amount to unlawful racial discrimination. This is so whether the discriminatory policy is worded positively ('Whites Only') or negatively ('No Non-Whites').

8.30 This type of discrimination is the most obvious to identify. The intention of the discriminator is irrelevant: a person who believes he or she is doing the right thing (for example, dismissing a pregnant woman 'for her own good') is liable in the same way as someone who is blatantly biased and actively discriminatory.

8.31 If an action is done for more than one reason, one of which is discriminatory on its face and the other of which is not (for example, refusing service in a hotel to someone of a particular race who is also drunk or improperly dressed) there may still be liability for unlawful discrimination, but this differs between jurisdictions. Under the RDA a complainant need only show that it was one of the reasons for the act 'whether or not it is the dominant reason or a substantial reason'.¹⁸

8.32 Indirect discrimination is less obvious and more difficult to identify. It is sometimes called 'adverse effect' discrimination because it focuses on the effect of the action rather than on the attributes of the person towards whom the action is directed, although the latter are still relevant. Australian law is not uniform with respect to the elements comprising indirect discrimination. Generally, it must be

¹⁶ *Racial Discrimination Act 1975* (Cth) ss 11–15.

¹⁷ *Ibid*, s 9(1).

¹⁸ *Ibid*, s 18.

shown that a requirement or condition is imposed which, even though neutral on its face, has an adverse impact on people with a particular attribute, in circumstances where this is unreasonable. An intention to discriminate is not necessary.

8.33 For example, a requirement that all users of public transport buy tickets that they validate for travel by scratching off segments may appear to be non-discriminatory. However, in *Waters v Public Transport Corporation of Victoria*¹⁹ it was held that this requirement has a greater adverse impact on people who have visual, motor or intellectual impairments than it does on people without such impairments. Such a requirement, where unreasonable, amounts to indirect disability discrimination.

Exemptions, exceptions and defences

8.34 Anti-discrimination laws contain a number of exemptions, exceptions and defences. If they apply, an otherwise valid complaint of discrimination cannot be sustained. Exemptions, exceptions and defences in Australian anti-discrimination legislation include ‘unjustifiable hardship’ in accommodating a person’s disability, and acts done to comply with other legislation, such as occupational health and safety legislation. These issues, which arise in the employment context, are examined further in Chapters 27, 28 and 29. Broad exceptions relating to superannuation funds and insurance policies, which raise important issues about the use of genetic information by the insurance and financial services industry, are discussed in detail in Chapter 24.

8.35 In some circumstances it may be possible for a person or body to apply to the agency administering the anti-discrimination legislation for an exemption with respect to a particular activity. In relation to the DDA and SDA, for example, a person may apply to the Human Rights and Equal Opportunity Commission (HREOC) for a temporary exemption from the operation of the legislation. HREOC may grant an exemption for a period of up to five years, provided it is not inconsistent with the objects of the legislation.²⁰

Vicarious liability

8.36 Most anti-discrimination legislation in Australia also provides for a regime of vicarious liability, such that an employer or principal will be liable for the unlawful acts of an employee or agent in certain circumstances. The defence to vicarious liability is that the employer or principal has taken all reasonable steps to prevent the discrimination occurring.²¹ This defence has been interpreted strictly in Australia and, as a consequence, failure to know that discrimination is occurring is

19 *Waters v Public Transport Corporation of Victoria* (1991) 173 CLR 349.

20 See eg *Disability Discrimination Act 1992* (Cth) s 55.

21 See eg *Ibid*, s 123.

no excuse. The defence requires active measures to be taken: an employer who has done nothing to prevent discrimination (for example, because it was not aware the conduct was occurring) is unlikely to be able to establish the defence.²²

Harassment and vilification

8.37 Another aspect of anti-discrimination law is harassment and vilification. State and territory legislation generally confines its specific coverage of harassment to sexual harassment. However, the DDA expressly makes it unlawful to harass a person in relation to his or her disability in the areas of employment, education and the provision of goods and services.²³ The term ‘harassment’ is not defined but has been held by HREOC to include derogatory remarks relating to a person’s disability.²⁴

8.38 Vilification is a concept that relates to the making of derogatory remarks, but not necessarily in one of the areas specified by the legislation. In Tasmania it is unlawful to publicly incite hatred towards, serious contempt for, or severe ridicule of, a person on the ground of his or her disability.²⁵ Most anti-discrimination legislation that contains specific provisions with respect to vilification restricts those provisions to the attribute of race.²⁶

Principal federal legislation

Sex Discrimination Act

8.39 The SDA prohibits discrimination on the basis of sex. The Act also extends to discrimination on the basis of a characteristic that generally relates to people of a particular sex or that is generally imputed to people of a particular sex.²⁷ The Act also prohibits discrimination on the ground of marital status, pregnancy or potential pregnancy and, in the area of employment, family responsibilities.

8.40 In certain circumstances discrimination on the basis of genetic status may amount to sex discrimination. For example, refusing to employ people with a genetic predisposition to prostate cancer or a family history of breast cancer may give grounds for a complaint of indirect discrimination under the SDA. This is because apparently neutral requirements such as these may have an unreasonable

22 *Boyle v Ishan Ozden* (1986) EOC 92-165; *Hopper v Mt Isa Mines Ltd* (1997) EOC 92.

23 *Disability Discrimination Act 1992* (Cth) ss 35–40.

24 *Adams v Arizona Bay Pty Ltd* (1997) EOC 92-885.

25 *Anti-Discrimination Act 1998* (Tas) para 19(b).

26 For example, racial vilification is covered in the *Discrimination Act 1991* (ACT) ss 65–67; vilification with respect to homosexuality and HIV/AIDS in the *Anti-Discrimination Act 1977* (NSW) ss 49ZS–49ZTA, ss 49ZXQA–49ZXC; and racial and religious vilification in the *Anti-Discrimination Act 1991* (Qld) ss 124A, 131A.

27 *Sex Discrimination Act 1984* (Cth) s 5(1).

adverse impact on men, in the first case, and on women, in the second case. Such practices may also amount to direct disability discrimination.

Racial Discrimination Act

8.41 The RDA prohibits discrimination based on race, colour, descent or national or ethnic origin.

8.42 Discrimination on the basis of genetic status may amount to racial discrimination because some disorders are known to be more prevalent in particular races and communities. For example, Tay Sachs disease is prevalent in some Jewish populations and sickle cell disease is prevalent in certain African populations. Refusing to provide goods and services to people with Tay Sachs disease or sickle cell anaemia may give grounds for a complaint of indirect racial discrimination under the RDA.

8.43 Refusing to employ people from a particular racial group because that racial group is more likely to have a genetic predisposition to a particular disorder may also give grounds for complaint of direct discrimination under the RDA. Another possibility is that the 'descent' element of the definition of race might be relied on in some cases to ground a claim of discrimination based on genetic status.

Disability Discrimination Act

8.44 The DDA is the most relevant piece of anti-discrimination legislation in this area. The DDA prohibits discrimination on the basis of disability. The definition of 'disability', and whether it is wide enough to cover discrimination on the basis of genetic status, is discussed in detail below.

8.45 The DDA covers a disability which a person:

- has now;
- had in the past (for example, a past episode of mental illness);
- may have in the future (for example, a late onset genetic disorder);
- is imputed to have (for example, a genetic disorder based on the person's family medical history).

8.46 Discrimination is prohibited in employment, education, access to premises used by the public, provision of goods, services and facilities, accommodation, buying land, activities of clubs and associations, sport and the administration of Commonwealth government laws and programs. Discrimination

on the ground of genetic status may, potentially, arise in many of these contexts. For example, one submission to the Inquiry discussed the possibility of selecting elite athletes for training programs based on genetic test results;²⁸ others discussed the potential for discrimination in education.²⁹ However, in accordance with the Inquiry's terms of reference and with the level of concern expressed in many submissions, this Discussion Paper focuses on discrimination in employment and insurance. These areas are considered in detail in Chapters 24, 27 and 28.

8.47 Under s 31 of the DDA, the Attorney-General may formulate Disability Standards which, once tabled in Parliament for a certain period, gain the force of law. Such standards are intended to provide greater detail and more certainty in relation to rights and responsibilities under the Act. Standards can be made in the areas of employment, education, public transport services, access to premises, accommodation and the administration of Commonwealth laws and programs. The first Disability Standard on access to public transport is expected to be tabled in the federal Parliament in 2002.

8.48 In addition, HREOC may issue guidelines under the DDA to assist persons and organisations with responsibilities under the legislation to avoid discrimination and comply with their responsibilities. HREOC have, for example, issued Guidelines for Providers of Insurance and Superannuation.³⁰ Unlike standards, these guidelines are not legally binding.

8.49 Section 30 of the DDA makes it unlawful to request or require information in connection with, or for the purposes of doing, an act of discrimination. The meaning and scope of this provision is not entirely clear. This provision is discussed in detail in Chapter 28.

Human Rights and Equal Opportunity Commission Act

8.50 The HREOC Act establishes HREOC and enables it to handle complaints under the SDA, the RDA and the DDA. HREOC may accept complaints under these three Acts, inquire into them, and attempt to settle them by conciliation. Where this is not possible, a complainant may choose to apply to the Federal Court or the Federal Magistrates Court to seek a binding determination.

8.51 In addition, HREOC may inquire into any act or practice, including any systemic practice, which impairs equal opportunity in employment on a wide range of grounds that might be relevant to genetic information. These include race,

28 A Miah, *Submission G139*, 15 March 2002.

29 See, for example, Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

30 Human Rights and Equal Opportunity Commission, *Guidelines for Providers of Insurance and Superannuation*, <http://www.hreoc.gov.au/disability_rights/standards/Insurance/insurance_adv.html>, 27 August 2001.

colour, sex, national extraction, social origin, age, medical record, sexual preference, impairment, physical, mental, intellectual or psychiatric disability. The definition of disability for the purposes of such an inquiry differs from the definition of disability used in the DDA. HREOC has used its power to inquire into systemic age discrimination practices in employment.

8.52 The HREOC Act also provides HREOC with the power to inquire into alleged breaches of human rights by or on behalf of the Commonwealth, for example, by a government department.

8.53 In contrast to complaints under the SDA, RDA and DDA, individual complaints of discrimination brought under these provisions of the HREOC Act cannot be dealt with by a court or tribunal and therefore cannot lead to an enforceable remedy. For this reason, complaints tend to be lodged under one of the other Acts where an enforceable remedy is available.

A separate ground? A separate Act?

8.54 IP 26 asked whether it would be better to amend existing anti-discrimination laws to clarify their application to genetic information or enact new legislation dealing specifically with genetic discrimination. The question was prompted, in part, by the Genetic Privacy and Non-discrimination Bill introduced into the federal Parliament by the then Deputy Leader of the Australian Democrats, Senator Natasha Stott Despoja, in 1998. The Bill was largely based on a Bill then before the United States Congress.³¹

8.55 There are two ways that separate treatment of genetic discrimination could be achieved. Discrimination on the ground of genetic status could be addressed in a new Act. Alternatively, genetic status could be included as a new ground of discrimination in the DDA, in the same way that marital status and pregnancy are included as separate grounds in the SDA. These options are considered below.

Consultations and submissions

8.56 The 'stand alone' legislation approach has been adopted in a number of States in the United States and in some European countries. Although ultimately rejecting this approach, the Centre for Law and Genetics set out some of the potential advantages in its submission:

31 The Australian Bill was returned to the Senate Notice Paper on 14 May 2002.

There would undoubtedly be some advantages in enacting legislation dealing specifically with genetic discrimination, including the advantage of greater certainty of protection, heightened visibility, and the consequential effect of public consciousness raising.³²

8.57 The Human Genetics Commission (HGC) in the United Kingdom has also recommended stand alone legislation in its final report. In relation to the *Disability Discrimination Act 1991* (UK), the HGC was of the view that it would be too difficult to amend the definition of disability in the Act, which adopts a very different approach to the DDA, to address genetic disorders, especially presymptomatic disorders.³³

8.58 In relation to the Genetic Privacy and Non-discrimination Bill 1998 the Senate Legal and Constitutional Committee concluded as follows:

5.28 The committee considers that it would be more appropriate to amend, where necessary, existing privacy and discrimination legislation to ensure that issues raised by genetic technology are adequately covered under that legislation, for example, the various federal anti-discrimination acts, the *Human Rights and Equal Opportunities Act 1986*, and the *Privacy Act 1988*.

5.29 The committee believes that such an approach provides a clearer legislative base. It avoids the administrative and legal confusion created by having different sets of rules applying to genetic information than to other personal information ...

5.30 Creating specific legislation such as the bill would also cut across a number of regulatory systems already in place, or in the process of being established, that are themselves the product of extensive consultation and negotiation between stakeholders and state, territory and federal governments.³⁴

8.59 This position was supported by a number of submissions received by the Inquiry, including the Centre for Law and Genetics,³⁵ the Australian Society for Medical Research,³⁶ and the Institute of Actuaries of Australia.³⁷ The NSW Anti-Discrimination Board shared the Senate Committee's concerns about administrative and legal confusion and went on to state in its submission:

There are numerous benefits to retaining genetic discrimination within [the] conceptual framework of existing anti-discrimination legislation. Many of the issues discussed above in relation to uniformity of legislation also apply to this issue including:

32 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

33 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 6.31.

34 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, para 5.28–5.30.

35 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

36 Australian Society for Medical Research, *Submission G124*, 18 March 2002.

37 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

- greater clarity about people's rights and responsibilities under anti-discrimination law where there are fewer pieces of legislation
- a reduction in the complexity of jurisdictional decisions for would-be complainants
- increasing the likelihood that case law from one jurisdiction is applicable in another and for precedent to be applied ...

Retaining genetic discrimination within [the] conceptual framework of existing anti-discrimination legislation will ensure that we do not afford different levels of protection to people with disabilities diagnosed by genetic testing, or future or imputed disabilities based on predictive genetic testing compared with other people with disabilities.³⁸

Inquiry's views

8.60 The Inquiry considers these submissions to be persuasive. Working within the existing legal framework will promote certainty and consistency and will build on existing understanding and practice in this field. The Inquiry proposes that discrimination on the grounds of genetic status be dealt with under existing anti-discrimination legislation subject to the amendments and safeguards proposed in this and subsequent chapters of the Discussion Paper. The Inquiry does not support the development of separate genetic discrimination legislation.

8.61 If discrimination on the grounds of genetic status is to be dealt with under existing legislation, as proposed, the most relevant piece of federal legislation is the DDA. There are two ways that genetic discrimination could be included in the DDA. The first is to clarify the existing definition of 'disability' to ensure that it includes genetic status. The second is to include genetic status as a new and separate ground under the Act.

8.62 This gives rise to the question whether it is appropriate to include genetic status in the definition of the term 'disability' as it is used in the DDA. In some cases a person's genetic status may give rise to a disability in the generally understood sense. This is not always the case, however, particularly in relation to genetic information that is merely predictive and which may indicate nothing more than an elevated level of risk of developing a disorder at some time in the future. The Inquiry has been advised that genetic counsellors spend a great deal of time reassuring clients that an inherited predisposition or carrier status does not amount to a disability. The concern has been expressed that the inclusion of genetic status in the definition of 'disability' in the DDA will reinforce the idea that the existence of a genetic variation is, of itself, abnormal or disabling.

38 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

8.63 A recent editorial in the British Medical Journal, however, made the following point:

On a fundamental level, genetic science is forcing a re-examination of the concept of normality itself, by showing that everyone's genome is different and that we are all in some sense 'abnormal'. We each carry genetic variants, many of which will have no detectable impact in normal circumstances, but some undoubtedly will alter our risk of disease or may, with a partner carrying similar variations in their genomes, result in the birth of a child with a recessive genetic disorder.³⁹

8.64 Professor Francis Fukuyama has made a similar point:

There is a long tradition, argued most forcefully in recent years by the French postmodernist thinker Michel Foucault, which maintains that what society considers to be pathology or disease is actually a socially constructed phenomenon in which deviation from some presumed norm is stigmatised.⁴⁰

8.65 The legal concept of disability as it is used in the DDA, and to varying degrees in other anti-discrimination legislation, is wide and does not necessarily equate with the general understanding of the term. This is because the DDA is not only intended to address discrimination against people with existing disabilities but is also intended to address the harm caused by incorrect assumptions made about the existence, or impact, of disabilities. Discrimination based on an incorrect assumption that a person has a disability has the potential to cause as much harm as discrimination on the basis of an actual disability. This is why the definition of disability in the DDA covers imputed disabilities, as well as disabilities that existed in the past or may exist in the future.

8.66 The Inquiry is of the view that discrimination on the basis of genetic status fits within this wider legal concept of disability discrimination. Although adding a separate ground of genetic discrimination to the Act may help to emphasise that genetic status does not necessarily equate with disability, it would also add considerably to the complexity of the legislation. On balance, the Inquiry does not support including genetic status as a separate ground under the DDA.

8.67 It may be, however, that there is merit in giving the issue of discrimination on the ground of genetic status a heightened emphasis or increased visibility in some other way. One suggestion is that the name of the DDA be changed to the *Disability and Genetic Discrimination Act 1992*. This change would bring some of the advantages cited in the Centre for Law and Genetics' submission quoted above, that is, heightened visibility and public consciousness raising. It may also assist to underline that genetic status does not necessarily equate with disability.

39 R Zimmern, 'Genetics and Medicalisation' (2002) 324 *British Medical Journal* 863.

40 F Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002) Profile Books, London, 209.

8.68 Another way this could be achieved is by amendment to s 3 of the DDA, which sets out the objects of the legislation. At present this provision does not expressly address the harm caused by discrimination on the basis of imputed, past or possible future disabilities. An amended objects provision could make clear that discrimination on the basis of genetic status is prohibited.

8.69 The Inquiry therefore proposes that discrimination on the ground of genetic status be dealt with under existing anti-discrimination laws and within the definition of ‘disability’ in those laws, but subject to the amendments canvassed in the proposals below. The Inquiry is of the view that it would be desirable to make a statement in the objects section of the DDA about discrimination on the basis of genetic status and imputed, past and possible future disabilities. The Inquiry is also interested in receiving comment on whether the name of the DDA should be changed to the *Disability and Genetic Discrimination Act 1992* (Cth).

Proposal 8–1. Discrimination on the ground of genetic status should continue to be dealt with under the framework of existing federal, state and territory anti-discrimination laws, subject to the specific proposals for legislative amendments identified in this Discussion Paper.

Question 8–1. Should the name of the *Disability Discrimination Act 1992* (Cth) (DDA) be amended to the *Disability and Genetic Discrimination Act 1992* (Cth)? Should the objects of the DDA be amended to clarify that discrimination on the basis of genetic status falls within the Act?

Definition of disability

Current law

8.70 If discrimination on the grounds of genetic status is to be dealt with under the framework of existing legislation it is important to ensure that the definitions in that legislation are wide enough to cover genetic issues. Section 4(1) of the DDA provides as follows:

‘disability’ in relation to a person means –

- (a) total or partial loss of the person’s bodily or mental functions; or
- (b) total or partial loss of a part of the body; or
- (c) the presence in the body of organisms causing disease or illness; or
- (d) the presence in the body of organisms capable of causing disease or illness; or

(e) the malfunction, malformation or disfigurement of a part of the person's body; or

(f) disorder or malfunction that results in the person learning differently from a person without the disorder or malfunction; or

(g) a disorder, illness or disease that affects a person's thought processes, perception of reality, emotions or judgement or that results in disturbed behaviour;

and includes a disability that:

(h) presently exists; or

(i) previously existed but no longer exists; or

(j) may exist in the future; or

(k) is imputed to a person.

8.71 The term 'disability' is defined to a high level of specificity in the DDA. For example, para (d) (the presence in the body of organisms capable of causing disease or illness) was included in the definition to make clear that asymptomatic conditions such as HIV were covered. The term 'impairment' is also defined in the HREOC Act but the term 'physical or mental disability' is not defined in the WRA.

8.72 There is little doubt that the existing definition of disability in s 4 of the DDA covers genetic disorders that currently manifest symptoms. Such symptoms may result, for example, in the partial loss of a person's bodily or mental functions (para (a)) or in the malfunction of a part of a person's body (para (e)). Under these paragraphs it is not necessary to consider the cause of the disability, only the effect on the individual.

8.73 The more problematic issue is whether the definitions in the DDA and in other anti-discrimination legislation are wide enough to address discrimination on the basis of genetic status where a person is presently asymptomatic. The DDA specifically covers disabilities that 'may exist in the future' or are 'imputed to a person', as well as past or present disabilities. The legislation in New South Wales and Tasmania is similar to the DDA in this respect.⁴¹ However, not all Australian legislation has such wide coverage.

8.74 The Northern Territory legislation does not expressly refer to future disorders, but contains an inclusive definition of impairment.⁴² It may be open to a court to find that disorders arising in the future fall within this definition. In Western Australia, South Australia and the ACT, the legislation includes

⁴¹ *Anti-Discrimination Act 1977* (NSW) s 49A; *Anti-Discrimination Act 1998* (Tas) s 3.

⁴² *Anti-Discrimination Act 1992* (NT) s 4(1), which states that 'impairment ... includes ...'.

impairments imputed to a person and the imputation is not limited to past or present impairments.⁴³ It is also possible that a court may interpret these provisions to include future disorders. In other States the legislation has exclusive definitions of disability or impairment, which do not refer to future disorders or imputations.

8.75 The definition of disability in the DDA is divided into two parts — the physical description of what amounts to a disability is set out in paras (a)–(g), while some of the circumstances in which disabilities will be recognised for the purposes of the Act are set out in paras (h)–(k). These circumstances include present, past, possible future and imputed disabilities. The difficulty with the definition is that paras (h)–(k) must be related back to a type of physical or mental manifestation in the terms of paras (a)–(g) of the definition.

8.76 Is a genetic mutation that increases a person's risk of heart disease, for example, an 'organism capable of causing disease or illness' (para (d))? Is it a 'malfunction, malformation or disfigurement of a part of the person's body' (para (e))? While it might be possible to argue that a genetic mutation is a malformation of part of a person's body, it seems clear that these provisions were not drafted with this issue in mind and that genetic mutations of this sort do not fit neatly into the existing terminology.

8.77 It is more likely that discrimination on the basis of a genetic mutation that increases the risk of a person developing a particular disorder is covered by para (j) of the definition of disability, coupled with para (a), (b) or (e). To take the case of a genetic mutation that increases the risk of heart disease, under the DDA the 'disability' does not arise directly because of the person's present genetic mutation, but because that mutation indicates that a 'partial loss of the person's bodily functions' (para (a)) 'may exist in the future' (para (j)). In short, the disability is not the genetic mutation itself but the possible future expression of that mutation through the malfunctioning of a part of the person's body.

Consultations and submissions

8.78 Both HREOC and the NSW Anti-Discrimination Board submitted that the existing definitions in the DDA and the *Anti-Discrimination Act 1997* (NSW) are likely to cover discrimination on the basis of genetic status.⁴⁴ The NSW Anti-Discrimination Board stated in its submission that:

43 *Equal Opportunity Act 1984* (SA) s 4(1), 'impairment'; *Equal Opportunity Act 1984* (SA) s 66(a); *Discrimination Act 1991* (ACT) s 7(2).

44 For the position under the *Americans with Disabilities Act* (US), see P Miller, 'Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace' (2000) 3(2) *Journal of Health Care Law & Policy* 225, 240.

In our view the definition of disability in both the DDA and the ADA already adequately covers discrimination on the ground of a person's genetic make up. Given the breadth of the definition of disability in the DDA, we cannot conceive of a condition or predisposition to a condition discernible by genetic testing which would not fall within the current definition.⁴⁵

8.79 Although the definition in the DDA may be wide enough to cover discrimination on the basis of genetic status, a number of submissions including the Genetic Support Council of Western Australia, the Australian Medical Association, the Australian Council of Trade Unions and the Human Genetics Society of Australasia⁴⁶ expressed the view that this should be put beyond doubt. The NSW Anti-Discrimination Board set out the benefits of clarification:

Although the ADB considers the definition of disability in the ADA and DDA covers genetic discrimination, there is a strong public interest rationale for making such coverage explicit in anti-discrimination legislation. Such clarification would:

- reflect the current state of the law under the DDA and ADA;
- have an educative effect;
- serve a symbolic function in clarifying that such discrimination is unlawful conduct under anti-discrimination law; and
- provide certainty regarding people's rights and responsibilities under anti-discrimination law.⁴⁷

Options for reform

8.80 The terms 'impairment' and 'disability' are defined in a variety of ways in different jurisdictions. The HREOC Act and the WRA, which are discussed in more detail in the employment context in Chapter 27, use general language such as mental, intellectual or psychiatric disability and physical disability without further defining these terms. The HREOC Act does, however, include a definition of impairment and expressly covers past and imputed disabilities. The WRA does not. Neither Act specifically includes possible future disabilities.

8.81 It is not clear, however, that using a basic definition of disability along these lines would assist in clarifying the operation of federal anti-discrimination law. Indeed, there is a danger that under the WRA, in particular, as currently drafted, it would be difficult to bring an action for unlawful termination on the basis of genetic status indicating an increased risk of future ill health.

⁴⁵ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

⁴⁶ Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Australian Medical Association, *Submission G091*, 29 January 2002; Australian Council of Trade Unions, *Submission G037*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

⁴⁷ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

8.82 The NSW Anti-Discrimination Board, while holding the view that the existing definitions in the DDA and the NSW *Anti-Discrimination Act* were wide enough to cover genetic status, went on to suggest in its submission to the Inquiry:

That the definition of disability in the DDA and all State/Territory anti-discrimination legislation be amended to make clear that disability includes genetic mutations or chromosome abnormalities:

- causing or capable of causing disease, illness, malfunction, malformation or disfigurement of a part of the person's body, or
- resulting in the person learning differently from a person without the disorder or malfunction, or
- affecting a person's thought processes, perception of reality, emotions or judgment or that results in disturbed behaviour.⁴⁸

8.83 This suggestion makes clear that not all genetic variation should be covered by the DDA. Many genetic variations result in differences that could not be described as disabilities, such as eye or hair colour. Even some genetic variations that can be described as abnormal do not result in any disabling difference and indeed may result in an individual who is placed at an advantage in relation to the rest of the community. Some genetic mutations, for example, appear to confer increased immunity to particular diseases. The object of the DDA is not to protect those who are different, because we all differ from each other, but to protect those who are, or who are perceived to be, disabled.

8.84 Another possible approach is adopted in the preface to the definition of 'disability' in the *Anti-Discrimination Act 1998* (Tas) which provides that:

"**disability**" means any of the following that presently exists, previously existed but no longer exists, may exist in the future, whether or not arising from an illness, disease or injury or from a condition subsisting at birth.

8.85 It is possible that 'a condition subsisting at birth' includes a person's genetic status, although this is not express.

Inquiry's views

8.86 The Inquiry considers that there is value in providing greater certainty and raising awareness in relation to the issue of genetic discrimination. There is a possibility that the existing definition in the DDA will be construed narrowly by the courts, so as to exclude predictive genetic information, and the Inquiry is of the view that there is no policy justification for such a distinction. As well as having an educative effect, an appropriate amendment would put the matter beyond doubt

48 Ibid.

and would ensure that the question did not need to be tested in the courts. The Inquiry proposes, therefore, that the definition of disability in the DDA be amended to specifically include genetic status and that other anti-discrimination legislation, at the federal, as well as the state and territory level, also be clarified along similar lines.

8.87 Given the complexities noted above, the Inquiry invites comment on the particular form that such an amendment should take.

Proposal 8–2. Federal anti-discrimination legislation should be amended to:

- define ‘disability’ in the DDA and define ‘impairment’ in the regulations made under the *Human Rights and Equal Opportunity Commission Act 1986* (Cth) (HREOC Act) to clarify the application of the legislation to discrimination based on genetic status;
- define ‘impairment’ in the regulations made under the HREOC Act to clarify the application of the legislation to a disability that may exist in the future;
- insert a definition of ‘disability’ in the *Workplace Relations Act 1996* (Cth) to conform with federal anti-discrimination legislation, as amended by these proposals.

Proposal 8–3. The States and Territories also should consider amending their anti-discrimination legislation to accord with the policies reflected in Proposal 8–2.

Question 8–2. What form of words should be used in federal anti-discrimination laws to ensure that they apply to discrimination based on genetic status?

Medical records

Current law

8.88 The HREOC Act, as well as the Tasmanian and the Northern Territory anti-discrimination legislation, includes provisions relating to discrimination on the basis of medical records. Under the HREOC Act it is possible to lodge a complaint of discrimination in employment on the basis of a distinction, exclusion or preference made on the ground of a medical record. The complaint procedure does

not give rise to a legally enforceable remedy. Section 16 of the Tasmanian anti-discrimination legislation and s 19 of the Northern Territory legislation provide that a person must not discriminate on the basis of an irrelevant medical record.⁴⁹

Consultations and submissions

8.89 The issue of discrimination on the ground of a person's medical record was raised in a small number of submissions.⁵⁰ One submission, from the Australian National Council of Women, expressed support for including medical records as a further ground of discrimination.⁵¹

8.90 The NSW Anti-Discrimination Board, on the other hand, expressed the view that:

The ADB does not consider that the prohibition in relation to discrimination on the ground of 'irrelevant medical record' in Tasmanian and Northern Territory anti-discrimination legislation adds anything additional to that which is already covered by the prohibition of discrimination on the ground of disability, combined with adequate provisions in relation to unlawful questions and requests for information and privacy protection in relation to health information.

Inquiry's views

8.91 At present, the Inquiry considers that amending the definition of disability to include a medical record of a disability would not increase the protection provided by anti-discrimination legislation in any significant way. The Inquiry would, however, be interested in receiving further comment on this issue.

Question 8–3. Should discrimination on the ground of a medical record be added to the DDA and other relevant legislation as a prohibited basis of discrimination?

Associates

8.92 Because of the familial nature of genetic information it is possible that individuals will be discriminated against, not on the basis of information about themselves, but on the basis of information about their genetic relatives. Employers may seek to rely on the fact that genetic information about a member of a person's

⁴⁹ *Anti-Discrimination Act 1998* (Tas); *Anti-Discrimination Act 1992* (NT).

⁵⁰ National Council of Women Australia, *Submission G095*, 31 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

⁵¹ National Council of Women Australia, *Submission G095*, 31 January 2002.

family may sometimes provide relevant information about the person. An employer may, for example, refuse to employ an applicant because of a family history of breast cancer. In the anti-discrimination context, this act may be characterised either as (a) an act on the basis of the applicant's 'association' with others, which is discussed below, or (b) an act on the basis of an 'imputed' disability, which has been discussed above.

Current law

8.93 Anti-discrimination legislation in Australia generally recognises that it is unlawful to discriminate against a person on the basis of their association with another person.⁵² For example, ss 15(1) and 15(2) of the DDA provide as follows:

(1) It is unlawful for an employer or a person acting or purporting to act on behalf of an employer to discriminate against a person on the ground of the other person's disability or a disability of any of that other person's associates:

- (a) in the arrangements made for the purpose of determining who should be offered employment; or
- (b) in determining who should be offered employment; or
- (c) in the terms or conditions on which employment is offered.

(2) It is unlawful for an employer or a person acting or purporting to act on behalf of an employer to discriminate against an employee on the ground of the employee's disability or a disability of any of that employee's associates:

- (a) in the terms or conditions of employment that the employer affords the employee; or
- (b) by denying the employee access, or limiting the employee's access, to opportunities for promotion, transfer or training, or to any other benefits associated with employment; or
- (c) by dismissing the employee; or
- (d) by subjecting the employee to any other detriment.

8.94 Associate is defined to include the following: a spouse of the person; another person who is living with the person on a genuine domestic basis; a relative of the person; a carer of the person; and another person who is in a business, sporting or recreational relationship with the person.

⁵² *Anti-Discrimination Act 1977* (NSW) s 49B; *Equal Opportunity Act 1995* (Vic) s 6; *Anti-Discrimination Act 1991* (Qld) s 7; *Equal Opportunity Act 1984* (WA) s 66A; *Anti-Discrimination Act 1998* (Tas) s 16; *Anti-Discrimination Act 1992* (NT) s 19; *Discrimination Act 1991* (ACT) s 7(1).

8.95 Some state and territory legislation deals with the issue slightly differently by including ‘association with a person’ as a further ground of discrimination. For example, s 6 of the *Equal Opportunity Act 1995* (Vic) provides:

The following are the attributes on the basis of which discrimination is prohibited in the areas of activity set out in Part 3 ...

- (b) impairment; ...
- (m) personal association (whether as a relative or otherwise) with a person who is identified by reference to any of the above attributes.

8.96 The *Equal Opportunity Act 1984* (SA), the HREOC Act and the WRA do not expressly address discrimination on the basis of association with another person. The language of the HREOC Act and the WRA is potentially wide enough to cover discrimination on the basis of personal association but the issue is unclear.

8.97 If an employer refused to employ a woman because of her family history of breast cancer, for example, it would be open to the applicant to lodge a complaint in most States and Territories, and under the DDA, that she was being discriminated against on the basis of her association with her genetic relatives. Under the DDA, and some state and territory legislation, the applicant could also lodge a complaint that she was being discriminated against on the basis of an imputed disability, that is, that the employer was acting on the basis of a belief that the applicant was likely to have or to develop breast cancer.

8.98 In *IW v City of Perth*⁵³ the High Court indicated, however, that problems may arise where a person who does not have a disability is discriminated against on the basis of his or her association with a person who does have a disability and the relevant legislation does not cover discrimination on the basis of association. On the facts of that case it would not have been possible to rely on imputed disability because the ‘person’ alleging discrimination was an organisation, which could not itself suffer an impairment.

Consultations and submissions

8.99 The NSW Anti-Discrimination Board expressed the view that, while coverage under the DDA and most state and territory legislation was adequate:

Precisely because the genetic information obtained from one person may be indicative of the genetic make up of that person’s blood relatives, it is essential that all State/Territory anti-discrimination legislation covers such circumstances.⁵⁴

⁵³ *IW v City of Perth* (1997) 191 CLR 1

⁵⁴ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

Inquiry's views

8.100 It appears that the issue of discrimination on the basis of disability among family members is adequately addressed in all jurisdictions, either under provisions dealing with 'associates' or under provisions dealing with 'imputed' disability. It is possible, however, that where a person is discriminated against on the basis of the genetic status of an associate who was not a genetic relative there may be a gap in coverage. While this is less likely to occur in relation to genetic disorders, it might occur where families comprise members who are not genetically related to some other members of that family, such as adopted children, step-children, or children born through artificial reproductive technology using donor sperm.

8.101 In the Inquiry's view there is merit in amending the regulations made under the HREOC Act expressly to address discrimination on the basis of association.

Proposal 8-4. The regulations made under the HREOC Act should be amended expressly to include discrimination on the basis of association with a person who has an impairment or disability.

9. Ethical Considerations

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Introduction

9.1 The terms of reference require the Inquiry to report on whether, and to what extent, a regulatory framework is required to reflect the balance of ethical considerations relevant to the collection and use of human genetic samples and information in Australia.

9.2 The management of ethical issues relating specifically to medical and other human research and to the collection of human genetic samples and information in databases are dealt with in this Discussion Paper in Chapters 10–16. However, ethical concerns permeate the subject matter of the Inquiry as a whole. As one submission remarked:

If ethics is understood as the rational study for approving or not approving conduct [as suggested in the Issues Paper], there is no question whether ethical concerns should be given recognition in law. Of course — how else ought we to decide what the law should be?¹

9.3 However, while it may be obvious that any regulation of the collection and use of human genetic samples and information ought to be informed by ethics, it is less obvious what the term ‘ethics’ means in this context. Nor is the relationship between law and ethics self-evident. Professor Nick Saunders and Associate Professor Paul Komesaroff described the elucidation of this relationship as ‘a major issue that requires examination at the philosophical level’.² The purpose of this chapter is to report on the discussion of this and related issues provoked by IP 26.³

What is meant by ‘ethics’?

9.4 In recent public debates relating to the regulation of genetic research, ‘ethics’ has sometimes figured as the adversary of science. This vision of ethics presents it as a set of moral constraints applied to scientific activity, which in itself is understood to be essentially amoral and potentially immoral.

9.5 Prime Minister John Howard, for instance, described the recent decision to allow limited use of embryos for stem cell research in Australia as balancing ‘ethical considerations with the need for medical research’.⁴ Professor Edwin C. Hui of the University of British Columbia takes a similar view in identifying an ‘inevitable tension’ between the ‘scientific community’ which he says wants unfettered opportunities for research and experimentation, and the ‘moral and ethics communities’, which seek guidelines and restrictions.⁵

9.6 However, ethics need not be defined in opposition to activities like medical research. Rather ethics may be seen as an integral aspect of such activities, especially as they relate to the interests of all members of a community, which encompasses both scientists and ethicists, as well as the many other people affected by advances in genetic research and its applications. The challenge, on this view, is not to ‘balance’ ethical commitments against scientific or medical interests, but to ensure that scientific and medical interests are pursued in ethical ways.

1 K Liddell, *Submission G141*, 23 March 2002.

2 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

3 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney.

4 *Transcript of the Prime Minister The Hon. John Howard MP Joint Press Conference with Premiers and Chief Ministers 5 April 2002*, Prime Minister of Australia, <<http://www.pm.gov.au/news/interviews/2002/interview1587.htm>>, 1 May 2002.

5 E Hui, ‘Human Stem Cells: Ethical Considerations on their Research and Applications’ (Paper presented at HGM 2002, Shanghai, 13 April 2002).

9.7 This interpretation of the ethical task accords with the approach taken by UNESCO's International Bioethics Committee, which recognises that science has not ignored its responsibilities in relation to ethical issues arising from the genetics revolution and that scientists have already taken an important role in developing ethical principles in this area.⁶ However, this does not imply that this task should be left exclusively to scientists and medical professionals.

9.8 The development of ethical principles to guide decision-making has been of central importance. In addition, submissions to the Inquiry emphasised the need to provide all interested parties the opportunity and means to contribute to ethical debate and decision-making in the area of genetics. As Saunders and Komesaroff remarked

In a given situation, there is often no unique single, valid ethical decision or action. What makes a decision ethical is therefore not its substantive content but the process that generated it — namely the quality of the dialogues and reflection in which the protagonists engaged.⁷

Meanings of the term

9.9 While the term 'ethics' is used in a wide variety of senses, its meaning consistently relates to an 'ethos' or 'way of life.' It is because genetic information has dramatic potential to change the 'way of life' of persons affected by it, and arguably even to alter our conception of the human 'person', that it raises ethical concerns.⁸ These concerns extend beyond the kind of moral dilemmas that may quickly be resolved by reference to pre-existing values, for several reasons.

9.10 First, some situations created by advances in genetic science and technology are unprecedented, except perhaps in the works of science fiction writers.⁹ As a community, we have yet to determine settled moral values and rules of conduct in relation to the novel possibilities opened up by the rapid development of this field of science. Consequently, the questions that arise in the course of this development call not merely for moral reflection, but for reflection upon morals.

9.11 This is the work of ethical analysis. It is concerned to examine how we make moral decisions, and to reveal the philosophical assumptions or attitudes that underpin processes of moral deliberation. Key examples of such assumptions in the context of the present Inquiry include ideas about the purpose of medical research, the identity of the human person and the application of the concepts of property and ownership to human genetic information.

6 For example, International Bioethics Committee, *Draft Report on Collection, Treatment, Storage and Use of Genetic Data* (2001), United Nations Educational, Scientific and Cultural Organisation, Paris, s 3.

7 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

8 See F Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002) Profile Books, London.

9 See, for example, the discussion of the film, *GATTACA*, in Ch 2.

9.12 Second, human genetic information does not operate within discrete and stable parameters. It tends to spill out from the scientific and medical domains to affect a growing range of human activities and interests. It is not sufficient that this type of information be evaluated solely in terms of its scientific validity. Rather, it must be judged with respect to its impact on our shared 'way of life'. Ethical inquiry aims to allow, and indeed foster, this kind of evaluation. It is centrally concerned with the kind of procedures or discussions that allow all relevant sources of information and viewpoints on a disputed matter to be taken into account in coming to a decision.

9.13 In this sense ethics is a rational and impartial activity, concerned to inform and justify decisions and actions. However, this does not imply that an ethical judgment will be a conclusive one. On the contrary, ethics is necessarily an ongoing activity, since our 'way of life' is continually developing. Nor does this emphasis on reason imply that ethical procedures seek to exclude or devalue emotion, but rather that they aim to place emotional responses (which are often based on strong moral commitments) in a framework in which they can be rationally assessed and balanced against all other relevant perspectives on an issue.

Sources of ethics: past and present

9.14 Among the many philosophical and theological concepts and theories that have contributed to the contemporary understanding of ethics, the Ancient Greek concept of prudence stands out as a principle of particular relevance to the area of genetics. According to Aristotle, the prudent person is one who engages in well-conducted deliberation which is timely, measured and takes into account the particular problems and circumstances of the case in order to foresee 'even the unforeseeable'. The fact that genetic information gives rise to unforeseen, and even unforeseeable, situations involving both benefit and risk, makes the concept of prudence and the standards of deliberation it entails particularly applicable in this area. The 'principle of caution' has emerged as the modern version of this concept and has come to dominate recent work on bioethics, in part due to the influence of Hans Jonas and his 'ethic of responsibility'.¹⁰

9.15 Jonas argues that the transformative potential of modern technology has altered the primary task of ethics. Traditional (Platonic) ethics is based on an understanding of the human condition as given once and for all, so that the good to be attained is readily determinable and eternally valid. Modern technological developments challenge this vision, shifting the focus of ethical inquiry from the perspective of eternity to that of temporality 'in its ever-new, always unprecedented productions, which no knowledge of essence can predict'.¹¹

10 H Jonas, *The Imperative of Responsibility: In Search of an Ethics for the Technological Age* (1984) University of Chicago Press, Chicago.

11 Ibid, 126.

9.16 In this context, the epistemological confidence that underpins traditional systems of morality gives way to a potent sense of uncertainty about the future, as the rate of technological change increases. Jonas makes this uncertainty a central tool in his approach to ethics, advocating a 'heuristics of fear', and arguing that the question of responsibility for the changeable and perishable, rather than concern for fidelity to eternally fixed norms, ought to be the dominant concern of modern ethics.

9.17 As a European, and a German, Jonas' approach to responsibility is coloured by the legacy of the Nazi period. The memory of abuses committed at that time gives a sense of urgency to the call for caution and responsibility with respect to the present and the future. In the Australian context, the troubled and troubling history of relations between non-indigenous and indigenous peoples could provide such a sense of urgency. We might question whether, in light of this history, it is adequate, appropriate or indeed just to rely on the Western philosophical and theological heritage in seeking a theoretical framework for contemporary Australian ethics.

9.18 In IP 26,¹² reference was made to a public opinion survey commissioned recently by the Human Genetics Commission in the United Kingdom, which found the level of concern over the ethics of genetic research to be higher among women and ethnic and racial minorities than among other parts of the population.¹³ It is logical that groups of people who are highly susceptible to being identified with their bodies (a category which notably includes those suffering from genetic related illness or disability) will feel especially vulnerable to potentially unethical developments in genetic research. Their fears are particularly relevant to the project of a 'heuristics of fear' designed to promote an ethic of prudence and responsibility in this area.

9.19 These concerns point to the importance of drawing on sources other than the dominant Western philosophical and theological tradition in developing a theoretical framework for Australian ethics, if 'ethics' is not to become yet another system that excludes the perspectives of those most affected by it. While this tradition is an undeniably rich source for ethical reflection, an account of ethics which reflects the balance of ethical considerations on genetic information in Australia will need to reflect the hybrid nature of Australian culture. An Australian approach to ethics may need to find a way to do justice to the perspectives and the 'ways of living' of all Australians.

12 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.10.

13 Human Genetics Commission, *Human Genetics Commission Publishes Results of Major Survey on Attitudes to Human Genetics*, < http://www.hgc.gov.uk/business_press10.htm>, 2 March 2001.

9.20 The theories of procedural ethics and the ethics of discussion, which will be discussed below in relation to bioethics, propose frameworks designed to facilitate such an inclusive approach. This discussion is necessarily brief and does not represent any concluded view of the Inquiry as to the primacy of any particular approach to ethics.

Bioethics

9.21 To date, ethical issues relating to genetic information have primarily been addressed within the specialised fields of health care and medical research ethics. Recent developments in these fields can usefully be understood as falling into three major schools: principlist ethics, critical ethics and the ethics of discussion.¹⁴

9.22 In Australia, the primary source of guidance in medical research ethics is the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).¹⁵ The basic ethical values reflected in the National Statement are integrity, respect for persons, beneficence and justice,¹⁶ and are a reflection of principlist ethics.

Principlist ethics

9.23 The school of principlist or jurisprudential ethics has dominated the field of research ethics since it first gained momentum in the 1960s. It is characterised by an assumption that scientific progress is essential for the good of humanity, coupled with a concern to protect individual and group rights that may be endangered in the course of scientific research. It seeks to establish principles that must be respected in carrying out this work, building upon traditional principles of medical practice such as those set out in the 'Georgetown mantra', which requires respect for autonomy, beneficence, non-maleficence, and justice.¹⁷ Many such principles are already enforced in legal and regulatory frameworks dealing with human rights and research protocols. Their application to the field of genetics is seen as a question of extending existing structures to cover a new but broadly similar area of research and medical practice.

9.24 This approach to ethics was endorsed in several submissions to the Inquiry. The Australian Medical Association emphasised the importance of the principles of the 'Georgetown mantra' in ensuring that patients' interests are

14 The following discussion is largely based on H Doucet, 'The Role of Ethics in the Development of Genetics' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 40.

15 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

16 Ibid, Ch 1 preamble.

17 The 'Georgetown mantra' was formulated by James Childress and Thomas Beauchamp in their seminal work, *Principles of Biomedical Ethics* (1979) and now in its 5th edition: T Beauchamp and J Childress, *Principles of Biomedical Ethics* (5th ed, 1999) Oxford University Press, New York.

protected.¹⁸ The Australian Academy of Science also favoured reliance on established principles of health care and research ethics, arguing that genetic information should not be regarded as inherently different from any other form of biological or medical information. The Academy expressed concern that new restrictions on the use of clinical data and samples might hinder clinical pathology and epidemiology to the detriment of the future of health care in our community, and the international standing of Australian research in these areas.¹⁹

9.25 The fact that principlist ethics already informs the regulation of health care and research means that it must be considered the starting point and the initial tool for the analysis of new ethical issues arising from the use of genetic information. However, this approach to ethics is not without its shortcomings.

Critical ethics

9.26 Critical ethics questions the principlist assumption that scientific progress is necessarily for the good of humanity. It criticises canonical bioethics for remaining silent on fundamental issues raised by the progress of genetics, arguing that bioethicists in this stream frequently do little more than legitimise the activities of laboratories and governments.

9.27 In relation to human genetic information, critical ethics highlights two key areas of concern. The first relates to the fact that genetic research depends on the medical-industrial complex and involves significant commercial interests. Such interests are likely to compromise commitment to ethical principles, in particular that of distributive justice. This concern was voiced in numerous submissions to the Inquiry.²⁰

9.28 The second critical concern relates to the special potential for abuses flowing from the ideological creation of a human standard based on genetic discoveries. This raises fears of eugenics and other forms of genetics-based discrimination. In submissions to the Inquiry, the fear that genetic testing may lead

18 Australian Medical Association, *Submission G091*, 29 January 2002.

19 Australian Academy of Science, *Submission G097*, 21 January 2002.

20 Ms Kathy Liddell flagged the general question of how the benefits and costs of genetic technology should be shared: K Liddell, *Submission G141*, 23 March 2002. UnitingCare NSW & ACT submitted that the professional codes of ethics currently used to regulate ethical decision making relating to genetics are ill-adapted to the current context of increasing corporate involvement in health care and the distribution of genetic goods and services: UnitingCare NSW & ACT, *Submission G052*, 14 January 2002. Others suggested that it is naïve to assume that ethical self-regulation will be effective where significant commercial interests are at stake: see *Confidential Submission G074BCON*, 13 January 2002.

to eugenic practices of selection, particularly in relation to sex and sexual orientation, was articulated.²¹

Ethics of discussion

9.29 A third style of ethics has emerged which attempts to integrate principlist and critical concerns. Known as procedural ethics, or the ethics of discussion, this approach recognises the pluralism of moral positions and emphasises the consequent need for effective discussion and debate. It takes the view that the role of ethicists is not to establish standards to control the genetics venture, but instead to promote discussion of the meaning and implications of this venture for communal life, and to identify (rather than prescribe) the moral imperatives that emerge from this debate.

9.30 Associate Professor Paul McNeill, a commentator on the operation of ethics committees in Australia, supports the view that an ethics of discussion is most appropriate to the field of bioethics. He echoes the concerns of critical ethics in suggesting that committees dominated by a principlist model of ethics tend to reduce ethics 'to an application of rules to situations in a poorly considered and legalistic manner'.²² A principlist style of ethics operates most easily within a hierarchical power structure, with the result that ethics committees are in danger of replicating the power imbalance between researchers and research subjects in their own relationship with researchers.²³ Another problem, said to be associated with the dominance of the principlist approach to bioethics, is a focus on technical issues, which tends to exclude laypersons and their broader concerns from the debate.²⁴

9.31 These problems, should they exist,²⁵ might be overcome with a shift away from the focus on ethical 'rules' toward an emphasis on discussion and critical reflection, involving the participation of representatives of all interested parties. McNeill argues that this shift is required, not only in the field of bioethics, but more generally in the contemporary approach to ethics:

21 C Somers, *Submission G021*, 14 November 2001. Others warned of the more general danger of 'genetic essentialism', or the reduction of personhood to genetic identity: I Barns, *Submission G056*, 8 January 2002; Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

22 P McNeill, 'Ethics Committees in Australia and New Zealand: A Critique' (Paper presented at Conference of the Italian Bioethics Association, Massa).

23 Ibid.

24 I Barns, *Submission G056*, 8 January 2002.

25 To some extent, criticisms may reflect unsubstantiated assumptions about the behaviour and collective thinking of ethics committee members. While ethics committee members may be comfortable using the 'Georgetown mantra', this does not mean that this is the only ethical framework they are using.

Increasingly, the ethics of research and the ethics by which we live our lives will depend on negotiation. Stripped of the certainties of the past, we have to take responsibility for reconstructing the world and finding perspectives we can live with. This is a communal and political activity, in the broadest sense.²⁶

9.32 If ethics is properly understood as a communal and political activity, any examination of ethics must consider how this activity is organised. Accordingly, the remainder of this chapter looks at the practical structures and possibilities that promote or hinder the activity of ethical decision-making in relation to genetic information.

Ethical decision-making: a hierarchy or a network?

9.33 In IP 26,²⁷ different aspects of ethical analysis were discussed in terms of a loose hierarchy of justification. Most fundamental are the values identified by theoretical ethics. These are then elaborated in the broad principles or rules typically dealt with by normative ethics. Finally, descriptive ethics records the details of particular ethical decisions or acts. Responses to IP 26 pointed to a different kind of hierarchy: one concerning different levels of decision-making and different types of decision-makers.

A hierarchy of decision-makers

The individual

9.34 The first level of decision-making is that of individuals who are confronted with ethical dilemmas relating to information about their own genetic status, often concerning whether and with whom to share such information. The examples set out in IP 26 illustrated this type of application of ethics in the area of genetics. At this level, where the interests involved are chiefly those of a specific person or persons, Saunders and Komesaroff suggested that ethics requires that the decision-making process be 'open and free from coercion and that adequate information is provided to allow individuals to make their own decisions after full and careful reflection'.²⁸

The community

9.35 While IP 26 focused on the ethics of decisions made by or regarding individuals, responses to the paper stressed that questions about the use of genetic information have the potential to touch the interests of whole communities. In this

26 M McNeill, 'International Trends in Research Regulation: Science as Negotiation' in, *Research Ethics* (1999) Elsevier Science, Oxford, 243, 263.

27 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney.

28 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

context, Saunders and Komesaroff pointed to the importance of diverse and extensive community input, channelled into responsive and democratic decision-making processes. They also emphasised the need for informed public debate and consultation on genetic issues.²⁹

9.36 Community interests were also highlighted by UnitingCare NSW & ACT (UnitingCare), which emphasised the particular importance of consulting groups who are directly affected by genetic related illness or disability, in order to ensure that ethical principles are applied in a way that meets the empirical needs of vulnerable individuals and families. UnitingCare pointed out that while the community has an ethical duty to consider the needs and perspectives of these people, they in turn bear a special burden of responsibility in relation to the use of genetic information. It is crucial that they be provided with appropriate services, such as counselling, to enable them to fulfil this responsibility.³⁰

9.37 On this point, the work of Canadian academic, Professor Bartha Knoppers, is relevant. She has proposed an interpretation of traditional concepts in bioethics, emphasising the principles of reciprocity, or greater exchange between health professionals and individuals, and mutuality, which refers to the obligation to share genetic information in a responsible manner. The latter principle is especially important since genetic diseases and information do not only affect individuals, but also families and communities.³¹

9.38 Professor Knoppers has predicted that the genetics of tomorrow will be 'population genetics' and argues that ethical discussion in this area will consequently need to move away from the current emphasis on protection of individual rights to focus on obligations to contribute to the common good. She has proposed the guiding principles of solidarity, equity and universality to ensure that the costs and benefits of these developments are justly distributed both within and between states.³²

The international context

9.39 The issue of distributive justice relates to a further level in the hierarchy of ethical concern and activity: that of the international arena. While the terms of reference of this Inquiry limit it to consideration of 'the range of Australian ethical opinion', it is also directed to have regard to 'the global dimensions of issues relating to research, regulation and the protection of interests'. These issues centrally include ethical matters.

29 Ibid.

30 UnitingCare NSW & ACT, *Submission G052*, 14 January 2002.

31 B Knoppers, *Human Dignity and Genetic Heritage* (1991) Law Reform Commission of Canada.

32 B Knoppers, 'Ethical Issues in Genetic Research in Populations' (Paper presented at HGM 2002, Shanghai, 13 April 2002).

9.40 Dr Nicholas Tonti-Filippini pointed to the importance of international ethical standards, notably those expressed in the UNESCO *Universal Declaration on the Human Genome and Human Rights*³³ in providing a framework for ethical practice within Australia.³⁴ Similarly, in proposing the establishment of a centralised committee for bioethics in Australia, the National Council of Jewish Women of Australia urged that this body maintain constant contact with the UNESCO International Bioethics Committee.³⁵ The Australian Academy of Science also stressed the need to ensure that ethical issues arising from genetic research are resolved in a way that is sensitive to the international context, in order to maintain and promote the profile of Australian science overseas.³⁶

9.41 The notion of a hierarchy of decision-making raises the question of how ethical responsibility should be distributed within this system. Should ultimate responsibility for taking decisions relating to genetic information rest with the individuals who are directly affected by or linked to this information, with community and international decisions regarded as informative guidelines only? Or should the hierarchy operate in the opposite direction, allowing, or at least encouraging, the priorities of individuals to be set aside where they come into conflict with community or international standards of ethics?

9.42 'Canonical' or 'principlist' health care ethics has a strong focus on the rights and interests of the individual, and tends to promote individual agency in decision-making. This reflects the fact that much of the work in this field has been published in countries such as the United States and Canada where an individualist ethos is dominant. Members of developing states generally show greater willingness to sacrifice the interests of individuals in order to uphold community decisions regarding what is ethical.³⁷ The responses to IP 26 suggest that the Australian attitude lies somewhere between these poles.

An ethical network

9.43 Such an attitude recognises the importance of communication between different types of decision-makers, ensuring that decisions at every level are taken in a spirit of cooperation and with awareness of all relevant information and

33 *Universal Declaration of the Human Genome and Human Rights*, UNESCO, <<http://www.unesco.org/ibc/en/genome/projet/>>, 29 July 2002.

34 N Tonti-Filippini, *Submission G014*, 16 November 2001.

35 National Council of Jewish Women of Australia, *Submission G008*, 21 May 2001.

36 Australian Academy of Science, *Submission G097*, 21 January 2002.

37 See eg J Tealdi, 'Physician's Charter and the New Professionalism' (2002) 359 *The Lancet* 2042, discussing reaction to the Charter on Medical Professionalism: 'The Charter's three fundamental principles — primacy of patients' welfare, patients' autonomy, and social justice — are those introduced by USA bioethics. However, in continental Europe, the term human rights was frequently used instead of principles, and in most African, Asian, and Latin American countries the terms values and human rights are more widely accepted. The ethical imperialism of principles over cultural differences and the inability of principles fundamentalism to protect human rights were also denounced'.

interests. For example, the parent of a child with a genetic disease remarked that ethical decisions about what ought to be allowed in the field of genetics are contingent on public understanding of scientific developments and the issues they raise. Public debate and democratic process must interact effectively with professional advice to enable decisions to be taken in an ethical manner.³⁸

9.44 Queensland Advocacy Inc took a similar approach in emphasising the discursive power of genetic information — the ethical effects of this kind of information depend importantly on how it is understood. Queensland Advocacy Inc called for ‘full community participation’ in ensuring that both popular and professional comprehension of genetic information is sensitive to its social impact, especially on vulnerable groups:

The issue is not how to protect the information. The issue is how to protect the people that the information marks out as disabled.³⁹

9.45 The disabled are not the only group vulnerable to the discursive power of genetic information. The vexed relationship between genetic and personal, racial or cultural identity is of particular concern to indigenous Australians, who have frequently been required to ‘prove’ Aboriginality by reference to biological descent or ‘genetic inheritance’.⁴⁰ Christine Morris raised the question of how ‘culturally appropriate interpretations of the meaning of [genetic] data’ can be established and suggested that indigenous artists might play an important role in this process.⁴¹

9.46 Many submissions emphasised the importance of education and debate in the area of genetics, and favoured the view that ethical authority should be concentrated neither at the ‘top’ nor the ‘bottom’ of the hierarchy. Ethics should not be regarded as a matter solely for individual judgment; but nor should it be the preserve of an elite, whether political, scientific, professional or moral. Instead, ethical authority should be distributed across the system, encouraging an open-minded and responsible attitude on the part of all decision-makers. All members of society, from schoolchildren⁴² to genetic scientists, have interests and a role to play in determining the development of ethics in this field. This suggests that rather than the conceptual model of hierarchy, the notion of an ethical network of decision-makers may be more appropriate to the Australian context.

38 C Roberts, *Submission G072*, 13 January 2002.

39 Queensland Advocacy Inc, *Submission G088*, 4 February 2002.

40 See eg *Queensland v Wyvill* (1990) 94 ALR 515; L de Plevitz and L Croft, *Submission G115*, 13 March 2002. See further Ch 32.

41 C Morris, *Submission G138*, 22 March 2002.

42 Arlette Mercae emphasizes the desirability of involving children in the discussion of the ethical dilemmas thrown up by advances in genetic science. She proposes that this be organized through State Education Departments and student representative councils in schools: A Mercae, *Submission G031*, 12 January 2002.

Promoting ethics in the field of genetics

Limitations of professional ethics

9.47 Several submissions expressed the view that codes of professional ethics and the principles upon which they are based, while important, are insufficient to ensure the ethical use of human genetic information. For example, UnitingCare and Henry Wellsmore both argued that the current dominance of the model of professional ethics in the field of genetics is problematic. This is because:

- the focus on the relationship between the individual professional and the patient or client means that broader social consequences of the decision for the family or community tend to be neglected;
- such codes of ethics do not cover everyone who has access to genetic information;
- these codes are not formulated to deal specifically with issues arising from genetic information, and the professionals using them frequently lack the expertise required to deal with the complexities of this area; and
- the interpretation of codes of ethics may be unduly affected by commercial considerations, given the increasing involvement of corporations in health care.⁴³

Ethical regulation?

9.48 In response to the limitations of professional ethics, a significant number of submissions to the Inquiry advocated greater formal regulation of dealings with genetic information, to supplement or replace reliance on professional or personal ethical standards. Such regulation would aim to render ethical practice in this area more consistent and systematic, and to address ethical problems arising from the 'special' nature of genetic information (such as the uncertainty associated with its predictive potential).⁴⁴

9.49 However, the Australian Society for Medical Research noted that definitive attempts to 'legislate ethics' would be 'doomed to failure as the current field is rapidly moving'.⁴⁵ Douglas Magendanz made a similar point in suggesting that the increasing use of genetic information will give rise to new social norms, so

43 UnitingCare NSW & ACT, *Submission G052*, 14 January 2002; H Wellsmore, *Submission G064*, 5 January 2002.

44 Caroline Chisholm Centre for Health Ethics, *Submission G061*, 26 December 2001; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

45 Australian Society for Medical Research, *Submission G124*, 18 March 2002.

that to attempt to regulate this new technology simply by applying present norms would be misguided.⁴⁶ Research Australia also pointed to the disjunction between established and developing norms in this field.⁴⁷

9.50 A further problem with the notion of ‘regulating’ ethics is that while the formulation of laws or rules frequently represents the effort to give definite content to ethical impulses, there is an important sense in which ethics exceeds and informs regulatory frameworks, rather than being defined by them. As IP 26 observed, action that is motivated by fear of a sanction is not normally considered to be properly ethical.⁴⁸ Rather, ethics is understood to involve a positive commitment to a certain mode of behaviour.

9.51 This suggests that rather than applying new sanctions to express and implement ethical standards relating specifically to genetic information, it would be preferable to commit resources to educational and reflective processes in order to nurture a culture of responsibility in this area.

Ethics and public policy

9.52 Saunders and Komesaroff observed that it is one of the critical functions of law in liberal societies to constitute and protect the dialogues and reflection essential to ethical processes of decision-making, without seeking to determine their specific outcomes.⁴⁹

9.53 UnitingCare made the same point in arguing that it is not appropriate for specific moral questions regarding the use of genetic information to be decided as a matter of public policy. Instead, their submission emphasised the practical importance of ensuring that appropriate resources are made available to individuals and families who are faced with the need to make this type of decision. UnitingCare suggested that public policy efforts should be directed to the task of providing all relevant information, accompanied by counselling services where appropriate, to clarify the practical and moral implications of this information for all involved.⁵⁰

Ethical education and debate

9.54 Taking into account the limitations and problems of attempting to regulate ethics, whether through public policy, legal mechanisms or professional codes, many submissions to the Inquiry proposed educational measures to ensure

46 D Magendanz, *Submission G093*, 1 February 2002.

47 Research Australia, *Submission G078*, 16 January 2002.

48 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 3.61.

49 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

50 UnitingCare NSW & ACT, *Submission G052*, 14 January 2002.

that decisions relating to genetic information are voluntarily taken in an informed and ethical manner. Such proposals called for two types of education: provision of specialised training and advice for those most directly involved with the use of genetic information, and public education designed to encourage ethical discussion and debate across society as a whole.

9.55 A key group who require specialised education in ethics are the individuals and families who are directly affected by genetically related disease. UnitingCare pointed out that such people bear a special burden of responsibility in relation to genetic information and it is crucial that they be assisted in carrying out their ethical responsibilities by the provision of services such as counselling. Their special interest in the area also means that their perspectives and insights into the ethical dilemmas posed by genetic information should be given particular weight in official and public discussions or deliberations on this topic.⁵¹

9.56 Specific educational programs will also be required to enable those who are handling genetic information in a professional capacity to keep pace with the ethical significance of developments in the area of genetics. To this end, the Australian Academy of Science recommended that professional training in ethics should be included in all medical science and allied health training programs at undergraduate and postgraduate level.⁵² The Australian Medical Association made a similar call for training in ethical issues for research workers and members of ethics committees.⁵³

9.57 Clearly, the general public cannot be expected to attain the same level of ethical expertise in relation to genetic information as that required by professionals working in the area, or that acquired by individuals whose personal circumstances give rise to special commitment to this branch of ethics. On the other hand, many submissions drew attention to the role of public perceptions in determining the social significance and effects of genetic information. This points to the importance of establishing and maintaining a healthy culture of discussion and debate, involving effective exchange between all interested parties on ethical issues relating to genetic information. It is envisaged that the proposed national standing body on human genetics might play an important role in this respect. This is discussed further in Chapter 3.

Conclusion

9.58 An important perspective on the relationship between law and ethics is that ethics should be regarded as a communal and communicative activity that supplements and informs legal regulation but cannot be replaced or captured by it.

51 Ibid.

52 Australian Academy of Science, *Submission G097*, 21 January 2002.

53 Australian Medical Association, *Submission G091*, 29 January 2002.

From this perspective, it would be both inappropriate and unnecessary to develop a special section of the law that sought to provide answers to particular ethical questions.⁵⁴

9.59 It is not acceptable to leave ethical concerns relating to the collection, use and disclosure of genetic samples and information to be regulated solely by the personal and professional ethics of health professionals, researchers and others. Equally, legal regulation of ethical standards cannot be the sole response to these concerns.

9.60 IP 26 highlighted a number of ethical principles that have come to have an enduring role in ethical discussion and decision making, reflecting a principlist approach.⁵⁵ These principles, influenced by the so-called 'Georgetown mantra' include:

- the principle of respect for the dignity of each human being, most commonly reflected in the requirement that a person must give his or her consent prior to any treatment or testing, and that such consent be informed by an understanding of adequate information;
- the principle of beneficence, most commonly expressed in the requirement that health care be aimed to produce beneficial outcomes;
- the principle of non-maleficence, most commonly reflected in the requirement that, on balance, treatment should not cause harm;
- The principle of justice, most commonly expressed in the requirement that treatment be made available on a fair and equitable basis.⁵⁶

9.61 In practice, these and other principles have a central influence on ethical decision-making, notably by Human Research Ethics Committees.⁵⁷ They are broad principles that offer guidance but do not prescribe the outcomes of decision-making.

⁵⁴ N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

⁵⁵ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Ch 3.

⁵⁶ Ibid para 3.26.

⁵⁷ See National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra Ch 1 (Principles of Ethical Conduct), which refers to integrity, respect for persons, beneficence and justice as guiding ethical principles in research involving humans.

9.62 To date, submissions to the Inquiry have not argued for the establishment of any fixed set of moral or legal standards to regulate the use of genetic information, but have emphasised the need to cultivate a robust and inclusive culture of ethical discussion and debate.

9.63 A balanced response to the range of ethical opinion expressed would also retain a central role for the established principlist conception of ethics. That role may be twofold — to define the position of important professional stakeholders and to provide a starting place from which to develop a more inclusive and mutually respectful approach to ethical discussion and decision-making.

Part D. Human Genetic Research

10. The Regulation of Human Genetic Research

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Introduction

10.1 This chapter introduces Part D, which considers ethical, privacy and related issues concerning the use of genetic samples and information in the conduct of medical and other research involving humans (referred to as human genetic research).

10.2 This chapter briefly summarises the present regulatory framework for the ethical conduct of research. This framework is centred on the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement)¹ and on review of research proposals by Human Research Ethics Committees (HRECs).

10.3 The adequacy or otherwise of the existing regulatory framework has been the subject of much comment and discussion in the course of the Inquiry to date. The nature of this comment and the issues raised in consultations and submissions are reflected in this chapter and those that follow.

¹ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

Present regulatory framework for research ethics

10.4 The present regulatory framework under which research is conducted in Australia — the processes required and the principles, especially ethical principles, that are to be followed, were described in detail in IP 26.² In addition to the ethical principles and procedure for ethical review of research set out in the National Statement, this framework also includes:

- relevant statutory restrictions on dealing with personal information (which may include genetic information) including those under the *Privacy Act 1988* (Cth) and related guidelines;³
- common law duties to exercise reasonable care owed by researchers, research organisations and HRECs to those with whom the requisite relationship of sufficient proximity arises, including duties to participants in research;⁴ and
- standards for the scientific validity of research, notably the *Statement and Guidelines on Research Practice* issued by the NHMRC and the Australian Vice-Chancellor's Committee.⁵

The NHMRC

10.5 The NHMRC is the statutory authority that governs the procedures and determines the principles applicable to the regulation of medical research and ethical matters relating to health. The *National Health and Medical Research Council Act 1992* (Cth) (NHMRC Act) establishes the NHMRC as a statutory corporation and prescribes its membership.⁶

10.6 The functions of the NHMRC are to inquire into, issue guidelines on and advise the Commonwealth, the States and the community on matters relating to the improvement of health; prevention, diagnosis and treatment of disease; provision of health care; public health and medical research; and ethical issues relating to health.⁷

2 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Ch 6.

3 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra; National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council.

4 In accordance with the common law relating to the tort of negligence.

5 National Health and Medical Research Council and Australian Vice Chancellor's Committee, *Statement and Guidelines on Research Practice* (1997), NHMRC, Canberra.

6 *National Health and Medical Research Council Act 1992* (Cth) ss 6, 20–21.

7 *Ibid.*, s 7.

The National Statement

10.7 In relation to medical research, the NHMRC Act requires the NHMRC to issue guidelines for the conduct of medical research on humans, which are to be issued precisely as developed by the Australian Health Ethics Committee (AHEC),⁸ one of its principal committees. The present National Statement was issued by the NHMRC on 28 June 1999 in exercise of these statutory obligations. It is the successor document to the NHMRC *Statement on Human Experimentation*, first issued in 1966.

10.8 The National Statement is endorsed by the Australian Vice-Chancellors' Committee, the Australian Research Council, the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of the Social Sciences in Australia.⁹ Briefly, the National Statement:¹⁰

- contains ethical principles relevant to all research involving humans;
- requires that particular matters are to be addressed when research involves children and young people, persons with an intellectual or mental impairment, persons highly dependent on medical care, those in dependent or unequal relationships, collectivities, and Aboriginal and Torres Strait Islander people;
- requires that specific matters be addressed in the consideration and approval of research involving radiation, assisted reproductive technology, clinical trials, epidemiology, human tissue samples, genetics, deception; and
- sets out the formation, membership and functions of HRECs.

10.9 The primary function of an HREC is to protect the welfare and rights of participants in research. An often overlooked secondary purpose is to 'facilitate research that is or will be of benefit to the researcher's community or to humankind'.¹¹

10.10 The National Statement provides that research proposals involving human participants must be reviewed and approved by an HREC and sets out requirements for institutions or organisations in establishing HRECs, researchers in submitting research proposals to HRECs and HRECs in considering and reaching decisions regarding those proposals and in monitoring the conduct of approved

8 Ibid, s 8.

9 The National Statement does not include updated references to the new private sector provisions of the *Privacy Act* (and the NPPs), particularly in relation to consent and collection issues.

10 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

11 Ibid, preamble.

research.¹² The National Statement places clear responsibilities upon institutions and researchers as well as providing the framework upon which HRECs are based. Selected issues concerning the membership and functions of HRECs are discussed in more detail in Chapter 14.

What is human genetic research?

10.11 The subject of the following chapters is ‘human genetic research’. Human genetic research is broadly defined in the National Statement as a process which

enhances our understanding of how genes and environmental factors interact to influence the health of individuals and populations and in doing so, generates knowledge with the potential to improve individual and community health.¹³

10.12 IP 26 noted that some human genetic research can be conducted without the need for genetic information that can be related to specific persons or communities. Research on molecular processes can explore genetic processes and the production of enzymes or proteins. Research can use anonymous population data to examine patterns of human inheritance of disease or conditions.¹⁴

10.13 Unless otherwise indicated, this Discussion Paper uses human genetic research to refer to any research that uses genetic samples or genetic information, whether or not those samples or information are identified, potentially identifiable, or de-identified.¹⁵ Such research must involve *human* genetics and would not, for example, include the use of human tissue samples in order to study the genetics of infectious agents, such as viruses.

10.14 When discussing the protection of privacy interests in genetic samples and information, the focus is on human genetic research that needs to use or will develop information that is either identified or potentially identifiable — privacy interests are not generally implicated where information is not about an individual whose identity is apparent or can reasonably be ascertained from the information.¹⁶

10.15 However, ethical concerns may be raised by the collection or use of genetic samples and information in human research, even where the samples or information are to be de-identified. Basic ethical principles, such as integrity and

12 Ibid, para 2.

13 Ibid, Ch 16.

14 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 6.7.

15 As these terms are used in the National Statement: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra 9. See also Ch 12–13.

16 See eg *Privacy Act 1988* (Cth) definition of ‘personal information’: s 6.

respect for persons¹⁷ should be observed even where samples or information are to be de-identified¹⁸ or where the research involves a collectivity.

The importance of human genetic research

10.16 The Wills Report referred to the need to take advantage of advances in biotechnology to improve the health of the Australian population, to build the economy and to create valuable jobs.¹⁹

10.17 Human genetic research generates knowledge with the potential to improve individual and community health. Research can also reveal information about an individual's susceptibility to disease and hence about the individual's future health. Such information may be of interest and benefit to research participants especially if preventive strategies exist.²⁰

10.18 IP 26 noted that the completion of the Human Genome Project has opened huge potential for research into the ways that these genes are related to human conditions, capacities, diseases, impairments and susceptibilities.²¹ The scope of such research may be illustrated by reference to the current activities of just one major Australian genetic research organisation. The Murdoch Childrens Research Institute is conducting research into, among other things, the underlying genetic causes of: neuromuscular disorders; inherited hearing loss; attention deficit hyperactivity disorder; cancers; ataxias and addiction.²²

10.19 Although no exact figures are available it seems likely that human genetic research will become an increasingly important component of medical research generally. One indication of this is that clinical trials of new drugs increasingly include genetic sub-studies.²³ It has long been known that drug toxicity and efficacy has a genetic component²⁴ and these sub-studies are intended to investigate genetic causes of individual variations in clinical response to drugs.

17 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 1.1–1.2.

18 The concept of de-identification and its relevance to issues of consent to participation in research is discussed in Chapter 12. Issues concerning the de-identification of genetic samples and the coverage of the *Privacy Act 1988* (Cth) are discussed in Ch 7.

19 Health and Medical Research Strategic Review, *The Virtuous Cycle, Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra, 1.

20 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 6.5.

21 *Ibid*, para 6.6.

22 Murdoch Children's Research Institute, *Gene Identification and Expression*, <http://murdoch.rch.unimelb.edu.au/pages/lab/gene_identification/overview.html>, 25 June 2002.

23 One estimate is that, at present, approximately 1 in 5 clinical trials have an associated genetic sub-study and this proportion is increasing: HREC Chairs and Officers, *Consultation*, Sydney, 20 June 2002.

24 Advisory Committee on Health Research, *Genomics and World Health* (2002), World Health Organization, Geneva, 71.

Balancing interests

Researchers need to access valuable human tissue samples in a manner which takes account of the precious nature of the resource, the responsibility of clinicians and pathologists to prioritise the diagnostic process, the rights of the individual donors, and the rapid rate of scientific and clinical advances.²⁵

10.20 The Inquiry aims to develop proposals that will enable human genetic research to be fostered while providing sufficient reassurance to the community that such research is subject to proper ethical scrutiny and legal control.

10.21 Any reform proposals need to balance the interests of researchers — who need access to human genetic samples and information from many sources — and the needs of individuals and their relatives — whose rights to autonomy and privacy must be respected.

10.22 Individuals whose samples or information is held want to assert their right to human dignity and autonomy (including by requiring consent before use or re-use after appropriate information has been provided) and need to be confident of the privacy of that information.

10.23 Genetic researchers need to be able to secure the willing and active participation of many volunteers. The ability to conduct human genetic research may be prejudiced if potential volunteers fear that participation in research will generate information that they may subsequently be required to disclose to insurers, employers or others.

10.24 In human genetic research, the interests of the genetic relatives of participants may also need to be considered. A particular feature of many human genetic research studies is that they require the participation of families, rather than individuals. Individuals may be asked to provide family histories and genetic samples that will be used in research, the results of which can be related back to them and to other family members.

10.25 As discussed in IP 26,²⁶ research results and genetic material and information collected for research may be of significance to the health of genetic relatives, including those who have not participated in the research and who may not have been aware that the research was being done. These family members may have an interest in their relatives' genetic material or information that the research generates, because testing that material or acquiring that information may create new options for life decisions, including those with potential to improve health.

25 Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

26 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 6.11–6.14.

10.26 However, some family members may prefer not to be given information that may provide knowledge of future health or health risks. In addition, other family members who are not genetic relatives, such as partners and spouses, may have an interest because of concerns about the health of offspring. The information generated by such family research may also be of relevance to people in the community unrelated to participants or their families but whose family histories or health condition may be similarly related to genetic effects. Not all of this information will be of positive benefit to families. Indeed, in certain situations, such as evidence of non-paternity, the implications of the information may be highly negative.

Reform of the regulatory framework for human genetic research

10.27 The Inquiry has received a wide range of views and comments about the adequacy of the regulatory framework for human genetic research. These views extend from those who are highly supportive of the existing framework through to those suggesting a broad agenda for change. In many cases the changes proposed were broadly applicable to all medical and other human research and not limited to addressing issues raised by human genetic research proposals specifically.

10.28 A common theme in consultations with individuals and organisations involved in human genetic research was concern about the present and possible future costs of compliance with regulatory requirements. It was noted that research funding rarely includes any allocation for compliance costs — such as the cost of operating HRECs, obtaining ethics approval for research proposals, complying with ethical requirements for the de-identification of samples and in relation to monitoring and reporting obligations.²⁷

10.29 The same groups, and HREC members, observed that the existing National Statement has only been in operation since 1999 and that there may not have been enough time to evaluate whether it operates effectively in protecting privacy and ethical conduct in human genetic research. Particular concerns were expressed about the need to avoid any retrospective reforms that might have adverse practical implications for existing long-term research projects.²⁸

²⁷ Eg Queensland Institute of Medical Research, *Consultation*, Brisbane, 13 December 2001.

²⁸ Eg *Ibid.*

10.30 Several submissions identified the commercialisation of human genetic research as an important background development.²⁹ For example, the Centre for Law and Genetics noted that

it is a feature of human genetic research that commercial arrangements include the hand over of tissue or blood samples. In this respect the samples and information they contain have become commercial commodities. Gene identification research usually involves analysis of large data sets with subsequent follow-up on samples carrying the identified gene. This research will usually involve identified or potentially identifiable samples. There are clearly implications for personal privacy ...³⁰

10.31 Many submissions suggested significant changes to the regulatory framework for protecting privacy and ensuring ethical conduct in human genetic research. For example, Privacy NSW suggested a range of reforms to improve the 'transparency and accountability of ethics review in respect of genetic research involving humans'. These included the establishment of an independent, national ethics review committee; enhancing the obligations of HRECs to report their decisions; a single, independent and transparent complaints mechanism to deal with decisions made by any HREC; strong civil and criminal sanctions where privacy is breached; and effective audit of an HREC's activities, including monitoring throughout the research period.³¹

10.32 Professor Nick Saunders and Associate Professor Paul Komesaroff highlighted several issues 'of particular interest to the research and ethics committee communities that deserve emphasis'.

10.33 These included concerns relating to the question of waiver of consent, the monitoring of research by HRECs, de-identification of genetic samples, withdrawal of participants from research projects, provision of advice to participants and the storage of data. It was suggested that most of these concerns could be addressed through a Supplementary Note to the National Statement.³²

10.34 Specific reforms suggested by submissions and in consultations are discussed throughout the following chapters.

29 M Dunne, *Submission G041*, 17 December 2001; Australian Academy of Science, *Submission G097*, 21 January 2002; A Rose, *Submission G116*, 18 March 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

30 The Centre for Law and Genetics noted that there is currently 'no systematic data collection or analysis of the changing features of research in an increasingly commercialised environment'. The Centre for Law and Genetics at the University of Tasmania is currently funded by the Australian Research Council to investigate this aspect of the changing research environment: Centre for Law and Genetics, *Submission G048*, 14 January 2002.

31 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

32 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

Enforcing compliance with the National Statement (Chapter 11)

10.35 The enduring value of the National Statement itself was highlighted in a number of submissions, including those which also suggested changes to its scope or content.

10.36 For example, the federal Privacy Commissioner observed that, like the Declaration of Helsinki and other international ethical guidelines, the National Statement has persuasive authority based on the standing and representativeness of its members, has been reviewed at appropriate intervals and has proven responsive to past challenges in medical research.³³ Saunders and Komesaroff observed that the National Statement ‘commands profound moral authority in the community’.³⁴

10.37 However, the requirements for institutions or HRECs to be registered with the NHMRC or to follow the processes set down in the National Statement are incomplete. As emphasised in many submissions, there is currently no obligation upon private research bodies to adhere to the provisions of the National Statement. Submissions and consultations suggested that, in view of the increasing commercialisation of human genetic research, the mechanisms by which compliance with the National Statement is enforced should be strengthened. Chapter 11 examines this issue.

Human genetic research and consent (Chapter 12)

10.38 The concept of consent is a fundamental to the legal and ethical regulation of medical and other human research and to the protection of privacy and was referred to often in submissions and in consultations. The National Statement generally requires consent to the use of human tissue samples, genetic material and genetic information in medical research, other than in limited and defined circumstances.

10.39 Submissions raised concerns about various aspects of consent and, in particular, whether adequate privacy protection is afforded by the current provisions under which HRECs may waive consent requirements in granting ethical approval for research proposals.

10.40 A related issue concerns the extent to which researchers are able to obtain consent from prospective research participants for the use of their genetic samples or information for as yet unspecified future research. Chapter 12 examines issues of consent in human genetic research and proposes related changes to the National Statement.

33 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

34 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

Encouraging best practice in human genetic research (Chapter 13)

10.41 Consultations have suggested that it may be useful for AHEC to augment the National Statement with:

- a model research protocol for human genetic research; and
- guidance on the drafting of consent forms for use in human genetic research.

10.42 The intention of these documents would be to give further guidance to researchers, and to HRECs, on what AHEC considers to be best practice in the conduct of human genetic research. The possible content of these documents is discussed in detail in Chapter 13. A particular concern relates to open and transparent disclosure, to prospective research participants, of the potential commercialisation of research outcomes.

Strengthening ethical review by HRECs (Chapter 14)

10.43 Submissions and consultations suggested a range of possible reforms aimed at strengthening the current system for ethical review of human genetic research proposals and the role of HRECs within that system.

10.44 These possible reforms, some of which may require changes to the National Statement, are discussed in Chapter 14 and include:

- reporting by HRECs on the review of research proposals;
- monitoring by HRECs of the conduct of approved research;
- the structure and membership of HRECs;
- the review or accreditation of HRECs;
- the education and development of HREC members;
- payment of HREC members;
- mechanisms for funding medical researchers' compliance costs.

11. Enforcing Compliance with the National Statement

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Introduction

11.1 The present regulatory framework for the ethical conduct of research is centred on the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement)¹ and on review of research proposals by Human Research Ethics Committees (HRECs).

11.2 This chapter examines the regulatory status of the National Statement and the consequences of non-compliance for researchers or research organisations. The chapter then discusses whether this status is adequate to protect genetic samples and information or whether different accountability and enforcement mechanisms are required.

¹ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

Consequences of non-compliance with the National Statement

11.3 The National Statement provides that the NHMRC, through AHEC, will audit the activities of HRECs to ensure compliance with the National Statement.² The National Statement also requires institutions and their HRECs to report information relevant to their ethics approval procedures on an annual basis.³ However, the requirements for institutions or HRECs to be registered with the NHMRC or to follow the processes set down in the National Statement or other NHMRC guidelines are indirect and incomplete.

Withdrawal of funding

11.4 The power to withdraw funding is the only direct mechanism available to the NHMRC to enforce compliance with the National Statement, although as described below, there are indirect legal and other factors that encourage compliance.

11.5 The NHMRC is one of the major providers of funds for medical research to institutions such as hospitals, universities and research institutes. The NHMRC also makes recommendations to the Commonwealth on expenditure for research and training in medicine and public health, including recommendations on the application of the Medical Research Endowment Fund.⁴ The National Statement has been endorsed by other bodies that have a direct or indirect role in the funding of research — the Australian Vice-Chancellors' Committee and the Australian Research Council.

11.6 It is a condition of an institution's continuing eligibility to receive NHMRC funds that all research involving human subjects conducted in the institution must be approved by an ethics committee that has been established under, and functions according to, guidelines issued by the NHMRC. Further, in the event that reporting by research organisations and their HRECs reveals that they have not complied with the National Statement, implementation of NHMRC policy may result in that institution ceasing to be eligible to receive funding for research.

11.7 Before considering the scope and effectiveness of withdrawal of NHMRC funding as the primary mechanism by which compliance with the National Statement is enforced, it has been observed that compliance with the National Statement (and other NHMRC guidelines) is encouraged by other factors,

² Ibid, para 2.46.

³ These reporting requirements are discussed in more detail in Ch 14.

⁴ The Medical Research Endowment Fund is established by the NHMRC Act: *National Health and Medical Research Council Act 1992* (Cth) s 49.

including privacy law, the therapeutic goods legislation and professional codes of conduct.

Compliance with Privacy Act guidelines

11.8 As discussed in Chapter 7, the federal *Privacy Act* and other privacy legislation imposes certain legal requirements to obtain consent to the collection, use or disclosure of personal information, including genetic information. These requirements may be waived where collection of the information is for research purposes and carried out in accordance with guidelines under s 95 or s 95A of the *Privacy Act* (the s 95 and s 95A Guidelines).

11.9 The s 95 and s 95A Guidelines require consideration, by an HREC, of whether the public interest in the research outweighs to a substantial degree the public interest in privacy.⁵ Therefore, in some circumstances, conduct that does not comply with the National Statement may also constitute a breach of the *Privacy Act*.

11.10 This may lead to researchers or research organisations being named in the NHMRC's annual report or in a report to a Commonwealth agency or the federal Privacy Commissioner⁶ — which can be expected to adversely affect the reputation of the named researchers or research organisations and their capacity to attract future research funding.

11.11 Further, where the conduct of a private sector researcher or research organisation is in breach of the *Privacy Act*, affected individuals may complain to, and have their complaints investigated by the federal Privacy Commissioner or by an adjudicator under an approved privacy code.⁷ The Privacy Commissioner may make determinations declaring that conduct constituting an interference with the privacy of an individual should cease and that compensation for loss or damage be paid.⁸ Such determinations, and similar determinations of adjudicators, are enforceable in proceedings before the Federal Court or Federal Magistrates Court.⁹

5 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra 3.2(b); National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, D.4.

6 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 4.3.

7 See *Privacy Act 1988* (Cth) Part V.

8 Ibid s 52.

9 Ibid s 55A.

Other consequences of non-compliance

11.12 Non-compliance with the National Statement may have medico-legal consequences for researchers and research organisations.¹⁰ The principles of ethical conduct and the process for ethical scrutiny of research proposals set out in the National Statement constitute accepted standards of research practice. The conduct of a researcher or research organisation may be compared against these standards in any litigation arising from a research project in which, for example, a question arises as to whether reasonable care was taken.

11.13 In this context, an analogy may be drawn with clinical practice guidelines,¹¹ including those issued by the NHMRC itself. Courts may take standards for the conduct of human research set out in the National Statement as a form of expert evidence or at least evidence of accepted standards of practice. It has been said that the evidentiary value of clinical practice guidelines depends on their purpose, development, ratification, dissemination, use, and whether they are current.¹² On this basis, a court might find the National Statement influential or even decisive evidence.

11.14 More generally, non-compliance with accepted ethical standards, including the National Statement, may have consequences for how individual researchers are viewed by their peers and their career prospects.

Professional peer pressures and the need for acceptance of research outcomes in the international scientific community are powerful drivers in this area.¹³

11.15 Importantly, compliance with the National Statement and other ethical standards may be a pre-requisite for publication of the results of research and the professional benefits that derive from publication.¹⁴

11.16 The World Medical Association's *Ethical Principles for Medical Research Involving Human Subjects* (the Declaration of Helsinki) states that reports of experimentation not in accordance with the ethical principles laid down in the Declaration should not be accepted for publication.¹⁵ The International Committee of Medical Journal Editors requires authors, when reporting

10 National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

11 See J Pelly and others, 'Clinical Practice Guidelines Before the Law: Sword or Shield?' (1998) 169 *Medical Journal of Australia* 330; 169: 330-333; B Bennett, 'Setting the Standard? Clinical Practice Guidelines and Medical Negligence Litigation' (1997) 20(3) *University of New South Wales Law Journal* 707, 707.

12 F Tito and L Newby, *Medico-Legal Implications of Clinical Practice Guidelines* (1998) National Breast Cancer Centre.

13 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

14 Although it is debateable whether, in the case of 'earth-shattering' new research results, publishers will be so scrupulous in this regard.

15 World Medical Association, *Ethical Principles for Medical Research Involving Human Subjects* (1964), Helsinki, Principle 27.

Funding of research

11.18 The effectiveness of this mechanism has not been tested in Australia, but American experience suggests that withdrawal of funding by the peak national research funding body has salutary effects upon institutions.¹⁷

Table 11-1

Commonwealth government and higher education	47.5%
State government	24.5%
Private non-profit	15.9%
Business enterprise	12.1%

16 International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to*
17 *Biomedical Journals*, <<http://www.icmje.org/index.html>>, 3 May 2002.

18 The death of a healthy volunteer involved in a research project at Johns Hopkins University in Baltimore
19 led to the shutting down of all research projects for a short period and was followed by massive
institutional reforms: R Steinbrook, 'Protecting Research Subjects — The Crisis at Johns Hopkins'
(2002) 346 *New England Journal of Medicine* 716. Withdrawal of NHMRC funding at an Australian
institution can reasonably be predicted to have similar effects, given the prestige and status associated
with the receipt of highly competitive NHMRC funding.

20 Health and Medical Research Strategic Review, *The Virtuous Cycle, Working Together for Health and*
21 *Medical Research* (1999), Commonwealth of Australia, Canberra, 166, Exhibit 5.0–5. These figures were
based on ABS 1996 and NHMRC 1994 data.

22 National Health and Medical Research Council, 2000 Grants Book, (2001) Canberra, NHMRC, 2. ~~(AHEC~~
~~to provide endnote)~~

through block funding to six institutes.²⁰ Competitive funding through the NHMRC accounted for 38.2% of Commonwealth funding, 25.2% of total government funding and 18.1% of total expenditure on health and medical research.²¹

11.21 While it may appear that much genetic and other medical research is outside NHMRC funding, in practice the influence of NHRMC funding decisions extends beyond projects that receive direct funding. While researchers and research organisations commonly derive funds from a variety of sources, it is common for research to be supported by private sector funding but conducted at publicly funded institutions that require compliance with the National Statement and other NHMRC guidelines.

11.22 Further, any withdrawal of funding by the NHMRC, once made public, would be likely to be followed by action by other funding bodies²² such as those responsible for the allocation of non-NHMRC Commonwealth government research funds or state government funds for hospital research activities.

11.23 One feature of medical and other research in Australia is the Cooperative Research Centre Program. Cooperative Research Centres (CRCs) are collaborative research ventures involving researchers from Commonwealth and state government funded organisations (such as universities and university-based research institutes), private non-profit organisations and business enterprise.

11.24 For example, the core participants in the CRC for Discovery of Genes for Common Human Diseases (the Gene CRC) are Cerylid Biosciences Ltd, an Australian biotechnology company, the University of Queensland's Institute for Molecular Bioscience, the Murdoch Childrens Research Institute, the Queensland Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research and the Menzies Centre for Population Health Research.

11.25 The total 1999–2000 public and private sector funding for the Gene CRC was \$40.6 million of which Commonwealth CRC program funding comprised \$13.1 million. The core participants, including the private sector partner (Cerylid), provided the balance of the resources.²³

20 Data extracted from: National Health and Medical Research Council, *2000 Grants Book*, (2001) Canberra, NHMRC. Note that block funding is being phased out over a three year period commencing from 2002.

21 Health and Medical Research Strategic Review, *The Virtuous Cycle, Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra, 166.

22 National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

23 CRC for Discovery of Genes for Common Human Diseases, *CRC for Discovery of Genes for Common Human Diseases*, Gene CRC, <<http://www.crc.gov.au/centres/medical/genes.htm>>, 3 May 2002.

Regulation of private sector human genetic research

[G]enetic research depends on the medical-industrial complex. The gene has become a kind of commodity as vital to the economies of developed countries as oil or uranium. ... Developed countries are fiercely competing with each other to take the lead; universities are running the risk of becoming the handmaidens of private industry; and corporations are locked in battle to be the first to perfect the molecule that will enable them to forge ahead of the competition and line the pockets of their shareholders.²⁴

11.26 IP 26 stated that investment in research by private commercial interests is likely to have at least two relevant consequences. First, institutions conducting privately funded research may not be as dependent on remaining eligible for public research funds. Second, the interrelation between self-interest and scientific research can lead to conflicts of interest that can compromise the validity and safety of research.²⁵

11.27 IP 26 highlighted findings of the House of Representatives Standing Committee on Legal and Constitutional Affairs in its September 2001 report on its inquiry into the scientific, ethical and regulatory aspects of human cloning and stem cell research.²⁶ In particular, the Committee observed that:

The growth and spread of cloning research and the substantial involvement of the private sector in it renders it very difficult for a body such as the NHMRC or AHEC to monitor this area of risk. The leverage of the NHMRC is very much tied to its capacity to grant or withhold funding and hence its real capacity to influence the private sector must be problematic as AHEC itself acknowledged. In such an environment sanctions such as the loss of research funding may have minimal influence.²⁷

11.28 The Committee concluded that the current regulatory environment for medical research was 'deeply unsatisfactory' and was the product of an era when the majority of research funding was provided by government and most research occurred within tertiary institutions that were publicly funded.²⁸ The Committee stated that consistent regulation should be applied to both publicly and privately funded research.

If the current framework continues ... it is likely to lead to the evolution of a system increasingly similar to that in the United States ... There the public sector is regulated

24 H Doucet, 'The Role of Ethics in the Development of Genetics' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 40, 43.

25 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 6.119–6.121.

26 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Parliament of the Commonwealth of Australia, Canberra.

27 Ibid, 162–164.

28 Ibid, 167.

and the private sector, where much of the research is undertaken, is subject to limited regulation.²⁹

11.29 Human genetic research also involves significant private sector funding and commercial pressures on public sector research, such as that conducted in universities. IP 26 noted, therefore, that these observations may be just as relevant to the regulation of human genetic research generally, as to human cloning and stem cell research.

Regulation of medical research overseas

11.30 While there are many significant differences, the approach taken to the ethical regulation of the conduct of medical research in Australia is broadly similar to that in Canada, the United Kingdom and the United States.

11.31 In each of these jurisdictions, national ethical standards have been established by government regulation or by government regulatory bodies. These national norms are applied to research proposals by multi-disciplinary ethics committees. In each jurisdiction, public funding mechanisms serve as the primary means by which compliance with ethical standards is enforced, whether directly or indirectly.

Canada

11.32 The centrepiece of regulation in Canada is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Tri-Council Policy Statement).³⁰ The Tri-Council Policy Statement was issued in 1998 by three Canadian government research funding bodies; the Medical Research Council of Canada (now known as the Canadian Institutes of Health Research); the Natural Sciences and Engineering Research Council of Canada; and the Social Sciences and Humanities Research Council of Canada. Each of these bodies is established under an Act of the Parliament of Canada to promote, assist and undertake research.

11.33 The Councils adopted the Tri-Council Policy Statement as their standard of ethical conduct for research involving human subjects. Under the Tri-Council Policy Statement all research that involves living human subjects requires review

29 Ibid, 167. The Committee made 14 recommendations relating to a uniform national legislative approach for the regulation of privately and publicly funded research involving human cloning and stem cell research, including the establishment of a licensing body: House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Parliament of the Commonwealth of Australia, Canberra, Ch 12, recs 1–14.

30 Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Canadian Institutes of Health Research, 8 May 2002.

and approval by a Research Ethics Board (REB).³¹ The Councils require, as a minimum condition of funding, that researchers and their institutions apply the ethical principles and articles of the statement.³²

United Kingdom

11.34 In the United Kingdom, the Department of Health published the *Research Governance Framework for Health and Social Care* in 2001.³³ The standards in this framework, which include ethical standards, are stated to apply to all research which relates to the responsibilities of the Secretary of State for Health.³⁴

11.35 Research within the NHS, which involves individuals, their organs, tissue or data must have the prior approval of an NHS Research Ethics Committee (REC).³⁵ The operational framework for RECs is set out in the *Governance Arrangements for NHS Research Ethics Committees*.³⁶ Ethics review by RECs is also required for research funded by the Medical Research Council³⁷ and General Medical Council.³⁸

United States

11.36 In the United States, the *National Research Act 1974*³⁹ established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission prepared the influential *Belmont Report*, which identified basic ethical principles that should underlie the conduct of human research and developed guidelines to be followed to ensure that research is conducted in accordance with those principles.⁴⁰

31 Ibid, art 1.1.

32 Ibid, art 1.1(a).

33 Department of Health (UK), *Research Governance Framework for Health and Social Care*, <<http://www.nserc.ca/programs/ethics/english/policy.htm>>, 7 May 2002.

34 Ibid, 3 (para 1.2). This is stated to include research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care services that might have an impact on the quality of those services. This includes clinical and non-clinical research, research undertaken by NHS staff using NHS resources, and research undertaken by industry, the charities, the research councils and universities within the health and social care systems.

35 Ibid, 33 (para 3.12.3).

36 Department of Health (UK), *Governance Arrangements for NHS Research Ethics Committees*, <<http://www.doh.gov.uk/research/gafrec.doc>>, 8 May 2002.

37 Medical Research Council, *Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials*, <<http://www.mrc.ac.uk/pdf-ctg.pdf>>, 8 May 2002.

38 General Medical Council, *Research: The Role and Responsibilities of Doctors*, <http://www.gmc-uk.org/standards/standards_frameset.htm>, 8 May 2002.

39 *National Research Act 1974* (US).

40 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Department of Health and Human Services (US), <<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm#xethica>>, 8 May 2002 (the Belmont Report).

11.37 The centrepiece of regulation of the conduct of medical research in the United States is known as the ‘Common Rule’. The Common Rule forms part of the Code of Federal Regulation and is found in regulations promulgated by the US Department of Health and Human Services (DHHS), the National Institutes of Health (NIH) and the Office for Protection from Research Risks (now the Office for Human Research Protections).⁴¹

11.38 The Common Rule applies to all ‘research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate action to make the policy applicable to such research’.⁴² As of August 2001, 15 federal departments and agencies had become signatories to the Common Rule.⁴³ The Office for Human Research Protections is responsible for ensuring compliance by institutions with the Common Rule.

11.39 The Common Rule applies to only research that is supported in some way by the federal government. Importantly, this includes research funded by the NIH, the federal focal point for medical research in the US. The NIH conducts research not only in its own laboratories but also supports research through the provision of grants, cooperative agreements and contracts. The *National Institutes of Health Grants Policy Statement* requires researchers to comply with the Common Rule,⁴⁴ including the requirement for research to be approved by an Institutional Review Board.

A need for reform?

11.40 The Inquiry recognises that the National Statement, and its predecessor documents, continue to have a crucially important, highly valued and continuing influence on the way in which research involving humans is conducted in Australia. Professor Nick Saunders and Associate Professor Paul Komesaroff stated:

The National Statement has played an important role in regulating research in Australia, in the absence of an explicit legal basis. This Statement has recently been revised and consolidated into a single document. However, it should be recognised that the historical approach adopted by the National Health and Medical Research Council of Australia (NHMRC) of providing a broad statement of principles largely focused on processes and procedures complemented from time to time by additional “supplementary notes” has proved an effective and flexible model for regulating

41 45 CFR Part 46 Subpart A. The regulations are officially entitled the *Federal Policy for the Protection of Human Subjects* (Basic DHHS Policy for Protection of Human Research Subjects).

42 45 CFR Part 46 §46.101.

43 National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants Vol I: Report and Recommendations of the National Bioethics Advisory Commission* (2001), National Bioethics Advisory Commission, Bethesda, 156.

44 National Institutes of Health, *Grants Policy and Guidance*, <<http://grants1.nih.gov/grants/policy/policy.htm>>, 13 May 2002.

research practices. As a result of this historical process, the Statement today commands profound moral authority in the community, independently of the theoretical sanction of the loss of NHMRC funding support.⁴⁵

11.41 In 1996, the *Report of the Review of the Role and Functioning of Institutional Ethics Committees* noted that many institutional ethics committees had been created in institutions which do not receive NHMRC funding and stated that ‘there is a growing ethical culture which requires proof of compliance and commitment to the highest ethical standards in research’.⁴⁶

11.42 Several submissions suggested that legislation to extend the scope or enforcement of the National Statement was not necessary.⁴⁷ For example, the Department of Human Services, Victoria submitted the current system of approval and oversight of human research ‘has served the community well’.⁴⁸ Other submissions questioned the effectiveness of the existing legal status of research ethics review. Privacy NSW observed generally that

[t]he commercial context in which the vast majority of research occurs undermines the traditional justification for the largely self-regulatory framework underpinning research involving humans. With reductions in public funding, even Universities and public hospitals now compete for private industry involvement and funding of their activities.⁴⁹

11.43 Many other submissions also made suggestions for strengthening the mechanisms by which compliance with the National Statement is enforced — to require all researchers and research organisations to comply with the National Statement.⁵⁰

11.44 The Office of the Federal Privacy Commissioner (while accepting that the current structures for the protection of the privacy of personal and health information to be used in medical research in Australia were ‘fundamentally sound’) submitted that current protection of genetic privacy could be strengthened

45 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

46 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

47 Eg Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; D Cavaye, *Submission G110*, 14 March 2002. One HREC member submitted that ‘legislation currently is **not** appropriate **nor** needed for HRECs to maintain the integrity of human research. Privacy and consent of the individual participating in the research is 100% assured’: D Cavaye, *Submission G110*, 14 March 2002.

48 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

49 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

50 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002; Australian Academy of Science, *Submission G097*, 21 January 2002; Queensland University of Technology, *Submission G109*, 14 March 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Caroline Chisholm Centre for Health Ethics, *Submission G061*, 26 December 2001; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

by a legislative requirement for all research bodies that undertake experimentation involving human beings to establish HRECs for their research.⁵¹

At present, only those research bodies which are publicly funded through the NHMRC are required to register their HRECs with the Council. By means of comprehensive registration requirements and supervision by the NHMRC, the accountability of the HRECs process would be greatly improved.⁵²

11.45 Other submissions made similar suggestions. The Australian Academy of Science submitted that all research with human subjects, not only that conducted with NHMRC support or in public hospitals and universities, should be legally required to go before an HREC for approval.⁵³ The Queensland University of Technology also submitted that the National Statement should be given further legislative force.⁵⁴ The Caroline Chisholm Centre for Health Ethics stated that

The relevant NHMRC guidelines are well constructed and offer quite good advice on the ethically appropriate ways to handle genetic information. However, they lack the force or authority that regulation of this area is likely to require. As the misuses and abuses of genetic information could benefit certain parties, such as employers or insurance companies greatly, simply having guidelines on how to manage and store this sensitive and potentially valuable information is inadequate. Regulations with more authority as well as appropriate penalties are required to ensure that genetic information is not misused.⁵⁵

11.46 The NSW Genetics Service Advisory Committee referred to the need to monitor the ethical performance of research that is not dependent on public research funds or carried out through the public health system. The Committee stated that the regulators should have power to review and oversee research undertaken by private organisations and supported where there have been breaches of ethical conduct, including targeted education programs for the researchers through to withdrawal of research funds.⁵⁶

Options for reform

11.47 Failure by researchers or research organisations to comply with the National Statement may result in withdrawal of public research support or funding. However, there are no such requirements for privately supported or funded research to comply.

51 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

52 Ibid.

53 Australian Academy of Science, *Submission G097*, 21 January 2002.

54 Queensland University of Technology, *Submission G109*, 14 March 2002.

55 Caroline Chisholm Centre for Health Ethics, *Submission G061*, 26 December 2001.

56 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

11.48 The Inquiry recognises the importance of private sector investment in Australian human genetic research. As the Australian Academy of Science has observed:

[n]o significant political or academic group argues against the underlying principle of commercial involvement in research, because ending this involvement would require a corresponding injection of several hundred million dollars per annum into biomedical research by the Australian government.⁵⁷

11.49 At present, most privately funded human genetic research in Australia is associated in some way with a university, public hospital or public agency (such as the CSIRO). Similarly, many individual researchers have ongoing employment or professional relationships with public bodies or membership of professional associations that expect, and in some cases require, compliance with the National Statement and other NHMRC guidelines.

11.50 Further, the Inquiry has not been made aware of any significant private sector funded genetic research in Australia that does not comply with the requirements of the National Statement. Indeed, some private sector organisations involved in research have voluntarily adopted the National Statement as an organisational policy⁵⁸ and some private sector organisations, including private hospitals, submit research proposals for ethics review by HRECs registered with AHEC.

11.51 Nevertheless, the Inquiry has concluded that there should be some more formal requirement for private sector research involving humans to comply with the National Statement and, in particular, with requirements for ethical review of genetic research proposals by an HREC constituted and operating in accordance with the National Statement.

11.52 The following discussion examines some of the options for reform. Most of these options, if taken forward, will involve close consideration of federal constitutional legislative powers and other mechanisms for achieving effective national regulation. The Inquiry has not developed detailed proposals in this regard and is interested in further comment on these options.

⁵⁷ Australian Academy of Science, *Submission G097*, 21 January 2002.

⁵⁸ eg Autogen Limited, an Australian biotechnology research and development company has established its own ethical standards for research. These standards require that ethics approval for Autogen research projects will be obtained through 'a recognised Human Ethics Committee in Australia and a Human Ethics Committee in any country from which samples are to be collected' and will comply with ethical principles identified in the National Statement: Autogen Limited, *Ethics Policy*, <<http://www.autogenlimited.com.au/ethics.html>>, 13 May 2002.

Legislating for compliance with the National Statement

11.53 One option for reform would be to enact legislation prohibiting the conduct of human genetic research, other than in compliance with the National Statement. Failure to comply would be a criminal offence punishable by fines or imprisonment.

11.54 As is the case with the other options presented in this chapter, there may be problems in defining human genetic research for this purpose and in establishing the most appropriate target or targets of such a prohibition (for example, individual researchers or research organisations). Further, should such a prohibition apply to all research involving humans, rather than just to human genetic research (however defined)?

11.55 There is an existing precedent for enforcing compliance with the National Statement through legislation. The *Therapeutic Goods Regulations 1990* (Cth) provide that unregistered therapeutic goods may be used in clinical trials only on certain conditions.⁵⁹ These conditions include a requirement that the use is in accordance with the National Statement as published by the NHMRC from time to time.⁶⁰ Non-compliance with the National Statement in effect renders continued use of the therapeutic goods unlawful.⁶¹

11.56 A question may be raised about whether such an ungraduated regulatory response is appropriate for regulating the conduct of human genetic research, as opposed to the use of therapeutic goods in clinical trials.

11.57 The National Statement comprises broad ethical principles and short statements of considerations relevant in specific research contexts. It offers guidance on, rather than prescription of, ethically sound research design and practice.⁶² Whether a research organisation has conducted research in compliance with the National Statement as a whole will generally not be conducive to definitive answer, although it is easier to establish whether an organisation has established and operates an HREC of the prescribed composition.

Licensing or registration of human genetic research

11.58 Another option is to establish a national licensing scheme covering human genetic research in Australia. The essential feature of licensing regimes is the creation of a specific relationship between the regulator and the licence-holder,

59 *Therapeutic Goods Act 1989* (Cth) s 19; *Therapeutic Goods Regulations 1990* (Cth) reg 12AD.

60 *Therapeutic Goods Regulations 1990* (Cth) reg 12AD(c).

61 *Therapeutic Goods Act 1989* (Cth) s 19–22.

62 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 1.

so that the licence-holder's conduct is restrained not only by rules of general application but by the conditions of the licence, and the relationship created by the licence. Rights, duties and causes of action arise out of the relationship itself.

11.59 The principal purpose of setting up a licensing regime is to ensure that minimum standards are maintained within the area of activity, in order to protect public safety, the environment, consumers, or the effective functioning of systems such as the financial markets.⁶³ This contrasts with the 'policing' role of regulators in enforcing laws of general application (such as a simple legislative prohibition on non-complying human genetic research) although policing obviously plays a part in ensuring licence-holders are meeting their legal requirements.

11.60 Administrative penalties used by licensing regimes commonly involve cancellation, suspension or variation of a licence. In addition, there are almost invariably criminal sanctions for undertaking licensed activities without obtaining a licence.⁶⁴

11.61 A licensing regime for the conduct of human genetic research could require an undertaking to comply with the National Statement as a condition of a licence to conduct research. A substantial breach of the National Statement would result in suspension or cancellation of the licence.

Gene Technology Act

11.62 One example of a licensing regime is that established under the *Gene Technology Act 2000* (Cth) (*Gene Technology Act*) in relation to certain dealings with genetically modified organisms (GMOs). The regime came into force on 21 June 2001.

11.63 The regulatory system set up by the Gene Technology Act is managed by the Gene Technology Regulator, a federal statutory office holder who derives power from both Commonwealth and state and territory legislation.⁶⁵ The *Gene Technology Act*:

63 Existing Commonwealth licensing regimes cover a wide range of activity including aged care, aviation, broadcasting and communications, customs, financial services, fisheries, navigation, superannuation and trade practices.

64 The amount of the fine varies considerably between Commonwealth licensing regimes, with a maximum fine of \$2.2 million in broadcasting and telecommunications and as little as \$2,000 and \$10,000 in health insurance and navigation respectively.

65 *Gene Technology Act 2000* (Cth) s 17.

- prohibits persons from dealing with GMOs (including in research, manufacture, production, commercial release and import) unless the dealing is licensed by the Gene Technology Regulator;⁶⁶ and
- creates a centralised, publicly available database of all GMOs approved in Australia (the GMO Register).⁶⁷

11.64 With certain exceptions all dealings with GMOs need to be licensed by the Office of the Gene Technology Regulator, 'based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public'.⁶⁸ Some dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time and the Gene Technology Regulator is satisfied that safety does not depend on oversight by a licence holder.⁶⁹

Research involving embryonic stem cells

11.65 A licensing regime was proposed for research involving embryonic stem cells by the House of Representatives Standing Committee on Legal and Constitutional Affairs in its report on its inquiry into the scientific, ethical and regulatory aspects of human cloning and stem cell research.⁷⁰

11.66 The Standing Committee's report recommended that a national licensing body be established to regulate any research involving embryonic stem cells and that a licence issued by that body should be required to undertake such research.⁷¹ The national licensing body would, among other things:

- grant research licences for stem cell research in accordance with legislative criteria (including the requirement that the research be approved by an HREC);
- develop and issue guidelines concerning various aspects of the conduct of research;

66 Or the dealing is exempt, a Notifiable Low Risk Dealing (that is, contained research work which has been demonstrated to pose minimal risk to workers, the general public or the environment) or on the Register of GMOs.

67 For a summary of the *Gene Technology Act*, see Office of the Gene Technology Regulator, *About OGTR*, Department of Health and Ageing, <<http://www.health.gov.au/ogtr/about/index.htm>>, 7 May 2002.

68 See *Ibid.*

69 See *Ibid.*

70 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Parliament of the Commonwealth of Australia, Canberra.

71 *Ibid.*, rec 6–8.

- ensure transparency and accountability by reporting annually to Parliament outlining all licences granted, the purposes for which they were granted and the outcomes of research;
- conduct inspections;
- monitor compliance with the conditions of the licence; and
- impose sanctions for the breach of licence conditions, including withdrawal or non-renewal of a licence or fines.⁷²

Registration

11.67 Licensing generally involves closer and ongoing supervision of the regulated activity. A more ‘light touch’ regulatory approach could involve a registration scheme. Under such a scheme there would be a legislative requirement to register with a regulatory agency and penalties for the conduct of unregistered human genetic research.

11.68 The provisions of the *Gene Technology Act* and the *Gene Technology Regulations 2001* (Cth) (*Gene Technology Regulations*) concerning ‘notifiable low risk dealings’ may be cited as an example of such a light touch approach.

11.69 The *Gene Technology Regulations* set out categories of dealings with GMOs which are low risk and which may proceed, provided that certain conditions spelt out in the regulations are observed. These conditions include requirements that the specified dealings be undertaken only in contained facilities, overseen by Institutional Biosafety Committees (IBCs) and are notified to the Office of the Gene Technology Regulator.⁷³

11.70 A registration scheme for human genetic research could focus on HRECs. The National Statement currently requires the NHMRC, through AHEC, to audit the activities of HRECs to ensure compliance with the National Statement.⁷⁴ As part of this process, HRECs are registered with AHEC and report annually on their membership and other information relevant to their operation.

11.71 One option for reform would be to enact legislation that requires human genetic research to be approved by an HREC constituted in accordance with the National Statement, and for HRECs to be registered with AHEC. Non-compliance with these requirements would be punishable by fine.

⁷² Ibid, para 12.55, rec 8.

⁷³ *Gene Technology Regulations 2001* (Cth), reg 13.

⁷⁴ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.46.

Designing a regulatory scheme

11.72 There are many issues involved in the design and implementation of an effective regulatory scheme for human genetic research. Some of these issues are discussed briefly below.

11.73 An important threshold issue would be the question of how to define human genetic research for the purposes of the regulatory scheme. As the primary purpose of the scheme would be to give legislative backing to the requirements of the National Statement, it might be suggested that the meaning given in the National Statement should be adopted.⁷⁵

11.74 The definition of human genetic research would be important to the coverage of the regulatory scheme and would have to take into account other regulatory regimes in related areas and, in particular, any new regime regulating human cloning and stem cell research.

11.75 The most appropriate target or targets of regulation would need to be established. Regulation could apply to individual researchers, research organisations or their HRECs, specific human genetic research projects or to specific collections of genetic samples or information (or some or all of these targets). The practical implications of the choice of regulatory target need to be carefully assessed. For example, it may be ineffective to seek to licence or register individual researchers or human genetic research projects due to the number of proposals and individuals concerned. It may be more practical to licence or register research institutes and other organisations or their HRECs.

11.76 Another important issue is to resolve what agency should have responsibility for operating the regulatory scheme. The regulatory responsibility could be given to an existing agency, such as AHEC (or another committee of the NHMRC) or the Office of the Gene Technology Regulator, to take advantage of expertise and systems and to save on costs. Alternatively, the responsibility could be placed with the proposed new Human Genetics Commission of Australia (HGCA).

11.77 Many other issues also arise; including how would such a licensing or registration scheme be funded, what would be the compliance costs for research organisations and how might the scheme affect the international competitiveness of Australian human genetic research.

⁷⁵ Human genetic research is defined in the National Statement as a process which enhances 'understanding of how genes and environmental factors interact to influence the health of individuals and populations and in doing so, generates knowledge with the potential to improve individual and community health': *Ibid*, Ch 16.

Industry self-regulation

11.78 As discussed above, the National Statement already has an important influence on the way in which research involving humans is conducted in Australia. There is no reason to suggest that its principles are not widely accepted by individuals working in the private sector. Therefore, it may not be necessary to legislate in order to further encourage compliance with the National Statement.

11.79 An alternative to legislation might involve a self-regulatory arrangement, under which organisations involved in the conduct of human genetic research might agree to comply with the National Statement or with an industry code of research ethics that incorporates similar principles of ethical review of research.

11.80 Self-regulatory arrangements sometimes provide for the establishment of industry-specific bodies with varying regulatory functions and powers. These bodies may deal with matters such as developing and monitoring industry standards and codes of practice and setting standards of accreditation for members.⁷⁶

11.81 The Inquiry understands that two established industry associations, AusBiotech Limited (formerly the Australian Biotechnology Association)⁷⁷ and the Australian Pharmaceutical Manufacturers Association Limited⁷⁸ represent virtually all significant private sector players that fund or support human genetic research in Australia. The activities of these bodies might be the appropriate starting point for the development of a self-regulatory scheme.

11.82 Questions may reasonably be raised about whether the ethical conduct of human genetic research is an appropriate area for self-regulation. For example, the federal Office of Regulation Review states that self-regulation should be considered where:

- there is no strong public interest concern, in particular, no major public health or safety concern;

⁷⁶ Examples are the various industry ombudsman offices, professional and trade associations, and industry councils and associations. There is a large number of such schemes: See eg the federal government's self-regulation website has a directory of 45 national self-regulatory schemes: Department of Treasury, *Directory of National Self-Regulatory Schemes*, <www.selfregulation.gov.au>, 20 June 2001.

⁷⁷ AusBiotech describes itself as 'the national body of companies and individuals dedicated to the development and prosperity of the Australian biotechnology industry' and the 'peak body for the Australian Biotechnology industry': AusBiotech Limited, *About AusBiotech*, <<http://www.ausbiotech.org/>>, 15 May 2002.

⁷⁸ The Australian Pharmaceutical Manufacturers Association Limited describes itself as 'the organisation that represents the prescription medicines industry in Australia'. Its member companies engage in 'the discovery, research, development, manufacture, marketing and export of prescription pharmaceuticals, and the ongoing improvement of medical and scientific knowledge about its products': Australian Pharmaceutical Manufacturers Association Limited, *About APMA*, <http://www.apma.com.au/headers/about_apma.html>, 15 May 2002.

- the problem is a low risk event and the consequences of self-regulation failing to resolve a specific problem are small; and
- the market is able to correct any problems and there is an incentive for the industry to comply with self-regulatory arrangements.⁷⁹

11.83 It is not clear that these criteria apply in the context of human genetic research.

Conclusion

11.84 The Inquiry has not yet had the opportunity to fully discuss detailed regulatory options in consultation with interested groups and individuals (and particularly with those in the Australian medical research community) and has not reached any firm view.

11.85 Submissions and consultations have suggested broad agreement that the conduct of all Australian human genetic research, whether funded by the private or public sector, should be subject to ethics approval by ethics committees (including members independent of the institution or organisation involved) and should observe widely accepted ethical principles.

11.86 The National Statement is developed by AHEC, whose membership is required to include experts in philosophy, the ethics of medical research, public health and social science research, clinical medical practice and nursing, disability, law, religion and health consumer issues.⁸⁰ In developing ethics guidelines, AHEC has statutory obligations to consult the community.⁸¹

11.87 This process provides the National Statement with considerable authority. The principles of ethical conduct and procedures for the scrutiny of research proposals set out in the National Statement constitute appropriate and widely accepted standards of research practice.

11.88 The Inquiry has concluded that, at least in relation to the conduct of human genetic research, legislation should explicitly require compliance with the National Statement. As noted above, there is an existing precedent for enforcing

79 Office of Regulation Review, *Guide to Regulation — Second Edition*, Productivity Commission, <www.pc.gov.au/ort/reguide2>, 16 October 2001, D4; Taskforce on Industry Self-Regulation, *Industry Self-Regulation in Consumer Markets: Report Prepared by the Taskforce on Industry Self-Regulation* (2000), Department of the Treasury, Canberra, 41.

80 *National Health and Medical Research Council Act 1992* (Cth) s 36.

81 *Ibid* ss 8, 13-15. AHEC consults extensively with individuals, community organisations, health professionals and governments, and undertakes formal public consultation when developing guidelines. AHEC monitors and advises on international developments in health ethics issues through liaison with relevant international organisations and individuals, including the World Health Organization.

compliance with the National Statement through legislation in the context of the use of unregistered therapeutic goods.⁸²

11.89 The Inquiry is less convinced that human genetic research should be subject to any new licensing or registration regime — leaving aside existing or augmented requirements for HRECs to be registered with AHEC. The exception to this position involves the establishment and operation of standing human genetic research databases. The regulation of research databases is discussed in more detail in Chapter 15.

11.90 One perceived advantage of a licensing or registration scheme for human genetic research would be the development, for the first time, of a comprehensive database of all human genetic research being conducted in Australia. Depending on the nature of regulation, this database might include information about organisations conducting human genetic research, their HRECs or information about specific human genetic research projects.

11.91 However, there are other ways in which such a database might be developed. Centralised collection of data on human research taking place in Australia could be achieved by the NHMRC placing an obligation on HRECs to provide such data to it, without recourse to new legislation.⁸³ A proposal to establish a centralised clinical trials database is under discussion within the NHMRC.

11.92 In addition, an AHEC working party is developing a ‘national common application form’ for research ethics approval applications based on an existing Victorian model. This involves an application form that will be used by all researchers for all forms of research involving humans. Ultimately such a form could be in electronic form and Internet-based. This could provide a mechanism for HRECs to provide standardised information to AHEC for a central database of research proposals and approved projects.

11.93 A second working party is examining proposals to strengthen the current compliance mechanisms and is exploring models of ‘accreditation’ of HRECs linked to a quality improvement framework. This work is at an early stage and stakeholders are yet to be involved.

11.94 More generally, there are also other ways in which to improve the transparency and accountability of the existing system without instituting a formal

⁸² *Therapeutic Goods Act 1989* (Cth) s 19; *Therapeutic Goods Regulations 1990* (Cth) reg 12AD.

⁸³ The National Statement provides that an institution or organisation and its HREC shall provide information from its records to the NHMRC on request: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.47.

licensing scheme. Some of these approaches are examined in Chapter 13 and Chapter 14.

11.95 If the proposal set out below is adopted, these and other improvements to the system for ethical review of human genetic research would apply to public and private sector research alike. AHEC would remain the principal ‘regulator’ of human genetic research. Further consideration needs to be given, among other things, to the following issues.

- The scope of the new statutory provisions requiring compliance with the National Statement — that is, how ‘human genetic research’ is to be defined? For example, should this, or other similar definition, refer only to genetic research using potentially identifiable human tissue or other genetic material?
- Where should the new statutory provisions be located? Does there need to be stand alone legislation or can the provisions be located in the NHMRC Act?
- What are the relevant constitutional limits on federal legislative power in this context? How can effective national application of these provisions be achieved?

11.96 In relation to this last question, the most obvious head of federal legislative power appears to be the corporations power.⁸⁴ However, this may be insufficient to regulate effectively all human genetic research.

11.97 In a related context, it may be relevant to note that while the corporations power underpins the *Therapeutic Goods Act*,⁸⁵ it was also found necessary to refer to the interstate or overseas trade or commerce power⁸⁶ and to laws of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits⁸⁷ — neither of which are obviously relevant to human genetic research.

11.98 As has been the case with the *Gene Technology Act* and with proposals relating to the regulation of human cloning and stem cell research, it seems likely that cooperation between the Commonwealth, state and territory governments will be necessary to achieve effective national regulation.

Proposal 11–1. The *National Health and Medical Research Council Act 1992* (Cth) should be amended to prohibit the conduct of any human

⁸⁴ Constitution s 51(xx).

⁸⁵ *Therapeutic Goods Act 1989* (Cth) s 6.

⁸⁶ Constitution s 51(i).

⁸⁷ Constitution s 51(xxiiiA).

genetic research, other than in compliance with the NHMRC's National Statement on Ethical Conduct in Research Involving Humans (the National Statement).

Question 11–1. How should 'human genetic research', or a similar term, be defined for the purposes of the NHMRC Act?

Question 11–2. What sanctions should apply to non-compliance with the National Statement and to whom should the sanctions be directed?

12. Human Genetic Research and Consent

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Introduction

12.1 The concept of consent is fundamental to the legal and ethical regulation of medical and other human research and to the protection of privacy. This chapter examines a range of issues related to consent in research using genetic samples or information.

12.2 The National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement)¹ generally requires consent to the use of human tissue samples, genetic material and genetic information in medical research.

12.3 In addition, the federal *Privacy Act 1988* (Cth) (*Privacy Act*) and other privacy legislation impose certain legal requirements to obtain consent for the collection, use or disclosure of personal information, including genetic

¹ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

information. These requirements may be waived where collection of the information is carried out in accordance with guidelines under s 95 or s 95A of the *Privacy Act*.

12.4 This chapter begins by briefly summarising the relevant provisions of the National Statement and the *Privacy Act*. The chapter then examines a range of issues concerning consent to the use of genetic samples and information in human genetic research.

12.5 A central concern is the extent to which privacy protection may be undermined by the current provisions under which Human Research Ethics Committees (HRECs) may waive consent requirements in granting ethical approval for research proposals. A related issue concerns the extent to which researchers are able to obtain consent from prospective research participants for the use of their genetic samples or information for as yet unspecified future research.

The National Statement and consent

12.6 The ethical principles and associated guidelines for research involving humans contained in the National Statement treat consent as a basic principle of ethical conduct and contain detailed provisions on how consent is to be obtained and in what circumstances research without consent may be approved by an HREC.

12.7 The National Statement states that the consent of participants in research must be obtained, except in specified circumstances, approved by an HREC.² Consent must be based on information about the purpose, methods, demands, risks, discomforts and outcomes of the research and be voluntary and not impaired by any coercion, inducement or influence. It must be given by the participant, where competent, or a person with lawful authority for one lacking competence.³ Research must be designed so as to clearly establish each person's consent and understanding that a person may refuse to participate without giving reasons.⁴ Consent may be withdrawn and advice given as to the consequences of withdrawal.⁵

12.8 The circumstances in which consent may be waived in research using human tissue samples, genetic material or genetic information are discussed in more detail below.

2 These circumstances include certain specified research: involving persons highly dependent on medical care (Ibid, para 6.9); using information for epidemiological research (para 14.4); using human tissue samples (para 15.8); or using genetic material or genetic information (para 16.13).

3 Ibid, para 1.7.

4 Ibid, para 1.8–1.9.

5 Ibid, para 1.12.

Consent and epidemiological research

12.9 The National Statement provides that the consent of participants should generally be obtained for the use of identified or potentially identifiable data for epidemiological research.⁶

12.10 An HREC may approve access to identified or potentially identifiable data without consent where the HREC is satisfied that obtaining consent is likely to cause unnecessary anxiety to those whose consent would be sought or would prejudice the scientific value of the research and there will be no disadvantage to the participants. Such research may only be approved where the HREC determines that the public interest in the research outweighs to a substantial degree the public interest in privacy.⁷

Consent and the use of human tissue samples

12.11 The National Statement provides that consent should generally be required for collection of human tissue for research purposes.⁸ Consent should be voluntary, specific to the purpose for which the tissue is to be used and follow the provision of full information about the research, including advice as to whether any remaining tissue samples are to be stored, following completion of the research.⁹

12.12 Where it is proposed that human tissue samples previously collected and stored with consent for research be used for a different research purpose, separate consent for the different research should be obtained.¹⁰

12.13 Consent should also be obtained for the use of human tissue samples that have been collected and stored after clinical procedures, held in tissue banks or removed but not required for clinical procedures, in any research which may lead to harm or injustice or be of benefit to the donor.¹¹

12.14 An HREC may waive the requirement for consent to the use of human tissue samples in research. In doing so an HREC may take into account certain matters:

- the nature of any existing consent relating to the collection and storage of the sample;

6 Ibid 14.3. Epidemiological research is concerned with the description of health and welfare in populations through the collection of data related to health and the frequency, distribution and determinants of disease in populations, with the goal of improving health.

7 Ibid, para 14.4.

8 Ibid, para 15.4.

9 Ibid, para 15.5.

10 Ibid, para 15.6.

11 Ibid, para 15.7.

- the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- relevant statutory provisions.¹²

Consent and the use of genetic material or genetic information

12.15 The National Statement provides that consent should generally be required for the use of stored genetic material or genetic information.¹³ Those from whom consent is sought must be informed about a range of prescribed matters, including whether it is intended to store their genetic material and information for as yet unspecified future research;¹⁴ whether their genetic material is to be disposed of on completion of research;¹⁵ and that participants may withdraw from the research and either request disposal of their genetic material and information or that it be retained in de-identified form.¹⁶

12.16 When human genetic research reveals information important to the future health of an identified or potentially identifiable participant or his or her offspring, the research protocol must provide for the same consent, counselling and confidentiality protection as would apply in a clinical setting.¹⁷ If participants are asked to consent to the use of their genetic material or information in future research, information and counselling about possible consequences should be provided.¹⁸ The National Statement notes that in general, genetic material and information will be used for future research in de-identified form and feedback will not be possible.¹⁹

12 Ibid, para 15.8.

13 Ibid, para 16.12.

14 Ibid, para 16.10(j). Conducted in accordance with para 16.12 and 16.16.

15 Ibid, para 16.10(k).

16 Ibid, para 16.10(l).

17 Ibid, para 16.15.

18 Ibid, para 16.16.

19 Ibid, para 16.16.

12.17 An HREC may waive the requirement for consent to participation in human genetic research. In reaching that decision, the HREC may consider factors, in relation to genetic material and genetic information, that mirror those applicable to waiving consent to the use of human tissue samples.²⁰

12.18 In addition, the National Statement anticipates that institutions or organisations may wish to conduct research on genetic material and information collected for non-research purposes. It states that such institutions or organisation should develop and disseminate a general policy that informs patients that such material and information may be used for future research following HREC approval and giving patients an opportunity to opt out of participation in such research.²¹

The Privacy Act and consent

12.19 Under the NPP 10.3 of the *Privacy Act*, health information may be collected without consent for research purposes if obtaining consent is impracticable, de-identified information would not be suitable, and the collection is in accordance with guidelines issued by the NHMRC and approved by the Privacy Commissioner under s 95A of the *Privacy Act* (the s 95A Guidelines).²²

12.20 The Privacy Commissioner may approve s 95 and s 95A Guidelines only where he or she is satisfied that the ‘public interest’ in research or in the use and disclosure of health information in accordance with the guidelines ‘substantially outweighs the public interest’ in maintaining adherence to the IPPs or the NPPs.²³

12.21 Under NPP 2.1(d), health information may be used or disclosed without consent for research purposes if obtaining consent is impracticable, the use or disclosure is conducted in accordance with the guidelines issued by the NHMRC and approved by the Privacy Commissioner under s 95A of the *Privacy Act* and, in the case of disclosure, it is reasonably believed that the recipient will not disclose the information.²⁴

12.22 Similarly, when a proposal for medical research would involve a breach of an IPP, consent requirements may be waived in accordance with guidelines issued under s 95 of the *Privacy Act* (the s 95 Guidelines).

20 Ibid, para 16.13.

21 Ibid 16.14.

22 *Privacy Act 1988* (Cth) NPP 10.3(a)–(d)(iii). Information may also be collected as required by law or in accordance with ‘rules established by competent health or medical bodies that deal with obligations of professional confidentiality’: NPP 10.3(d)(i)–(ii).

23 Ibid ss 95(2), 95A(3).

24 Ibid NPP 2.1(d).

12.23 The s 95 Guidelines apply to medical research that involves access to personal information held by Commonwealth agencies where it is proposed to use personal information without the consent of the person to whom the information relates. The s 95A Guidelines apply to the collection, use or disclosure of health information held by organisations in the private sector.

12.24 The s 95 and s 95A Guidelines provide that if the HREC considers that the public interest in the research does not outweigh to a substantial degree the public interest in privacy, it should not approve the research.²⁵

12.25 Each set of guidelines provides a similar framework for weighing the public interest in proposed research against the public interest in the protection of privacy.²⁶ HRECs are directed to consider certain specified matters. These include:

- the degree to which the research may contribute to the identification, prevention or treatment of illness or disease, scientific understanding relating to health, the protection of the health of individuals and communities or the improved delivery of health services or scientific understanding or knowledge;
- any likely benefits to individual participants, or to the class of person to which they belong, arising from the research being undertaken in the manner proposed;
- whether the research design can be satisfied without risking infringement of the IPPs or NPPs and any scientific defects of the medical research not being conducted in the manner proposed;
- the financial costs of not proceeding with the research;
- the public importance of the medical research;
- the extent to which the data being sought is ordinarily available to the public;
- whether the risk of harm to individuals is minimal;

25 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra 3.2(b); National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, D.4.

26 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra 3.3; National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, D.5.

- the standards of conduct observed in medical research, including the study design and credentials of researchers, and the procedures applicable to contact with participants to ensure they are treated with integrity;
- whether access to personal information is restricted to appropriate researchers and the risk that a person or group could be identified in published results; and
- the procedures to be followed at the end of research to ensure that data containing personal information is secure.²⁷

12.26 Non-compliance with the guidelines may lead to researchers being named in the NHMRC's annual report or in a report to a Commonwealth agency or the federal Privacy Commissioner.²⁸ Where the conduct of an organisation or agency is in breach of the *Privacy Act*, affected individuals may complain to, and have their complaints investigated by an adjudicator under an approved privacy code or by the federal Privacy Commissioner.²⁹

12.27 The s 95 and s 95A Guidelines do not apply to the collection, use and disclosure of health or other personal information in research by individuals or organisations that are not covered by the federal *Privacy Act*. For example, the *Privacy Act* does not apply to federal or state public sector entities including, for example, public teaching hospitals and associated research bodies, where such bodies are established for a public purpose under a law of a State.³⁰ However, these organisations may be covered by state legislation.³¹

Waiver of consent

Operation of the National Statement

12.28 The National Statement provides that HRECs may 'sometimes' waive consent after taking into account a number of factors, such as the extent to which it

27 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 3.3(a)–(h). The s 95A Guidelines also require the HREC to consider the degree to which the proposed collection, use or disclosure of health information is necessary to the functions or activities of the organisation and the degree to which the research is relevant to public health or public safety: National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, D.5(a); D.5(b).

28 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 4.3.

29 See *Privacy Act 1988* (Cth) Part V.

30 Ibid ss 6C(1), 6C(3)(c).

31 Eg see *Health Records Act 2001* (Vic) Health Privacy Principle 1.1(e)(iii); 2.2(g)(iii). These provisions allow for the collection, use and disclosure of health information for research without the consent of the individuals concerned in accordance with guidelines issued or approved by the Health Services Commissioner under s 22.

is 'impossible or difficult or intrusive' to obtain consent.³² The Issues Paper asked whether these waiver principles are operating satisfactorily in practice or whether other safeguards are required.

12.29 In their submission Professor Nick Saunders and Associate Professor Paul Komesaroff noted that the term 'waiver of consent' might not accurately describe the process by which an HREC may approve research under the National Statement:

[R]ather than dispensing with the consent process, it may be more accurate to consider the ethics committee to be assuming responsibility for providing consent on behalf of certain individuals or classes of individual.³³

12.30 Some submissions criticised the current operation of the waiver of consent principles in the National Statement. The Centre for Law and Genetics submitted that:

These provisions may require rewriting to emphasise that, where commercial considerations are involved, or where the sample is identified or potentially identifiable (which is usually the case), these principles should not be used to avoid the primary requirement for participant consent. The current high levels of public support for medical research may be damaged irrevocably by misuse of these provisions.³⁴

12.31 The Centre for Law and Genetics advised that it was aware of research project applications in Victoria, New South Wales and Queensland involving large collections of samples where application has been made to use the waiver of consent provisions. They stated that the original intent of these provisions were that such applications should be 'exceptional'.³⁵

12.32 Privacy NSW also expressed concerns about the waiver provisions, observing that the National Statement states simply that an HREC *may* take into account the listed matters.

This is not a mandatory requirement and would be difficult to enforce, nor are the listed factors sufficient to ensure that consent is protected in all but strictly defined and exceptional circumstances.³⁶

32 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.8; 16.13.

33 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

34 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

35 Ibid.

36 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

12.33 The submission emphasised that explicitly defined and enforceable ethical standards should govern the circumstances in which consent may be waived in cases of research involving genetic information and that consent should only be waived in very limited, closely defined, circumstances.³⁷

12.34 Other submissions, from those involved in the conduct or funding of medical research, considered that the existing consent requirements in the National Statement were adequate and appropriate.

12.35 The Victorian Department of Human Services Genetics Advisory Committee (PMCI) stated that the waiver of consent provisions are operating in a satisfactory manner.³⁸ Jeremy Kenner, Ethics Coordinator at the Peter MacCallum Cancer Institute stated that the current guidelines 'strike the necessary balance between the interests of the research community, research participants and the public exceptionally well'.³⁹ Mr Kenner referred to lack of consensus about appropriate research consent requirements and stated that:

As a consequence, in the research context, leaving to individual HRECs, who are best situated to protect the interests of the research subjects for whom they bear responsibility, the task of evaluating the necessary components of informed consent in a given case and under what circumstances consent should be obtained and under which the requirement should be waived is the wisest path.⁴⁰

12.36 The NHMRC Research Committee made a similar point. The Committee noted that HRECs are intended to function as an 'autonomous body which is particularly responsive to the environment and community group with which it is associated'. Therefore:

Reducing or changing the autonomy of the HRECs by selecting out specific issues over which that body no longer has the final say is acceptable but only if the reason is well justified.⁴¹

Privacy Act research guidelines

12.37 The Issues Paper asked whether the current guidelines on privacy in the National Statement and the s 95 and s 95A Guidelines were adequate for the purpose of protecting the privacy of genetic information.⁴²

37 Ibid.

38 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

39 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

40 Ibid.

41 National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

42 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 6–3.

12.38 Privacy NSW submitted that the existing framework does not adequately address the specific privacy issues in relation to the use of genetic information for research.

The Guidelines only operate where consent is not sought or obtained. They only apply to the collection and disclosure of identifiable personal information. Given the difficulty in truly deidentifying genetic samples, it would generally be appropriate to treat 'de-identified' genetic information in accordance with the principles contained in the Guidelines and the National Statement.⁴³

12.39 Privacy NSW was critical of the 'public interest' test under which the s 95 and s 95A Guidelines are approved by the Privacy Commissioner and under which HRECs determine whether to approve collection, use or disclosure of health information without consent. As discussed above, the test in each case refers to whether the public interest in research 'substantially outweighs' the public interest in privacy.⁴⁴

It is of concern that this effectively utilitarian test does not address the substantial ethical issues ... in relation to obtaining consent in relation to genetic information. The permissive scope of the public interest test, and its application by HRECs under conditions of limited oversight, also conflicts with the need for consistent and transparent principles that are applied regardless of where information is collected, used and disclosed.

Waiver of consent and tissues obtained for clinical purposes

12.40 Waiver of consent issues often arise where researchers propose to access and use material collected for therapeutic or diagnostic purposes, such as pathology samples. The individuals from whom such samples have been taken have not necessarily consented to the use of these samples in any research at all, let alone any broad research purpose.

12.41 It may be argued there should be a stronger presumption that consent is required for any use of clinical tissue samples in research. It is easier to argue that consent should be waived for new research on tissue originally collected for research purposes, than for research on tissue originally collected for other purposes. In privacy law terms, there can be no doubt that research is an unrelated secondary purpose — rather than a purpose that is related to the primary purpose⁴⁵

⁴³ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

⁴⁴ *Privacy Act 1988* (Cth) ss 95(2), 95A(3); National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, 3.2(b); National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, D.4.

⁴⁵ Research may be a related purpose where it is connected with the clinical care of the patient — '[t]here is no dividing line between clinical care and research and the clinician/scientist has a duty to his/her patient to conduct every possible test to find the cause and best treatment for a disease': Australian Academy of Science, *Submission G097*, 21 January 2002.

and arguably might be within the reasonable expectations of the individual concerned.⁴⁶ On the other hand, requirements to seek consent to the use of archival tissue will, in practice, often be difficult to comply with because, for example, it is no longer possible to contact the individuals to whom the samples relate.

12.42 Some organisations may seek to avoid consent requirements by claiming that some uses of clinical tissues are for the purposes of quality assurance, rather than research. The Office of the Federal Privacy Commissioner's *Guidelines on Privacy in the Private Health Sector* state that an organisation's quality assurance or clinical audit activities may constitute a directly related secondary purpose, for which consent may not be required.⁴⁷ In other circumstances, consent may be required unless waived in accordance with the s 95A Guidelines.⁴⁸ An AHEC working party is currently drafting advice for HRECs on how they should approach the ethical and privacy dimensions of quality assurance activities.

12.43 Several submissions focussed on concerns about the use of clinical tissues. One submission, from a woman whose family is affected by Huntington's Disease stated:

The collection and use of human tissue samples certainly should be regulated. Tissue samples could be used for research, but the samples should be de-identified first. People who have tests done for therapeutic reasons may not be aware that they have 'interesting' DNA. ... When these tissue samples are used for genetic research, then that is when the researchers have crossed the 'consent' line.⁴⁹

12.44 The Androgen Insensitivity Syndrome Support Group (AIS Support Group) submitted that much of the controversy surrounding the use of human tissue samples relates to what the AIS Support Group termed 'grey samples' — samples initially obtained for therapeutic or diagnostic purposes. The AIS Support Group accepted that obtaining express consent to access such human tissue samples for research would be 'unworkable' but stated that:

There is still a need, however, to ensure that adequate consent is provided prior to obtaining samples in the first instance. As a minimum standard, any person that provides a sample for any specific purpose or purposes, should have explained the potential for the sample to be later used for research before consent is obtained. We believe that it is ethically indefensible, especially in the contemporary ethical

46 That is in terms of *Privacy Act 1988* (Cth) NPP 2.1. In this context, Professor Loane Skene has suggested that more research is needed on community attitudes to the use of genetic information without specific consent: L. Skene, 'The Genetics Debate: Why Doctors Must be Heard' (Paper presented at 2001 UMMS Lecture, 15 November 2001). The article refers to the unpublished results of a survey conducted by Susan Patterson and Lynn Gillam at ethics committee seminars in which 29% of respondents (n=177) stated that they wanted to be contacted for consent to the use of their stored tissue in research, 40% if the research was on a disease that affected them and 52% if there was a possibility of commercialisation.

47 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 14–15.

48 Ibid, 4.

49 *Confidential Submission G051CON*, 14 January 2002.

environment, to obtain samples without a person having explained to them at least in broad terms all purposes for which that information may be used.⁵⁰

12.45 In this context, it may be observed that the vast majority of stored clinical samples are never used for research but are retained, in accordance with industry standards and guidelines, for quality assurance, medico-legal and other reasons.⁵¹

12.46 Privacy NSW raised the specific concern that the National Statement 'effectively dispenses with the need for fully informed consent' where a person's genetic information is not initially collected for research purposes but is later used for research.⁵²

12.47 The National Statement anticipates that institutions or organisations may wish to conduct research on genetic material and information collected for non-research purposes.⁵³ However, consent is required unless waived in accordance with the principles contained in the Statement.

12.48 Individuals and organisations (including support groups for people with genetic disorders) involved with medical research emphasised the need to use tissues collected for therapeutic or diagnostic purposes. The PMCI noted that while consent for the use of all samples in their tissue bank is obtained at collection:

there are circumstances where we seek to access archival samples collected at other sites for diagnostic purposes. We strongly support the current model and would attest that the waiver principles currently in effect operate satisfactorily.⁵⁴

12.49 The PMCI stated that archival tissue collected for diagnostic purposes is often of very substantial research value and that the PMCI ethics committee has allowed researchers to access such material where re-consent is impractical,⁵⁵ for example where many of the individuals have died. The PMCI submitted that:

It is hard to overstate the importance of controlled access to archival material. Although the movement to prospectively collected consented material will ultimately result in an increase in the number of samples available for research, this will take time. ... the increasing sophistication of (molecular) sub-typing of cancer requires large sample sets to achieve statistical power. Hence, there will continue to be a need to supplement tissue bank sets with archival material for the foreseeable future. In addition, there are circumstances where it is essential to review, for clinical and research purposes, the pathology on samples collected for diagnosis. For example, in

50 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

51 See Ch 16.

52 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

53 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.14.

54 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

55 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

many large molecular-epidemiology studies, confirmation of diagnosis is critical for substantiating apparent familial histories of specific cancers.⁵⁶

12.50 The Association of Australian Medical Research Institutes (AAMRI) and the Human Genetics Society of Australasia (HGSA) submitted that research should be allowed to continue on any historical collections of tissue samples, provided that the samples are de-identified, that the samples were collected in the course of diagnosis or treatment of diseases, and that approval from an HREC is obtained.⁵⁷ In this context, AAMRI noted that

there are many sample collections of small sections of tissue, cells or DNA from affected humans, many of whom have died of serious diseases. These have been collected over many years, in some cases for over 100 years. The donors were aware that these samples were collected and would be used in research to prevent disease in future, and welcomed this in a fitting spirit of altruism at a time before detailed forms were filled in to meet any possible contingency.⁵⁸

12.51 AAMRI submitted that it would be disastrous for research and ‘disrespectful’ to the donors to prevent research on such collections of samples or to insist on consent from relatives.⁵⁹ The HGSA summarised the options for dealing with consent to the use in research of tissue samples collected primarily for clinical purposes:

- Allow the collection and storage of clinical samples for research without consent and require approval by an HREC if the sample is to be used subsequently for research. The HREC will require de-identification in nearly all cases to protect the privacy of the individuals whose genetic material is to be used.
- Require general consent for research use to be obtained at the time the tissue sample is obtained and require approval by an HREC if the sample is to be used subsequently for research. The HREC will require de-identification in nearly all cases.
- Require specific consent to be obtained from the individual each time a tissue sample is to be used for a research study, as well as approval of the research by an HREC.⁶⁰

56 Ibid.

57 Association of Australian Medical Research Institutes, *Submission G007*, 27 April 2001; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

58 Association of Australian Medical Research Institutes, *Submission G007*, 27 April 2001.

59 Ibid.

60 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

12.52 The HGSA favoured the first option ‘as the benefits for research are considerable and the likelihood of harm to individuals is very small’ and because obtaining informed consent is impractical every time a tissue sample is collected in routine hospital work.⁶¹ The HGSA also noted, where possible, consent should later be sought from the patient.

Wherever possible, it is already the clinical practice of geneticists to seek consent to obtain access to samples for clinical management. For example, DNA extracted from a stored sample on a relative may enable definitive testing of other family members who are specifically seeking the information. Ideally the same should apply in the research field and wherever possible, consent should be sought from a patient to use their identified pathological specimen for research purposes. The patient will have the opportunity to discuss the research and make an informed choice.⁶²

12.53 The PMCI noted that seeking retrospective consent for individual research projects ‘becomes progressively more impractical as time passes and may, in any case, be distressing to the donors or to their surviving relatives’⁶³ and submitted that:

Research is developing at such a rapid rate that it is simply not possible to anticipate in any detail the projects that will in the future require the use of archival tissues. The rights of donors can be protected by restricting all access to archival tissue to specific projects that have been approved by the Human Research Ethics Committees of (a) the Institution where the archival tissue/information is stored and (b) the Institution where the work is to be carried out.⁶⁴

De-identification and consent

12.54 As discussed in Chapter 13, the National Statement makes distinctions between identified, potentially identifiable and de-identified personal information or material.⁶⁵ The concept of de-identification is relevant in several ways to issues of consent to participation in research — and to the privacy and ethical implications of consent requirements.⁶⁶

12.55 The National Statement provides that when consent is being sought from individuals for the collection of genetic material or information, they should be informed whether their genetic material and information will be used in an identified, potentially identifiable or de-identified form.⁶⁷

61 Ibid.

62 Ibid.

63 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

64 Ibid.

65 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9.

66 Issues concerning the de-identification of genetic samples and the coverage of the *Privacy Act 1988* (Cth) are discussed in Ch 7.

67 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.10(b).

12.56 Coded data is not ‘de-identified’ for the purposes of the National Statement (because coding, by its very nature, is reversible).⁶⁸ Unlike the *Privacy Act*, the provisions of the National Statement continue to apply to de-identified material and information. However, where information is completely de-identified it may be impossible to seek consent to its further use from individuals.⁶⁹

12.57 The extent to which coded data can be considered to be de-identified is not entirely clear under either the *Privacy Act* or the National Statement. For example, in the context of human genetic research where an independent person holds the code and it is not possible for the researchers themselves to ascertain the identity of the individual concerned (without the assistance of the independent person), is information de-identified so that it is not governed by the *Privacy Act*?

12.58 The Victorian Department of Human Services Genetics Advisory Committee considered that specific consent should not be necessary for ‘de-identified research’.⁷⁰ Other submissions also stated that consent to the use of clinical samples in research should not be required where the samples are de-identified.⁷¹

Reform of the waiver of consent provisions

12.59 Some submissions have argued for significant reform of the waiver of consent provisions of the National Statement, *Privacy Act* and s 95 and s 95A Guidelines. For example, Privacy NSW recommended that the Inquiry consider

a more rigorous form of ethics approval applicable to processing of genetic information which emphasises the importance of fully informed consent and goes beyond the threshold issues of collection and/or disclosure.⁷²

12.60 The Centre for Law and Genetics submitted there should be clarification of the circumstances in which genetic samples and information can be collected for research purposes without the consent of the donor, including clarification of the circumstances in which obtaining consent would be impracticable and where de-identified information would not be suitable.⁷³ They concluded that

68 Although one of the factors that may be taken into consideration by an HREC is determining whether consent should be waived is the ‘extent to which it is possible to de-identify the sample’ — suggesting that de-identification need not be complete anonymisation: Ibid, para 15.8; 16.13.

69 However, consent may still need to be sought from collectivities where research involves a collectivity. See Ibid, Ch 8.

70 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

71 Association of Australian Medical Research Institutes, *Submission G007*, 27 April 2001; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G051CON*, 14 January 2002.

72 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

73 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

[b]ecause consent is such a fundamental requirement in the conduct of research involving genetic information, permission to waive the consent requirements should not be granted lightly.⁷⁴

12.61 Other submissions firmly supported the current system. For example the Department of Human Services Victoria Genetics Advisory Committee stated that

The NH&MRC's National Statement already contains specific and we believe adequate provisions dealing with the use of human tissue samples in research. We believe that the current system of approval and oversight by Human Research Ethics Committees has served the community well, and should not be replaced by a more restrictive system.⁷⁵

HREC reporting

12.62 HRECs report to AHEC on various matters related to their membership and procedures.⁷⁶ These reporting obligations, and proposals for their augmentation, are discussed more generally in Chapter 14.

12.63 There is no requirement for HRECs to report on waiver of consent under the National Statement itself. HRECs are specifically required to report annually to AHEC on decisions made under the s 95 and s 95A Guidelines.⁷⁷

12.64 However, as discussed above, these guidelines have limited operation and apply only to Commonwealth agencies and private sector organisations respectively. Much human genetic research in Australia is conducted by universities, teaching hospitals and publicly funded research institutes. Further, the extent of the existing reporting requirements under the s 95 and s 95A Guidelines have been criticised. Privacy NSW stated that

it is not clear that the reporting and auditing processes in any of these instruments are sufficiently transparent and accountable to effectively protect people's genetic information privacy. Accordingly there is a real risk that Sections 95 and 95A will facilitate rather than restrict the conduct of research involving human genetic information other than in accordance with strict ethical principles and practices.⁷⁸

74 Ibid.

75 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

76 See Australian Health Ethics Committee, *AHEC HREC Annual Report Form*, <<http://www.nhmrc.gov.au/issues/pdfcover/annrpt.htm>>, 2 May 2002.

77 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.46–2.48; National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 3.4; 4.1–4.3; National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, para D.6, E.1–E.3.

78 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

12.65 The general requirement for obtaining consent in research is fundamental to the protection of interests in privacy and ethical treatment of individual's genetic samples and information.

12.66 Given this central importance, the Inquiry considers that the transparency and accountability of the present system would be better served by requiring HRECs to report specifically on research proposals for which waiver of consent has been granted. This would enable AHEC to better monitor the operation of these provisions of the National Statement.

12.67 The Inquiry is interested in comments on the desirable content of such reporting. Minimum reporting might include the number of human genetic research proposals in relation to which waiver of consent was sought, granted or declined under paragraphs 15.8 and 16.13 of the National Statement. More extensive reporting might require HRECs to provide details of proposals in relation to which waiver of consent was granted, and a statement of the matters taken into account in reaching this decision.

12.68 The Inquiry's proposal is limited to human genetic research, as defined in the National Statement. The Inquiry observes, however, that similar reporting in relation to other research covered by the National Statement may also be desirable.

Proposal 12-1. HRECs should be required to report annually to AHEC with respect to human genetic research proposals for which waiver of consent has been granted under the National Statement.

Question 12-1. What sort of information should be contained in HREC reports to AHEC on waiver of consent?

Other issues concerning the waiver of consent provisions

12.69 A range of more specific issues concerning waiver of consent were raised in the submissions. Saunders and Komesaroff suggested that more guidance and legal clarification is needed in relation to the legal status of waiver of consent under the National Statement. They stated that the law remains unclear about the extent to which it is 'legally possible to omit specific consent' on the basis that consent requirements have been waived by an HREC in accordance with the National Statement.⁷⁹

79 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

12.70 The Inquiry understands the point to be that even where consent has been waived by an HREC, individuals or others may still be able to bring a claim against researchers or others relying on an act done without their consent.

12.71 For example, some state and territory guardianship legislation, such as the *Guardianship and Administration Act 1986* (Vic) prescribes consent requirements for procedures carried out for the purposes of medical research.⁸⁰ Where a person is subject to a guardianship order, consent for such procedures must be given by the Victorian Civil and Administrative Tribunal and these consent requirements cannot be overridden by an HREC.

12.72 Other submissions contained more minor and specific suggestions for changes to the operation of the waiver of consent provisions of the National Statement. For example, the HGSA noted that, in determining whether consent may be waived, an HREC may take into account ‘the extent to which the proposed research poses a risk to the privacy or well being of the individual’— that is, the donor of the human tissue or genetic material. The HGSA suggested review of this provision, given that human genetic research may involve not only the privacy or well being of the donor, but be of material concern to genetic relatives.⁸¹

Further information required

12.73 In order to assess whether there is any need to reform the waiver of consent provisions of the National Statement and to take account of any special characteristics of human genetic research, the Inquiry needs to understand more fully how these provisions operate in practice.⁸²

12.74 Consultations have confirmed that circumstances in which HRECs waive consent requirements typically involve the use of archival tissues originally collected for therapeutic or diagnostic purposes. However, one impression was that because more research involves the prospective collection of tissue samples than in the past, there are fewer instances in which such waiver of consent is sought by researchers.⁸³

12.75 Another situation in which waiver of consent may be sought is where clinical samples have been collected from a cohort of individuals with serious illnesses, such as cancer. Researchers may be reluctant to seek consent because many of the subjects of the research may have died recently, or be dying.⁸⁴ In such

⁸⁰ *Guardianship and Administration Act 1986* (Vic) Part 4A, Division 4.

⁸¹ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

⁸² The NHMRC Research Committee referred to the importance, in this context, of knowing how many waivers have actually been approved by HRECs: National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

⁸³ HREC Chairs and Officers, *Consultation*, Sydney, 20 June 2002.

⁸⁴ *Ibid.*

circumstances while it may be considered ‘impossible or difficult or intrusive’ to obtain consent in terms of the National Statement,⁸⁵ the mere fact that distress may be caused may be insufficient to avoid the consent requirements of the *Privacy Act*.⁸⁶

12.76 The Inquiry will continue to seek further information about how often and in what circumstances waiver of consent in the conduct of human genetic research is approved by HRECs.⁸⁷ Until further information has been received and assessed, the Inquiry does not consider that it will be in a position to make any firm proposals for reform in this area. In the meantime, however, the Inquiry is interested in further comments on what specific changes to the current provisions regarding waiver of research consent may be justified.

Question 12–2. Are any changes needed to: (a) the National Statement; or (b) the s 95 or s 95A Guidelines under the *Privacy Act*, in relation to waiver of consent by HRECs to the collection, use or disclosure of genetic samples or information for research purposes?

Specific consent

12.77 One question that frequently arose in submissions⁸⁸ and consultations⁸⁹ related to how specific consent needs to be. In particular concerns were raised about whether researchers should be able to obtain consent to the future unspecified use of genetic samples or information and, if so, subject to what processes or safeguards.

85 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.8; 16.13.

86 The *Privacy Act* requires that it be impracticable to collect health information without consent: *Privacy Act 1988* (Cth) NPP 10.3(c).

87 HRECs are required to keep records of all decisions and to provide information to the NHMRC on request: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.30, 2.47.

88 Eg Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; Queensland Institute of Medical Research, *Submission G036*, 14 January 2002; Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001; Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; M Dunne, *Submission G041*, 17 December 2001; N Zeps, *Submission G047*, 14 January 2002.

89 Eg Queensland Institute of Medical Research, *Consultation*, Brisbane, 13 December 2001; Children’s Cancer Research Institute, *Consultation*, Perth, 4 December 2001; Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002; Professor Loane Skene, *Consultation*, Melbourne, 15 March 2002.

The National Statement, Privacy Act and specific consent

12.78 The starting point under the National Statement is that obtaining consent should involve:

(a) the provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results; and

(b) the exercise of a voluntary choice to participate.⁹⁰

12.79 This guidance appears to be consistent with the meaning of consent as it is used in the *Privacy Act*. For example, the *Guidelines on Privacy in the Private Health Sector* state that there are three key elements involved in seeking consent to use health information in particular ways. The key elements are consent must be provided voluntarily, the individual must be adequately informed, and the individual must have capacity to understand, provide and communicate his or her consent.⁹¹

12.80 The National Statement provides that consent to the collection of human tissue for research purposes should be specific to the purpose for which the tissue is to be used.⁹² Where it is proposed that human tissue samples previously collected and stored with consent for research be used for a different research purpose, separate consent for the different research should be obtained.⁹³

12.81 The provisions relating to the use of genetic material and information more clearly anticipate that researchers may seek consent to ‘as yet unspecified future research’. The National Statement provides that when consent is being sought for prospective collection of genetic material and information, individuals should be informed:

(j) about any intention to store their genetic material and information for as yet unspecified future research in accordance with paragraphs 16.12 and 16.16 below. If consent is given, the duration of storage should be specified. If consent for future research use is refused, the genetic material and information should be disposed of at the end of the research, once the sample storage and record keeping requirements of good research practice have been met.⁹⁴

90 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 1.7.

91 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, xii. The definition of ‘consent’ under the *Privacy Act* includes ‘express or implied’ consent: *Privacy Act 1988* (Cth) s 6.

92 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.5(b).

93 *Ibid*, para 15.6.

94 *Ibid*, para 16.10(j).

12.82 The *Human Research Ethics Handbook* notes, in its commentary on paragraph 16.10(j) of the National Statement, that while consent should normally be specific

the nature of genetic research may make it difficult to be specific at the time of collection. It is appropriate to ask potential research participants to consent to storage of genetic material for unspecified future use, on the basis that consent will be sought at the time a specific research project is identified.⁹⁵

12.83 Therefore, while researchers may ask participants to consent to the storage of genetic material, further consent to the use of that material in future research will normally need to be sought.

12.84 To avoid the need to obtain subsequent consent from research participants, researchers may seek to invoke the waiver of consent provisions. As discussed above, these provisions allow consent to be waived by the HREC which may take into account, among other things the nature of any existing consent relating to the collection and storage of the sample and whether the research proposal is an extension of, or closely related to, a previously approved research project.⁹⁶

Interpretation of consent requirements

12.85 Many submissions, notably from medical researchers and research organisations, expressed concerns that too strict an interpretation of specific consent requirements would handicap the conduct of genetic research. The HGSA expressed concerns that privacy legislation:

gives primacy to privacy (and the consent requirements) making it increasingly difficult to use stored samples, even in de-identified form. It is the experience of the membership of the HGSA that the community is supportive of research, in general and when asked personally to participate. Current privacy legislation, and the application of that legislation, constrains that community support by setting in place requirements that are likely to lead to the situation in which specific current consent is the only acceptable mechanism for using a stored tissue sample for research – it would be unfortunate if that proves to be the case.⁹⁷

12.86 Dr Joe Sambrook from the Peter MacCallum Cancer Institute submitted that the requirements of genetic research cannot be served by ‘restricting the use of patient material or information to a single specified project or a specific time-span’.

95 National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra, C105.

96 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.8; para 16.13.

97 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

Instead consent should be obtained in a general fashion to enable tissue to be used for both present and future research purposes, even though those purposes may not be precisely defined.⁹⁸

12.87 The Victorian Department of Human Services Genetics Advisory Committee considered that specific consent should not be necessary for de-identified research. The Committee stated, it should be sufficient for 'generic consent' for de-identified research to be obtained to enable tissue to be used for both present and future research purposes, even though those purposes may not be precisely defined.

We believe that the standard of "general" consent for use in research, combined with the waiver system (described in 15.8 of the National Statement) and review of the use of tissue in specific research projects by a HREC, constitute a model that best protects both the interests of patients and the research community.⁹⁹

12.88 Other groups considered that current guidelines relating to consent were inadequate to protect the interests of those whose genetic material or information are proposed to be used for research. The Genetic Support Council WA stated that where future research purposes are contemplated but not known at the time consent is given, further written consent from the individual should be required.¹⁰⁰ The AIS Support Group asked

Can a person who has no real understanding of the potential ultimate uses of genetic information, truly give informed consent for the taking of a tissue sample for research purposes? Should express consent be obtained each and every time a researcher seeks to use a tissue sample for research? If consent is obtained in an environment where it is felt that adequate understanding of the nature of research exists, is such consent perpetual?¹⁰¹

12.89 The AIS Support Group observed that the complexities of the issues involved require 'at least a reasonable base level of specific medical or scientific knowledge' and that to ask a person to give consent to the use of their tissue samples for research purposes, without this knowledge existing 'challenges the very concept of informed consent'.

12.90 Some submissions emphasised the importance, in this context, of carefully distinguishing between concepts of consent in the clinical and research settings.¹⁰²

98 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

99 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

100 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

101 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

102 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001; L Skene, *Consultation*, Melbourne, 15 March 2002.

12.91 The most well known test for determining the information that doctors should give patients before medical procedures was established in *Rogers v Whitaker*.¹⁰³ Doctors have an obligation to inform patients about the material risks of a proposed procedure. Briefly, a risk for these purposes is considered material if the patient would be likely to attach significance to it.¹⁰⁴

12.92 Such a test may be appropriate where research involves some clinical intervention, but is not necessarily an appropriate guide to how much information should be provided by researchers to research participants about the proposed use of human tissue, genetic material or information in medical research.¹⁰⁵

Defining the research purpose

12.93 Concerns about the practical implications of specific consent requirements were emphasised by individuals and organisations involved in large scale medical research projects using major collections of genetic samples for multiple research projects. For example, the Queensland Institute of Medical Research noted that their studies depend upon

our ability to correlate different measures on the same people over long periods of time. To require that we go back to subjects every time we want to do a different assay on their blood, or type a different gene, would impose an unsustainable burden. Were this to be mandated, it would close us down. We trust that decisions on these issues will continue to be left to the discretion of local IECs. We believe that this system is currently working well for both subjects and researchers.¹⁰⁶

12.94 The Peter MacCallum Cancer Institute supported the existing principles relating to consent contained in the National Statement¹⁰⁷ but warned that these principles should not be interpreted

to mean that either retrospective or prospective consent is required for use of genetic information or human tissue in a specific *study* (as opposed to *purpose*) that was not contemplated at the time that the consent was originally obtained. This interpretation, analogous to that operative in the clinical setting, is not appropriate in the research setting and would seriously impede the research endeavour. Therefore, the only modification that need be made to the current principles, as delineated, is a clear distinction between the application of the informed consent requirement in the clinical setting and the research setting.¹⁰⁸

103 *Rogers v Whitaker* (1992) 175 CLR 479.

104 *Ibid.*, 634.

105 L Skene, *Consultation*, Melbourne, 15 March 2002.

106 Queensland Institute of Medical Research, *Submission G036*, 14 January 2002.

107 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

108 *Ibid.*

12.95 Similar points were made in other submissions and in consultations with researchers.¹⁰⁹ The view was put that it should be sufficient, for example, to obtain consent to a broad research purpose, such as ‘biochemical and genetic studies in cancer’¹¹⁰ — without the need to specify exactly what sorts of analysis might be performed on genetic material. The emergence of new genetic research technologies, such as micro-array technology, may mean that researchers wish to re-test samples and this should not necessitate fresh consent if it is for the same broad research purpose.¹¹¹

12.96 The National Statement refers to a requirement that consent to the use of human tissue samples be specific to the ‘purpose’ for which the tissue is to be used¹¹² and that where previously collected samples are to be used for a different ‘research purpose’ further consent should generally be obtained.¹¹³ While it has been suggested that the parameters of this provision might be clarified,¹¹⁴ the Inquiry is not convinced any change is necessary. It seems sufficiently clear that a distinction may be made between a broad research purpose and the particular research techniques that may be used in the pursuit of that purpose.

Consent and related research

12.97 A closely linked concern is the meaning of ‘related’ research. As noted above, the waiver of consent provisions of the National Statement allow consent to be waived taking into account, among other things, whether the research proposal is an extension of, or closely related to, a previously approved research project.¹¹⁵

12.98 One view was that related research could be defined no closer than ‘research sufficiently related to put up to an HREC’ — that is to ask an HREC to approve the research without further consent being obtained.¹¹⁶ The structure of the National Statement with its focus on individual ethics committees may mean that it is not appropriate to reduce or define the concept of related research precisely.

109 Queensland Institute of Medical Research, *Submission G036*, 14 January 2002; Queensland Institute of Medical Research, *Consultation*, Brisbane, 13 December 2001; Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002.

110 Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002.

111 Ibid.

112 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.5(b).

113 Ibid, para 15.6.

114 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001; Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002.

115 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.8; 16.13.

116 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

Consent to as yet unspecified future research

12.99 It is common practice for researchers to seek consent from donors for their tissue to be used in a particular experiment and then store tissue for possible later inclusion in other experiments, the details and potential implications of which are unspecified.¹¹⁷

12.100 This practice may be criticised as inappropriate because, as a matter of principle, valid consent cannot be provided in the absence of full and complete disclosure of the uses to which the tissue is to be put.¹¹⁸

12.101 However, there was also broad consensus within the medical research community about the need for procedures under which prospective research participants may provide consent for as yet unspecified future research — provided that such research is approved by an HREC (which might, in some circumstances require researchers to obtain renewed consent from the donors).

12.102 Suggestions for appropriate procedures often focussed on the idea of tick box consent options. That is, prospective research participants could elect from a graduated set of consent options so that, for example, in addition to the participant being asked to consent to participation in a specified research study, the following options might be presented:¹¹⁹

My sample:

May be stored for future research related to this study (including DNA studies) but only if my consent is obtained at the time for this future research and the research is approved by a Human Research Ethics Committee (HREC) Yes/No

May be stored for future research related to this study (including DNA studies) without my further consent being required, provided the research is approved by an HREC Yes/No

May be stored for future research unrelated to this study (including DNA studies) but only if my consent is obtained at the time for this future research and the research is approved by an HREC Yes/No

May be stored for future research unrelated to this study (including DNA studies) without my further consent being required and, provided that the research is approved by an HREC, and may be used

- in de-identified form (anonymous) Yes/No

¹¹⁷ N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

¹¹⁸ Ibid.

¹¹⁹ B Uren, undated pro forma consent form: *Consent for Collection, Storage and Testing of Human Tissue for Research*.

- | | |
|--|---------|
| • in potentially identifiable form (coded) | Yes/No |
| • in identifiable form. | Yes/No. |

12.103 Saunders and Komesaroff noted that an approach presently followed by a few HRECs is for individuals to be given the opportunity to choose whether their samples are to be destroyed after the specified experiment has been completed, to be kept and preserved for possible uses approved by an ethics committee, or to be kept and preserved for possible use subject to subsequent renewed individual consent.¹²⁰ That is, prospective participants in research are presented with the sorts of consent options referred to in the discussion above.

12.104 This sort of consent process was seen as having significant advantages for research and, at the same time, respecting the wishes of many donors of human tissue. The Queensland Institute of Medical Research (QIMR) stated that in future studies they envisaged using consent forms with tick boxes to indicate consent to restricted or more general use of samples.¹²¹

The suggestion that subjects cannot give informed consent to future uses that have not even been invented yet seems to us to ignore the obvious point that the subjects who tick this box are overwhelmingly altruistic in the matter of medical research, and that an [HREC] is perfectly able to make a judgement on whether a future use is reasonable or not without going back to the subject.¹²²

12.105 The advantages of obtaining consent for as yet unspecified future research are significant for the organisations conducting genetic research. For example, the QIMR conducts genetic research using the Australian Twin Registry — a national registry of twin pairs who are willing to consider participating in health related research.¹²³ A wide range of research projects are undertaken in conjunction with the Registry, including studies on alcohol and tobacco use, asthma, cholesterol, diabetes, anxiety and depression, osteoporosis, heart disease, epilepsy, dietary salt, Alzheimer's disease, eating disorders, prostate size, male infertility, premenstrual tension, endometriosis, teeth, Attention Deficit Disorder, and breast cancer.¹²⁴

12.106 The QIMR's research involves genetic testing of twins to decide whether they are homo-zygotic or dizygotic — that is, identical twins or not, followed by broad genome scans looking for around 400 genetic markers. The cost of such testing is \$1200–\$1400 per pair of twins. The QIMR noted that the cost of this

120 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

121 Queensland Institute of Medical Research, *Submission G036*, 14 January 2002.

122 Ibid.

123 Australian Twin Registry, *Introduction to the Australian Twin Registry*, <<http://www.twins.org.au/aboutatr/introductiontoatr.htm>>, 24 April 2002. More than 30,000 pairs of twins have joined the Registry, making it the largest volunteer registry of its kind in the world.

124 Ibid.

research means that the information ‘infrastructure’ created needs to be used for multiple studies of many genetic conditions, some of which will not be foreseeable at the time participant consent is sought.¹²⁵

12.107 Sister Regis Mary Dunne submitted that consent to future use, as approved by an HREC, could be implied from any donation for research purposes. In this context, she noted that donors of blood to the Red Cross are informed that their blood may be used for transfusion, for the extraction of blood products, or for research.

Such an Australian system already in place could provide a model for the use in research of altruistically donated blood, and tissue surplus to diagnostic purposes. The initial donation could be accepted with the guarantee that all research will be done only after Ethics Committee approval.¹²⁶

Consent and human genetic research databases

12.108 As discussed further in Chapter 15, human genetic research databases (often referred to as tissue banks) are maintained by private and public hospitals and research institutes. Unlike archival pathology samples, samples in human genetic research databases are stored solely for their possible use in research.

12.109 Some Australian human genetic research databases utilise procedures that involve obtaining broad consent for the use of tissue in research, generally, from donors whose tissue is being surgically excised for diagnostic and therapeutic purposes. In effect, this consent purports to cover as yet unspecified future research.

12.110 The PMCI uses broad consent, rather than specific protocol-based consent, to facilitate the future research use of tissue, as approved by its ethics committee.¹²⁷ A similar approach is used by the West Australian Tissue Bank.¹²⁸ The consent form for donors to the PMCI tissue bank states simply that the sample will be used for ‘biochemical and genetic studies on the cause of cancer’.¹²⁹ Donors are informed that researchers associated with the PMCI will have access to the samples for approved research purposes only and that access to donated tissue will be regulated by the PMCI ethics committee.¹³⁰

125 Queensland Institute of Medical Research, *Consultation*, Brisbane, 13 December 2001.

126 M Dunne, *Submission G041*, 17 December 2001.

127 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001; Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002; Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002.

128 N Zeps, *Submission G047*, 14 January 2002; Children’s Cancer Research Institute, *Consultation*, Perth, 4 December 2001.

129 Peter MacCallum Cancer Institute, *Information and Consent Form Protocol No 98/36* (2002).

130 Ibid.

12.111 Similarly, the consent form for the West Australian Tissue Bank refers to donation of tissue or blood for biochemical and genetic medical research into cancer and states that storage of and access to tissue will be managed by an Advisory Committee and only released where approved by an HREC.¹³¹

12.112 Obtaining subsequent consent from donors for future research is clearly a costly and time-consuming process for research organisations. The primary reason for favouring such an approach to consent is that obtaining further consent is not considered to be necessary when researchers wish to apply new research techniques¹³² or to conduct new research projects that could not be foreseen at the time of the donation.

Research techniques are developing at such a rapid rate that it is was not possible 5 years ago to describe with any detail projects that are being pursued today. The same is true of the relationship between techniques available today and research five years from now.¹³³

12.113 In the context of cancer research there are other important considerations. For example, some cancers, such as ovarian and gastric cancer, are highly fatal.¹³⁴

To consent donors retrospectively for individual research projects would be difficult in cases of aggressive and fatal disease. Constantly re-consenting patients for new studies may be impossible, due to death, or disturbing to surviving patients ...¹³⁵

12.114 The PMCI submitted that the timely conduct of research into the causes of cancer would be significantly prejudiced if, instead of being able to use existing collections of human tissue for new cancer research, fresh collection of tissue was to be required.

Cancer of any tissue is heterogeneous and, as a result, studies often require very large numbers of samples to achieve any statistical power. For example, a researcher may wish to determine whether particular molecular sub-types of breast cancer correlate with outcome. If the sub-type represents only a small percentage of the samples tested, then it is necessary to investigate many additional samples. It can take years to accumulate enough samples to perform such analyses. Clearly, the implementation of new prognostic tests will be greatly delayed if sample collection has to be done prospectively as each new technology or marker is identified.¹³⁶

131 Western Australian Tissue Bank, *Western Australian Tissue Bank: Application for Approval of a Patient Information Leaflet and Consent Form to Collect Fresh Tissue Samples from Surgically Removed Tissues for Research Purposes* (2001) Western Australian Tissue Bank.

132 Eg new DNA microarray techniques: Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

133 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

134 Eg in the case of a national study of ovarian cancer the majority of patients die within 3-5 years of diagnosis. Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

135 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001.

136 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

Reform of specific consent requirements

12.115 The National Statement anticipates that researchers may seek consent to storage of genetic material for as yet unspecified future research on the basis that consent to its use will be sought at the time a specific research project is identified.¹³⁷ However, no specific guidance is provided on whether an HREC may waive this requirement to seek further consent or in what circumstances.

12.116 The Inquiry understands that the National Statement is currently being interpreted, by at least some HRECs, to permit researchers and research organisations to obtain consent for as yet unspecified future research, as approved by an HREC, and without the need for later, specific, consent.

12.117 The interpretation has met with concern in some quarters, as an unjustified erosion of the protection provided by requirements for specific consent to participation in research. Others have expressed the view that procedures to allow for the obtaining of ‘broad and durable’ consent should be facilitated and that the National Statement may not sufficiently mandate such processes.

12.118 At the centre of this debate are differing views about the application of the concept of consent where people cannot be informed in any detail about the nature of the research. It has been suggested that the language of consent should, in some contexts, be augmented by the concept of ‘donation’ or ‘gifting’. That is, it should be recognised that individuals may choose to ‘gift’ samples for research purposes — for example by leaving their body to science or where blood is donated to the Red Cross.

12.119 In respect of the last example, Mary Dunne observed that donors to the Red Cross are informed that their blood may be used for transfusion, for the extraction of blood products, or for research.

They do not know, nor have the need to know where their blood has gone. However, the documentation is such that individual identity is protected, yet donors could be contacted again if necessary. Such an Australian system already in place could provide a model for the use in research of altruistically donated blood, and tissue surplus to diagnostic purposes. The initial donation could be accepted with the guarantee that all research will be done only after Ethics Committee approval.¹³⁸

137 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.10(j); National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra, C105. In its general provisions dealing with privacy the National Statement also states that the consent of participants should be obtained for the use of the personal information where the information is to be held on registers for use by researchers in future research projects: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 18.4.

138 M Dunne, *Submission G041*, 17 December 2001.

12.120 Also at the centre of this debate, as is the case with debate about the operation of the waiver of consent provisions generally, are differing perceptions of the role of HRECs. In particular, to what extent should HRECs take it upon themselves to act as proxy or surrogate consent-givers (by waiving specific consent requirements) as opposed to pursuing their primary role of protecting the rights of participants in research — including their right to refuse to consent to the use of their genetic materials in research.

12.121 As discussed above, consent to as yet unspecified future research is obtained by some Australian human genetic research databases and the ability to do so may be important to the effective operation of these databases. The PMCI observed that

The HREC and the tissue bank act together as the gatekeeper of the samples. Patients consent to the use of the material as controlled by the HREC, which, in turn, can respond to changing expectations and increased information over time. Patients may always elect to have their samples removed from the bank at any time.¹³⁹

12.122 There was much support, from medical researchers and others for procedures allowing researchers to obtain consent for as yet unspecified future research, subject to future approval by an HREC.

12.123 In particular, those involved in the development and ongoing operation of Australian human genetic research databases submitted that the use of tissue banks, with a structure of broad patient consent for research on prospectively collected samples and controlled access to samples through HRECs is the best way to protect the rights and privacy of patients as well as facilitating research.¹⁴⁰

12.124 However, there may be valid distinctions to be made between allowing major centralised tissue banks, applying best practice collection, storage and security standards (with access to samples under the control of standing management and ethics committees) to obtain broad consent to the use of the samples they collect in future research, and permitting individual researchers to do the same, maintaining their own small private holdings of such samples.

12.125 One incentive for major centralised tissue banks to participate in some form of licensing or registration scheme might be that they and other licensed human genetic research databases would be expressly authorised to use genetic material and information for research approved by their HREC, without further consent from the donors.

139 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

140 Ibid; N Zeps, *Submission G047*, 14 January 2002.

12.126 However, whether or not additional regulation of major tissue banks is recommended, the National Statement needs to more clearly deal with the issue of consent to future research. The Inquiry considers that this is a matter that should be covered by the proposed new chapter of the National Statement dealing with human genetic research databases (see Proposal 15–1).

Proposal 12–2. The proposed new chapter of the National Statement dealing with human genetic research databases (see Proposal 15–1) should provide guidelines dealing specifically with obtaining consent to unspecified future research.

13. Encouraging Best Practice in Human Genetic Research

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Introduction

13.1 The National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement)¹ offers guidance on, rather than prescription of, ethically sound research design and practice.

13.2 In relation to human genetic research, comprehensive guidance is provided on a range of issues including the social significance and consequences of genetic research, privacy and confidentiality, consent, waiver of consent and genetic counselling.² The *Human Research Ethics Handbook*³ provides further advice on, and clarification of, these provisions for the assistance of Human Research Ethics Committee (HREC) members, researchers and research participants.

13.3 In this Discussion Paper, the Inquiry proposes a number of changes to the National Statement to better protect privacy and ensure ethical conduct in human genetic research. However, in most respects the Inquiry considers that the provisions of the National Statement provide appropriate general ethical guidance and do not require revision.

1 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

2 Ibid, Ch 16.

3 National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra.

13.4 In the course of the inquiry suggestions have been made about a range of desirable practices in the conduct of human genetic research including — for example, in relation to the content of consent forms and participant information sheets, de-identification of genetic samples or information and disclosure of commercial interests.

13.5 As discussed in this chapter, the Inquiry proposes that further detailed guidance on these and other matters could usefully be provided by AHEC, through the preparation of model research protocols for human genetic research. These model protocols would not be intended to prescribe research design but to assist researchers to do so.

Model research protocols

13.6 Consultations have suggested that it may be useful for AHEC to augment the National Statement with model research protocols for human genetic research. The intention of these protocols would be to augment the National Statement, as revised, to give further guidance to HREC members, researchers and research participants on what AHEC considers to be best practice in the conduct of human genetic research. The possible content of such protocols is discussed below.

Coding and de-identification of genetic samples and information

13.7 One area of research practice that may be an appropriate subject for guidance relates to the de-identification of genetic samples and information. The de-identification of samples and information is an important mechanism by which privacy is protected in the conduct of research.

From a privacy-protection perspective, there is a very wide distinction between personally identifiable data and truly anonymized data. But in practice the demarcation between these extremes is not sharp. Attending assiduously to where particular data lie on the spectrum between them, and especially to data that are somewhere in the middle, is a crucial protection strategy.⁴

13.8 In this context, the National Statement makes distinctions between identified, potentially identifiable (coded or re-identifiable) and de-identified (not re-identifiable, anonymous) personal information or material.⁵

4 W Lowrance, *Privacy and Health Research: A Report to the US Secretary of Health and Human Services*, Department of Health and Human Services (US), <<http://aspe.os.dhhs.gov/datacncl/phr.htm>>, 8 July 2002, 32.

5 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9. The National Statement states that 'It should be recognised that the term "de-identified" is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain "potentially identifiable"': National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9.

13.9 Genetic samples and information used in human genetic research are commonly coded — that is, identifiers such as the individual's name, date of birth or address are removed and replaced by a code. This information is potentially identifiable.⁶

13.10 For the purposes of the National Statement information or material is 'de-identified' only if the process of de-identification is irreversible — for example because the identifiers have been removed permanently or if the data have never been identified. Coded data is not 'de-identified' because coding, by its very nature, is intended to be reversible.⁷

13.11 Human genetic research often requires information obtained from genetic testing to be linked to health information contained in clinical records, making true de-identification impractical.

13.12 Submissions and consultations emphasised that complete de-identification is often not a practicable solution to privacy concerns about the collection and use in research of genetic samples or information. For example, in relation to tissue banks, the PMCI stated that:

It is important that the samples remain 'identified' to the managers of the tissue bank. Retaining identifiers allows the collection of follow-up information, such as survival data. A recommendation that broadly consented material should be de-identified would prevent the ongoing collection of clinical information. For certain diseases, such as breast or prostate cancer, survival outcome may not be known for years. High quality, centrally collected samples with long term outcome information are extremely valuable for testing potential markers of therapeutic response and outcome ...⁸

13.13 There are other reasons why de-identification may not be desirable in the context of human genetic research. In particular, human genetic research may reveal information of potential importance to the future health of participants or their children. The HGSA noted that:

With regard to research uses, de-identification protects privacy but does not address other interests of research subjects such as the possibility of receiving health information that comes out of the research. Obtaining consent for research that uses identified samples/information allows information to go back to participants and may place an obligation on researchers to do so.⁹

6 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9.

7 Although one of the factors that may be taken into consideration by an HREC is determining whether consent should be waived is the 'extent to which it is possible to de-identify the sample' — suggesting that de-identification need not be complete anonymisation. Ibid, para 15.8, 16.13.

8 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

9 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

13.14 The National Statement notes that researchers should consider carefully the consequences of storing genetic material or information in de-identified form for the proposed research, for future research and for communication of research results to participants.¹⁰

13.15 The HGSA stated that HRECs may consider it inappropriate to approve research using de-identified material or information if the research is likely to produce useful health information for the participants.¹¹ Some of the dilemmas were illustrated in the HGSA's submission to the Inquiry.

A problem may arise if the research could identify an important family condition, which may have great significance for their health. In these cases, both the researchers and the HREC should undertake careful consideration as to which is the best way to approach the condition. For example, if a sample from a baby who had died from SIDS were found to have a genetic problem which could occur in either a parent or future sibling, would the duty of the researchers be to inform that family if further harm could be prevented? The family would then be aware that genetic research had been carried out without their consent. If the samples were anonymised initially and a subsequent research study undertaken where consent was sought, harm may have come to the family because of the delay. However, if the hypothesis about the genetic problem were wrong, is it appropriate to contact many parents about the test when there may be no benefit and potentially distress them unnecessarily?¹²

13.16 Professor Nick Saunders and Associate Professor Paul Komesaroff commented on the confusion surrounding the concept of de-identification in medical research contexts. They considered that HRECs should be more aware of practical difficulties involved in de-identifying samples¹³ (and the fact that true de-identification is often not possible).

[E]thics committees should be aware that certain genetic material, such as that stored as a legal requirement or for potential clinical use in addition to research use, cannot be de-identified and must retain its identifiers, and the practical difficulties with coding or de-identification, as with tissue blocks stored by pathology laboratories, which cannot have identifiers removed as these are often an integral part of the tissue specimen, should be emphasised.¹⁴

13.17 A need to raise awareness about the issues involved in de-identification of genetic samples and information was also evidenced amongst groups most affected by genetic research. Representatives of genetic support groups in Western Australia, in a round table discussion facilitated by the Genetic Support Council Western Australia (Inc)

10 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.6.

11 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

12 Ibid.

13 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

14 Ibid.

strongly believed that researchers should only work with de-identified samples, and that a code of practice for de-identifying donor samples should be drafted at the federal level to ensure uniformity in practice. However they noted that more information on the de-identification process and what it means would be useful for the groups.¹⁵

13.18 The Inquiry considers that model human genetic research protocols should include guidance on the different mechanisms for coding or de-identifying genetic samples and information used in research, and the relative advantages and disadvantages of each approach in different research contexts.

Managing coded samples and information

13.19 Where genetic samples or information are coded the privacy of the samples and information is protected because they are not immediately identifiable. The level of protection afforded by coding is dependent on who has access to the identifying code and for what reasons.

13.20 There is an emerging international standard for genetic privacy protection that provides for the use of independent intermediaries to hold the code linking genetic samples or information with the identifiers.¹⁶

13.21 The National Statement recognises the possible desirability of such intermediaries in the conduct of human genetic research by providing that '[w]here an HREC approves the use of potentially identifiable data that has been coded, the HREC should decide whether an independent person should hold the code'.¹⁷

13.22 The Institute of Community Genetics has developed the concept of the 'gene trustee' — an independent third party acting on behalf of persons submitting genetic samples for testing.

The GeneTrustee is a key intermediary layer, inserted between the client and the testing laboratory. The GeneTrustee holds the coded links that can identify the client's DNA with personal details of the client - thereby assuring total anonymity for the client from the perspective of the testing laboratory, while at the same time allowing access to the identifying links with the client's consent, or under other defined circumstances. This model is one of the competing proposals for an emerging international standard for the conduct of genetics programs.¹⁸

15 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

16 W Lowrance, *Privacy and Health Research: A Report to the US Secretary of Health and Human Services*, Department of Health and Human Services (US), <<http://aspe.os.dhhs.gov/datacncl/phr.htm>>, 8 July 2002, 35–36.

17 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 14.5.

18 Institute of Community Genetics, *Submission G156*, 19 April 2002.

13.23 The perceived advantage of independent intermediaries is that a high level of privacy protection, and research participant control over the use of their samples and information, may be extended without incurring the disadvantages of de-identification. That is, it remains possible for researchers to contact participants (through the intermediary) in order, for example, to seek consent to future research or to inform them about research outcomes relevant to their health.¹⁹

13.24 This level of protection may not be practical for all human genetic research projects, particularly those that are small-scale. However, at the very least it may be argued that the persons who have access to the identifying code should be specified in research protocols.

13.25 There was broad agreement in submissions²⁰ and amongst those consulted by the Inquiry that the use of coded information and independent intermediaries should be encouraged in genetic research, wherever possible.

The current idea that locked cabinets or password protected files are adequate cannot be sustained. The processes of independent intermediary protection should be specified.²¹

13.26 The Inquiry considers that model human genetic research protocols should include guidance on the appropriate use of independent intermediaries to hold codes linking genetic samples or information with the identifiers.

Feedback to research participants

13.27 The possibility of feedback of health information to research participants has been identified as raising important ethical issues relevant to human genetic research. This is another area where a model research protocol could provide additional guidance.

13.28 These issues are closely related to considerations about the coding or de-identification of genetic samples and information. In this context, the National Statement provides that:

When research may reveal information of potential importance to the future health of identified or potentially identifiable participant's further health or the participant's offspring, the research protocol must provide for consent procedures, counseling, support, test quality and test result confidentiality as would apply if the participant sought such information in a clinical setting. Otherwise such research may only be performed if the genetic material has been de-identified.²²

19 Ibid.

20 Eg Ibid; Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

21 D Chalmers, *Correspondence*, 8 May 2002.

22 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.15.

13.29 When consent is being sought from individuals for the collection of genetic material, the National Statement provides that they should be informed

that the researchers will endeavour to provide information about the outcome of the research. Participants should be advised when it is not intended to provide feedback. If relevant, participants should be asked whether they wish to be notified of research results which relate to them as individuals.²³

13.30 Nick Saunders and Paul Komesaroff referred to the complexities involved in providing individual results to research participants:

Complexities arise as a result of uncertainty about the reproducibility of results, their implications for the individual concerned or for blood relations, their effect on the ability to take out life insurance, and other matters. In recent years it has come to be regarded as a right of participants in research to receive their individual results; it is likely that this assumption will need to change.²⁴

13.31 Concerns were also expressed by researchers in submissions and consultations about the discharge of their legal or ethical duties to contact research participants about specific test results.²⁵

13.32 It is possible that, in some circumstances, a legal duty to contact a research participant about a genetic test result might be derived from common law principles relating to the tort of negligence and the concept of a duty of care. There is no legal authority regarding the possible imposition of such a duty.²⁶

13.33 Whatever the legal position, it is clear that some researchers are keenly aware of ethical obligations to inform research participants about the health implications of genetic testing conducted on genetic material provided by them. However, there are recognised practical and resource implications involved in providing individualised feedback to participants.

13.34 The Inquiry considers that model human genetic research protocols should include further guidance on the discharge of these legal or ethical obligations to research participants. One possibility would be to provide that, in appropriate circumstances, researchers' ethical duties to contact research participants about test results may be discharged by providing general information to all research participants, for example, by way of a regular newsletter.

13.35 Information provided in this way could alert research participants about the implication of test results found in the course of the research and advise that, if participants are concerned about these implications, they should obtain individual medical advice about whether clinical genetic testing is indicated.

23 Ibid, para 16.10(d).

24 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

25 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

26 The duty to warn is discussed in more detail in relation to health professionals (see Ch 18).

Disclosure of commercial arrangements

13.36 At least in terms of overall funding it is clear that private sector involvement in health and medical research is significant (see Chapter 11). As a new and burgeoning area of medical research, private sector involvement in human genetic research specifically can be expected to grow. In this context, it is express government policy to increase private funding of research and to improve Australia's record in the commercialisation of the outcomes of research.²⁷

13.37 In consultations, the Inquiry was told that it is increasingly common for universities and publicly funded research institutes to 'spin off' private biotechnology firms including those engaged in aspects of human genetic research.

13.38 Concerns were often expressed in consultations, and in public meetings in particular, about the involvement of commercial enterprises in human genetic research. While people who volunteer as participants in medical research generally have altruistic motives, it was seen as important that the outcomes of research enhance the public good.

13.39 While the Inquiry recognises that the benefits of the new genetic medicine are unlikely to be achieved without substantial private sector research investment, the commercial background to research projects seems an important factor for many prospective research participants — both in terms of the perceived societal benefits of research and concerns about privacy. In the absence of Australian data, empirical evidence about public attitudes to research in the United Kingdom may have some relevance in this context.

13.40 A survey conducted by the Human Genetic Commission in the United Kingdom has found that levels of public trust in the responsible use of human genetic information vary markedly, depending on the nature of the individuals or bodies holding it. In particular, respondents trusted academic scientists more than health and pharmaceutical companies.²⁸

27 Health and Medical Research Strategic Review, *The Virtuous Cycle, Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra, Ch 8, Appendix 1 (Government Response to the Recommendations and Actions in the Report of the National Health and Medical Research Strategic Review — NHMRC to Action).

28 MORI Social Research, *Public Attitudes to Human Genetic Information: People's Panel Quantitative Study Conducted for the Human Genetics Commission*, <http://www.hgc.gov.uk/business_publications_morigeneticattitudes.pdf>, 1 December 2000, 41. Respondents were asked the following question (n=1,038): Q68 Please tell me which, if any, you trust to use the human genetic information held on medical databases responsibly? The responses included: An expert government scientific advisory committee (39%); Academic scientists (38%); Health and pharmaceutical companies (20%); Government (13%).

13.41 Extensive public consultation has been conducted in relation to the BioBank UK initiative.²⁹ One of the reported outcomes of this research, conducted through interactive workshop sessions,³⁰ was that

The first reactions were that commercial companies should not have access [to genetic data], although some participants were quick to realise that the results [of research] would be published and therefore widely accessible to anyone. Further debate brought the realisation that if medicines are going to be developed, pharmaceutical companies must have access.³¹

13.42 Another report on qualitative research connected with the development of the BioBank initiative concluded that the fact that sample collection would be a 'publicly funded initiative and not set up as a profit-making exercise was reassuring and important in communicating its credibility'³² and that

[t]here are likely to be questions from the general public and in the media about commercial access to, and use of, the samples and information. Assuming samples are donated freely by donors, there needs to be careful explanation of the financial implications of this.³³

13.43 Australian academics have expressed the view that, from an ethical perspective, there are strong grounds to suggest that 'the potential for commercial exploitation' of genetic samples and other biological materials is a very relevant consideration for individuals to take into account in deciding whether to give consent to participation in research, particularly given that subject participation is typically altruistic in nature.³⁴

13.44 Therefore, it may be argued that there is a clear need for open and transparent disclosure, to prospective research participants, of the potential commercialisation of research outcomes and the commercial interests of the researchers involved. It has been suggested that such disclosure may protect the interests of both prospective research participants and researchers themselves:

In order to avoid feelings of exploitation, and possibly even deception, it is of crucial importance that they be given the opportunity to consent to participation in the knowledge that there is a possibility of commercial gain being made from their donated biological material. To do otherwise risks damaging the perception of

29 BioBank UK is discussed in more detail in Chapter 15.

30 People Science and Policy Ltd, *BioBank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust Report prepared for the Medical Research Council and the Wellcome Trust March 2002*, People Science and Policy Ltd (2002), People Science and Policy Ltd, London, 1: see http://www.mrc.ac.uk/pdf-biobank_public_consultation.pdf.

31 Ibid, 19.

32 CR Dawson, *Public Perceptions of the Collection of Human Biological Samples*, MRC and Wellcome Trust, <http://www.mrc.ac.uk/pdf-biobank_public_perceptions.pdf>, 8 July 2002.

33 Ibid, 17.

34 D Nicol, M Otlowski and D Chalmers, 'Consent, Commercialisation and Benefit-Sharing' (2001) 9(1) *Journal of Law and Medicine* 80, 80, 93.

research and may thereby reduce the willingness of people in the community to participate.³⁵

13.45 The National Statement contains a number of provisions relating to the disclosure of funding and financial interests. However, there is no general requirement to disclose this information, or other information about the actual or anticipated commercial arrangements connected with the research, to research participants.

13.46 The National Statement provides that a researcher must disclose to the HREC reviewing the research proposal the amount and sources or potential sources of funding for the research and must declare any affiliation or financial interest. The HREC must consider the extent to which it should disclose that information about funding sources to research participants.³⁶ The HREC may decide that no such disclosure is justified.

13.47 The disclosure requirements in relation to clinical trials specifically are somewhat more rigorous — a researcher must inform an HREC ‘of any business or other similar association which may exist between a researcher and the supplier of a drug or surgical or other device to be used in the trial’.³⁷ Further, an HREC must examine those aspects of the budgets of clinical trials which raise ethical issues.³⁸

13.48 The Australian Academy of Sciences submitted that ‘all applications to HRECs should be required to include details of any commercial support obtained or envisaged’.³⁹ It is not clear to what extent this suggestion goes further than the existing provisions of the National Statement requiring disclosure to HRECs. What seems more important is the question of disclosure to research participants.

13.49 The Center for Law and Genetics suggested that the provisions of the National Statement dealing with disclosure of commercial arrangements to research participants should be tightened.

As a general principle research participants have an ethical right to be informed of all aspects of the research project including any commercial arrangements.⁴⁰

13.50 There is presently no ethical guidance on the desirable extent of such disclosure. The Inquiry considers that model human genetic research protocols should include guidance on the disclosure by researchers to research participants, of information about actual or anticipated commercial arrangements connected with the research proposal.

35 Ibid, 80, 93.

36 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.21.

37 Ibid, para 12.5.

38 Ibid, para 12.6.

39 Australian Academy of Science, *Submission G097*, 21 January 2002.

40 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

Proposal 13–1. AHEC should develop model research protocols for human genetic research to provide guidance to HRECs, researchers, and research participants about best practice in the conduct of human genetic research. These protocols should include guidance on:

- the mechanisms for coding or de-identifying genetic samples and information used in research, and the relative advantages and disadvantages of each approach in different research contexts;
- the use of independent intermediaries to hold codes linking genetic samples or information with the identifiers;
- the discharge of legal and ethical obligations to inform research participants about the health implications of testing of their genetic samples; and
- full disclosure by researchers to research participants of information about actual or anticipated commercial arrangements connected with human genetic research proposals.

Consent forms

13.51 The Inquiry considers that model research protocols for human genetic research should include guidance on the drafting of consent forms. Guidance is required on the following matters:

- The use of a graduated set of consent options — from consent to specific research through to consent to related research use, and consent to as yet unspecified future research (as approved by an HREC). Issues concerning consent to the use of genetic samples and information in human genetic research — including issues relating to obtaining consent to as yet unspecified future research were discussed in Chapter 12 above;
- Disclosure by researchers to research participants, of information about actual or anticipated commercial arrangements connected with human genetic research proposals (as discussed above);
- Clarification of ownership or property interests in any genetic samples (or the information derived from such samples). Issues relating to property in genetic samples are discussed in Chapter 17.

13.52 There is a range of other matters that might usefully be included in guidance on the drafting of consent forms. These might include:

- Model statements about how privacy protection is to be handled — that is, through coding or de-identification of genetic samples or information. Saunders and Komesaroff submitted that the implications of decisions about coding or de-identification should be more fully presented to prospective research participants, when their consent is being sought.⁴¹
- Model statements about whether, and if so how, consent to participation may be withdrawn. The National Statement provides that a participant must be free at any time to withdraw consent to further involvement in research and the consequences of withdrawal must be explained when obtaining consent.⁴² Saunders and Komesaroff stated that, in human genetic research, ‘withdrawal may affect not only the research participant but also her or his blood relations’. They also noted that it is often the case that ‘to avoid critical biases in statistical analysis withdrawal of a subject enrolled in a research project does not lead to retrospective withdrawal of the data relating to him or her’.⁴³ These sorts of matters may need to be made clearer to prospective research participants on consent forms.

Proposal 13–2. AHEC should develop guidelines for preparing consent forms for human genetic research, covering such matters as:

- graduated consent options;
- full disclosure by researchers about actual or anticipated commercial arrangements;
- ownership or property interests in genetic samples or information;
- methods of protecting privacy; and
- withdrawal of consent by participants.

41 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

42 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 1.12.

43 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

14. Strengthening Review by HRECs

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Introduction

14.1 The Inquiry has received a wide range of comment on the adequacy of the existing system of research ethics review, from those who felt that, despite resource constraints, the current system works well to those who were vehemently critical of it. A number of submissions suggested possible reforms aimed at strengthening the current system for ethical review of human genetic research proposals and the role of Human Research Ethics Committees (HRECs) within that system.

14.2 This chapter discusses possible reform relating to the operation of HRECs. Some of these possible reforms, for example in relation to reporting or monitoring of human genetic research by HRECs might require changes to the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).¹ Others may be matters for AHEC or research institutions themselves to examine further.

¹ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

14.3 While this inquiry must focus on human genetic research, any suggested changes to the ethics review process will have implications for all the other human research which HRECs are expected to review. The present regulatory framework for the ethical conduct of research is centred on the National Statement.² The National Statement is scheduled for formal review by AHEC during the 2003–2005 triennium, consistent with NHMRC policy to revise guidelines on a five year cycle.

14.4 AHEC advises the NHMRC on ethical issues relating to health and in developing guidelines for the conduct of medical research involving humans. In this context, AHEC has an ongoing role in developing proposals for improving the system of ethical review. During the present triennium (2000–2003), a major element of the strategic plan of AHEC and the NHMRC has been to strengthen the level of support provided to HRECs, by way of training workshops, access to advice and the production of the *Human Research Ethics Handbook*.³ Current relevant AHEC initiatives are referred to throughout this chapter.

Human Research Ethics Committees

14.5 The primary function of an HREC is to protect the welfare and rights of participants in research.⁴ Under the National Statement, all research projects involving humans must be reviewed by an HREC and must not be undertaken or funded unless and until approval has been granted.⁵

14.6 An important secondary purpose of HRECs under the National Statement is to ‘facilitate research that is or will be of benefit to the researcher’s community or to humankind’.⁶ In addition, the National Statement makes it explicitly clear that the integrity of the researcher and the researcher’s respect for persons are critical to the conduct of research.⁷ While this chapter focuses on HRECs, it is assumed that researchers will strive to conduct themselves ethically and that they will be held to account if they fail in this regard.

14.7 The provisions of the National Statement relating to the institutional status and accountability of HRECs, their functions and responsibilities and membership requirements were set out in detail in the Issues Paper.⁸

2 Ibid.

3 National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra.

4 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.5.

5 Ibid, para 1.16.

6 Ibid, preamble.

7 Ibid, Ch 1.

8 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 6.65–6.79.

14.8 At present there are around 213 HRECs in Australia, of which 100 are in hospitals, 45 in universities, 35 in government and 33 in other institutions.⁹ The composition of HREC membership must conform to the minimum requirements of the National Statement. The workload of these HRECs appears to vary significantly. Some review in excess of 250 proposals per annum, while others deal with far fewer.

14.9 No exact figures are available in relation to the number of research proposals considered by HRECs that involve human genetic research. However, the Executive Officer of one New South Wales Area Health Service HREC estimated that, of 300 or so proposals considered annually, there could be expected to be around 20 major human genetic research proposals and another 30 genetic sub-studies related to clinical trials.¹⁰

Reporting on and monitoring of human genetic research

14.10 IP 26 asked whether there should be more comprehensive reporting requirements applicable to HRECs and whether there should be more emphasis on the obligations of HRECs to monitor the ongoing conduct of research.¹¹ A range of issues concerning the reporting and monitoring obligations of HRECs were raised in submissions and in consultations and are discussed below.

Reporting on human genetic research by HRECs

14.11 The National Statement provides that the NHMRC, through AHEC, will audit the activities of HRECs to ensure compliance with the National Statement.¹² The National Statement requires an institution or organisation and its HREC to report annually to the NHMRC information relevant to its procedures including:

- membership and membership changes;
- number of meetings;
- confirmation of participation by required categories of members;
- the number of protocols presented, the number approved and rejected;

9 Data provided by Health Ethics Section, NHMRC. However, it is acknowledged that there are likely to be ethics committees in existence within the community not-for-profit or private sectors that are not registered with the NHMRC.

10 HREC Chairs and Officers, *Consultation*, Sydney, 20 June 2002.

11 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 6–2.

12 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.46.

- monitoring procedures in place and problems encountered;
- complaints procedures and the number of complaints handled; and
- the extent of the use of guidelines under s 95 and s 95A of the *Privacy Act*.¹³

14.12 The National Statement also requires HRECs to maintain a record of all proposed research projects including specified information and to preserve the protocols in their approved form. HRECs accept an obligation to provide information from their records to the NHMRC on request.¹⁴

14.13 Submissions emphasised the importance of reporting mechanisms in ensuring that ethical standards, such as the National Statement are upheld.¹⁵ To ensure that strict ethical standards are upheld when using human subjects, effective regulation must provide for research processes that are transparent and accountable to both research subjects and the public.¹⁶

14.14 Privacy NSW was scathing about the existing audit and reporting mechanisms relating to the implementation by HRECs of *Privacy Act* research guidelines.¹⁷

The current audit mechanism of HREC activities is scarcely adequate to enable even the NHMRC to assess the fundamental question of whether an HREC has the competence and necessary resources and procedures to weigh up the public interest in privacy and the public interest in research as required by the Section 95 and 95A Guidelines. This lack of transparency is a significant concern in light of the composition of HRECs, which may include interests that are not independent of the interests attached to the research itself. Inevitably, implementation of the Guidelines varies depending upon the personal, institutional and commercial context in which an HREC operates.¹⁸

14.15 Privacy NSW suggested a number of reforms, including that records of HREC decisions¹⁹ should be provided to research subjects, an independent national ethics review committee and the federal Privacy Commissioner.²⁰

13 Ibid, para 2.48.

14 Ibid, para 2.30–2.32; 2.47–2.47.

15 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Australian Academy of Science, *Submission G097*, 21 January 2002.

16 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

17 *Privacy Act 1988* (Cth) ss 95, 95A.

18 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

19 Eg National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 3.4; National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council, para D.6.

20 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

14.16 Other submissions also referred to the need for additional reporting. The Centre for Law and Genetics submitted that, while ‘the current annual reporting requirements by HRECs are evolving and becoming more detailed’, it was desirable that the reporting requirements in relation to human genetic research and commercial arrangements be expanded:

Applications for research approval to HRECs are the major source of information about both human genetic research and commercial arrangements. Reporting could include summary details about the number of applications, whether the approval was for identified, non-identified or potentially-identifiable samples, whether there was any waiver of the general consent requirement and whether the commercial arrangements provided full or partial funding and whether there were any specific restrictions on publications.²¹

14.17 The Australian Academy of Science also considered that there should be a more comprehensive reporting system for applications that come before HRECs and their outcomes and that these changes ‘would allay some concerns over pressures on the system due to commercial arrangements’.²²

14.18 Other submissions were concerned that additional reporting obligations may be unnecessary and place further stress on the system for ethics review without any significant countervailing benefit.²³ The NHMRC Research Committee considered that it would be ‘counterproductive’ to add more reporting requirements:

Pressure on researchers and HRECs has continued to mount over the years, and it would be counterproductive to add more reporting requirements, or other demands at either the researcher or HREC levels. This is not to say that changes might be beneficial, but if so, they should be seen within the global context so that changes at one level lead to a relaxing or facilitation of the regulatory process rather than just adding another layer of bureaucracy.²⁴

14.19 One HREC member stated that

Although there may be slight variation in the performance of HRECs it is not necessary to introduce different mechanisms of accountability. Annual reports of HRECs to their institutions and to AHEC are adequate.²⁵

21 Centre for Law and Genetics, *Submission G048*, 14 January 2002. The AHEC Human Research Ethics Committee Annual Report form for the year to 30 June 2001 requires HRECs to report on, among other things, the number of research proposals approved and the number that did not receive ethical approval.

22 Australian Academy of Science, *Submission G097*, 21 January 2002.

23 D Cavaye, *Submission G110*, 14 March 2002; National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

24 National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

25 D Cavaye, *Submission G110*, 14 March 2002.

14.20 As discussed in Chapter 12, the Inquiry has concluded that HRECs should be required to report annually to AHEC on human genetic research proposals for which waiver of consent has been granted (Proposal 12–1).

14.21 The Inquiry will continue to examine whether HREC reporting requirements should also be augmented in other ways and is interested in further comments on this topic.

Monitoring of human genetic research by HRECs

14.22 Research organisations and HRECs have responsibilities to ensure that there is appropriate monitoring of approved research projects. The frequency and type of monitoring is determined by the HREC and should reflect the degree of risk to participants.²⁶

14.23 The National Statement provides that, as a minimum, an HREC must require, at least annually, reports from principal researchers on matters including progress to date (or outcome) of the research; maintenance and security of records; compliance with the approved protocol and with any conditions of approval.²⁷

14.24 Additional monitoring mechanisms may be implemented. HRECs are directed to require that researchers report immediately anything that might warrant review of the ethical approval of the project including serious or unexpected adverse effects on participants, proposed changes to the protocol and unforeseen events that might affect continued ethical acceptability of the project.²⁸ HRECs are to impose, as a condition of approval, the requirement that researchers inform the HREC, with reasons, if the research is discontinued before the expected date of completion.²⁹

14.25 As the focus of this inquiry is human genetic research, respondents were not expected to raise general issues of monitoring of research. AHEC has observed that monitoring of clinical trials, especially those sponsored by pharmaceutical companies, is quite extensive and sophisticated, while the monitoring of other research varies widely across institutions. This is not seen to be an urgent issue by AHEC, but it is agreed that more attention will need to be paid by institutions and their HRECs to the monitoring of high risk human research in the future.

26 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.33–2.34.

27 Ibid, para 2.35, 2.36.

28 Ibid, para 2.37.

29 Ibid, para 2.38.

14.26 The Inquiry has received differing views on the adequacy of the current monitoring requirements. Some individuals and organisations were critical of the existing arrangements for monitoring of research by HRECs. However, the resource implications of implementing more onerous monitoring were also widely recognised.

14.27 The NSW Genetics Service Advisory Committee stated that there should be uniform policies and guidelines with regards to the reporting and monitoring requirements of HRECs.³⁰ Privacy NSW submitted that monitoring should be conducted by HRECs throughout the research period and that the current minimum requirement of annual inspection was inadequate.³¹ Professor Nick Saunders and Associate Professor Paul Komesaroff stated that, in general, HRECs do not effectively monitor approved research.

It is likely that to achieve adequate monitoring a fundamental change in approach will be needed, including possibly routine questioning of research participants. This is an important question that will in due course require detailed attention.³²

14.28 In this context, the NHMRC Research Committee emphasised the resource constraints on monitoring:

Monitoring of research by HRECs presently requires annual reports and the HREC can undertake further monitoring if this were felt to be essential. Again, the administrative load currently required of a HREC would make the requirement for more active or frequent monitoring difficult to implement unless some other part of the regulatory process could be relaxed or simplified.³³

14.29 The Queensland University of Technology stated that it currently exceeds the requirements in the National Statement by conducting 'limited random audit of active ethical clearances'. The University submitted that this approach should be considered as an additional minimum monitoring requirement. The University is also in the early stages of considering compliance audits to capture research not submitted for review.³⁴

14.30 The Inquiry does not intend to make any specific proposal to amend the provisions of the National Statement in relation to the monitoring of human genetic research. The existing provisions are flexible and allow HRECs to monitor the conduct of human genetic research to the extent that they deem appropriate, or practicable.

30 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

31 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

32 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

33 National Health and Medical Research Council Research Committee, *Submission G128*, 18 March 2002.

34 Queensland University of Technology, *Submission G109*, 14 March 2002.

14.31 The Inquiry is not in a position to judge whether the monitoring currently done by HRECs is sufficient. However, if monitoring procedures are currently insufficient, it is likely that any solution to this problem will be fundamentally a question of the resources made available to HRECs by the organisations and institutions within which they are located.

Membership of HRECs

14.32 The National Statement prescribes the required membership of HRECs. An HREC must comprise:

- a chairperson;
- at least one man and one woman who have no affiliation with the institution, are not currently involved in medical, scientific or legal work and who are preferably from the community in which the institution is located;
- at least one person with knowledge and current experience in the areas of research regularly considered by the HREC;
- at least one person with knowledge and current experience in professional care, counselling or treatment of people;
- at least one person who is a minister of religion or who performs a similar role in the community; and
- at least one person who is a lawyer.³⁵

14.33 The membership of an HREC must be such that it will be able to address all relevant considerations arising from the categories of research submitted to it and the HREC must ensure that it is sufficiently informed on all aspects of each research protocol relevant to deciding whether the protocol is acceptable on ethical grounds. Appointment of additional members with relevant expertise may be necessary, but in making additional appointments institutions should maintain the diversity of categories of members and the relative proportion between institutional and non-institutional members.³⁶

14.34 AHEC has redesigned its annual compliance reporting format to obtain more complete information about the balance of institutional versus non-institutional membership of HRECs. A limited survey of a range of HRECs from the hospital and university sectors conducted earlier in 2002 showed that on

35 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.6.

36 Ibid, para 2.7–2.9.

average three or four of the seven core membership categories were filled by persons who had no affiliation with the institution, although this varied quite widely.

14.35 Some submissions expressed concerns about the existing membership composition of HRECs. In the expressing concern about the perceived inadequacies in the audit of HRECs, Privacy NSW stated that:

This lack of transparency is a significant concern in light of the composition of HRECs, which may include interests that are not independent of the interests attached to the research itself. Inevitably, implementation of the Guidelines varies depending upon the personal, institutional and commercial context in which an HREC operates.³⁷

14.36 As noted above, there need only be two members of the HREC who have no affiliation with the institution. In consultations, concerns have been expressed that independent HREC members may be disempowered in their contributions to the review process by a preponderance of institutional members, who may be employees of the research organisation whose research proposals are being reviewed and other members with specialist expertise.³⁸

14.37 An alternative view is that institutions are entitled to have their own interests and values maintained by the appointment of persons who hold the values of the institution strongly, including staff members, and that such persons also understand that the primary purpose of the HREC is to protect the interests of human participants. It is not in the interests of institutions to be seen to support unethical research.

14.38 Associate Professor Paul McNeill has written that internationally there is a trend towards stronger community representation on ethics review committees. This consists of a growing trend for equal or greater number of community members on committees, chairpersons to be elected from community members, the selection of people 'of standing' as community members who are more capable of withstanding pressure from other committee members, and suggestions that community members represent research participants or particular groups of participants.³⁹

37 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

38 See more generally M McNeill, 'International Trends in Research Regulation: Science as Negotiation' in, *Research Ethics* (1999) Elsevier Science, Oxford, 243.

39 Ibid, 254.

Structure of ethics review

14.39 The National Statement requires research proposals to be reviewed by an HREC of the prescribed composition. However, there is nothing to prevent organisations from applying additional levels of review or delegate functions to subcommittees.⁴⁰

14.40 The Peter MacCallum Cancer Institute ethics review process utilises a two-stage review process. Research proposals are first reviewed by a biomedical committee, in relation to the scientific and research value of the proposals, and then by an HREC. One perceived advantage of this approach is that the composition of the HREC may more easily lean towards non-expert and non-institutional members.⁴¹

14.41 Two-stage review may also be used to review issues arising out of human genetic research involving collectivities — including research involving Aboriginal and Torres Strait Islander peoples. The Joint Human Research Ethics Committee of the Menzies School of Health Research and the Royal Darwin Hospital convenes an Aboriginal Sub-committee that reviews such research proposals. The sub-committee is assisted by a scientific advisor and reviews proposals, consults with leaders of the relevant Aboriginal communities and where ethical concerns remain, may veto the research.⁴²

14.42 Some submissions suggested that human genetic research should be subject to a more centralised system of ethics review.⁴³ For example, Privacy NSW suggested the establishment of ‘an independent, national ethics review committee with substantial lay and community representation’ and ‘a single, independent and transparent complaints mechanism to deal with decisions made by any HREC’.⁴⁴

14.43 This would represent a significant change to the present system. In Australia, as in the United States, Canada, New Zealand and the United Kingdom, ethics review committee are based in an institution, usually a research institution

40 Eg the *Human Research Ethics Handbook* notes that appropriate task-based subcommittees might include scientific review sub-committees, committees for conducting expedited review of low-risk research, discipline-based subcommittees for review of research related to degree qualifications, other special-purpose subcommittees and policy subcommittees: National Health and Medical Research Council, *Human Research Ethics Handbook* (2002), National Health and Medical Research Council, Canberra, E77.

41 Peter MacCallum Cancer Institute, *Consultation*, Melbourne, 15 March 2002.

42 Menzies School of Health Research, *Consultation*, Darwin, 18 March 2002.

43 L. Martinovic, *Submission G006*, 30 May 2001; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

44 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

within which the research is conducted, or are established within a regional authority, such as an area health service.⁴⁵

14.44 The current ethics review model combines peer review and community involvement. In comparison, a national committee may be seen as representing a 'top-down' model — the prescription of research ethical values by a government appointed body. A centralised system of ethics review would ignore the legitimate interests of institutions in establishing and adhering to institutional values and not having these over-ridden by a national appeals body. Ethical review decisions are not legal decisions and it is not automatically wrong if two HRECs come to different decisions about the ethical implications of a research proposal.

14.45 Centralisation of the ethics review process to a national committee may also be impractical. The volume of research proposals that require review can be expected to exceed the capacity of a single national review body to deal with them. The resource implications of establishing such a committee would be significant.

14.46 There seems no logical reason to establish a national ethics committee to review only human genetic research (however defined) and not other research involving humans. While human genetic research does involve a particular constellation of ethical issues, the ethical hazards are not greater than some other categories of research — such as clinical trials or research involving vulnerable persons.

14.47 One precedent for such a national advisory review committee is the Gene and Related Therapies Research Advisory Panel (GTRAP). GTRAP is an NHMRC subcommittee established to provide the NHMRC and HRECs with advice on human gene therapy trials, and to assist researchers in the establishment of best practice standards.⁴⁶ Although GTRAP is primarily an advisory body it now plays a role in an extended approval process for human gene therapy trials. AHEC has stated that HRECs should not approve research that involves gene therapy without the prior approval of both the Institutional Biosafety Committee and GTRAP.⁴⁷

14.48 This review process was thought necessary because the technology involved 'novel approaches to treatment, the short or long term potential for harm was still undetermined, and it would be difficult for HRECs to gain expertise as the number of research studies would be small'.⁴⁸ It needs to be emphasised that this

45 M McNeill, 'International Trends in Research Regulation: Science as Negotiation' in, *Research Ethics* (1999) Elsevier Science, Oxford, 243.

46 National Health and Medical Research Council, *Gene and Related Therapies Research Advisory Panel (GTRAP)*, <<http://www.health.gov.au/nhmrc/research/gtrap/about.htm>>, 23 July 2002.

47 Australian Health Ethics Committee, *Information Sheet for HRECs #2* (2001) Australian Health Ethics Committee.

48 National Health and Medical Research Council, *Gene and Related Therapies Research Advisory Panel (GTRAP)*, <<http://www.health.gov.au/nhmrc/research/gtrap/about.htm>>, 23 July 2002.

approach by the NHMRC was specifically based on the possibility that human gene therapy might accidentally affect the germ cell line and that therefore it was unreasonable that a single HREC be expected to make ethical judgements on such studies without access to the best available scientific advice.

14.49 While some genetic research may be in that category much will not be. HREC members do need expertise to understand the complexities of genetic information. This need may be best addressed by adding appropriately qualified new members to HRECs and through education and training initiatives.

Review or accreditation of HRECs

14.50 In 1996, the *Report of the Review of the Role and Functioning of Institutional Ethics Committees* received submissions suggesting a need for greater transparency, monitoring and supervision of HRECs.⁴⁹ However, the report stated there was

no persuasive evidence of unsatisfactory or poor conduct in the current operation of IECs [as HRECs were then known] to justify the introduction of more stringent inspection (for example, external independent audits) of IECs. Independent audits and the like should not be routinely introduced and should be a 'last-choice' option used when there is evidence of misconduct. There was little support in the submissions for the conduct of random audits.⁵⁰

14.51 The review concluded that the most effective method for ensuring the accountability of the institutional ethics committee system was through reporting by such committees to AHEC and by AHEC to the NHMRC.⁵¹

14.52 There continues to be debate about the accountability of the HREC system. The House of Representatives Standing Committee on Legal and Constitutional Affairs, in its inquiry into human cloning and stem cell research, heard evidence criticising the structure and operation of HRECs including 'the lack of public accountability in the process and the in-house nature of committees' and the non-representative nature of their membership.⁵² The Committee recommended in September 2001, that the federal government establish an independent review of the institutional ethics committee system in Australia.

49 D Chalmers, *Report of the Review of the Role and Functioning of Institutional Ethics Committees: Report to the Minister for Health and Family Services* (1996), Commonwealth of Australia, Canberra.

50 Ibid, 54.

51 Ibid, 54.

52 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Parliament of the Commonwealth of Australia, Canberra, 162–65.

14.53 It has been suggested that there should be serious consideration of instituting a system for the accreditation of HRECs.⁵³ The term accreditation is capable of referring to a wide range of processes, from simple registration based on annual returns, to detailed scrutiny of committee procedures and decision making processes. Depending on its nature, an accreditation role may be beyond the present functions and powers of AHEC.

14.54 In Canada, a task force set up by the National Council on Ethics in Human Research (NCEHR) recommended in March 2002 that the NCEHR affirm the need for a nationwide oversight process for ethics review taking the form of an accreditation program to be conducted by 'an arm's-length, non-governmental organization'.⁵⁴ The entities to be accredited would include Research Ethics Boards (the Canadian equivalent of HRECs).

14.55 An AHEC working party is currently developing policies relating to ongoing review of HRECs by their institutions. One proposal being considered would require all institutions, to remain eligible for research funding, to conduct a review every three years of their processes for review and monitoring of human research. The review would be conducted by reference to standards established and published by the NHMRC and the Australian Research Council.

Resources for HRECs, HREC members and researchers

14.56 Concerns were expressed in submissions and in consultations about the resources available to HRECs. For example, the Office of the Federal Privacy Commissioner (OFPC) argued that while the current structures for ethics review are 'fundamentally sound' there needs to be sufficient resources made available to support members of HRECs.⁵⁵

The current HRECs structure currently depends heavily on the good will of respected members of Australian society, who generously give their already limited time to this very important process. HRECs are finding it increasingly difficult to meet additional obligations and processes as they are introduced.⁵⁶

14.57 The OFPC submitted that, in order to preserve the integrity of the HREC review process, adequate funding should be allocated to enable HREC members to appropriately perform their duties, proper administrative and secretarial support be made available and appropriate training and research support for HRECs provided.

53 D Chalmers, *Correspondence*, 8 May 2002.

54 The National Council on Ethics in Human Research, *Final Report of the Taskforce to Study Models of Accreditation for Human Research Protection Programs in Canada* (2002), The National Council on Ethics in Human Research, Ottawa.

55 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

56 Ibid.

Unless this significant additional assistance is provided, HRECs may not be in a position to meet their critical responsibilities in the manner that society expects. With the further demands and challenges of genetic research, such measures are essential.⁵⁷

Education and training

14.58 The Queensland University of Technology submitted that there is a need for greater resourcing for exchange of information between HRECs; the promotion of excellence in the area; training for HREC members; and training for researchers.

14.59 The need for education and training of HREC members was recognised by the 1996 *Report of the Review of the Role and Functioning of Institutional Ethics Committees*.⁵⁸ The report recommended that AHEC should develop a statement of core competencies for IEC members to assist in the development of courses for their in-service training and that institutions should make available sufficient (ongoing) funding to enable their IEC members to take up opportunities for such training and development.⁵⁹

Payment of HREC members

14.60 A related issue concerns payment of HREC members. Many HREC members are employed by the institution within which the HREC is located (institutional members). While institutional members may be remunerated for work connected with service on HRECs (as it forms part of their duties of employment) non-institutional members are usually unpaid.⁶⁰ It has been suggested that this may present a barrier to the effective operation of HRECs.

Because non-institutional members are volunteers, one feels constrained not to ask too much of them and so meetings are not scheduled frequently enough. I believe the solution is to offer payment for attendance at [HREC] meetings at consultancy rates, so the institution does not feel embarrassed at calling on people's voluntary time. I see no conflict of interest for members in accepting such payments, any more than should be felt by any other consultant such as an auditor. Of course, [HREC] members are free to waive their fee if they prefer that their service be seen as for the public good, but this should not be expected. I believe that only in this way can IECs attain the efficiency now required for their important role in the regulatory process for medical research.⁶¹

57 Ibid.

58 D Chalmers, *Report of the Review of the Role and Functioning of Institutional Ethics Committees: Report to the Minister for Health and Family Services* (1996), Commonwealth of Australia, Canberra, Ch 7.

59 Ibid, rec 14–15.

60 Some institutions pay non-institutional members eg the Alfred Hospital in Melbourne pays HREC members \$150 per meeting.

61 N Martin, *Correspondence*, 22 April 2002.

14.61 Commonwealth agencies with HRECs pay sitting fees to non-institutional members on the Remuneration Tribunal scale. This applies, for example, to non-institutional members of HRECs in the Australian Institute of Health and Welfare, the Departments of Health and Ageing and Defence.

14.62 Such fees may not be affordable for some universities or hospitals whose committees meet monthly. There may also be other reasons to suggest that simply making payment of non-institutional members the norm may not necessarily improve the system of ethics review.

14.63 Most people who agree to assist institutions in the operation of HRECs do so for altruistic reasons. Formalising the HREC system, including by introducing payments, may make it less likely for HRECs to attract members (or the right sort of members). Time, rather than money, may be the more important limiting factor on member's involvement in ethics review. There may be better ways to optimise the use of member's time, for example by finding ways to streamline ethics approval of low risk research or by augmenting HREC secretariat resources.

14.64 The *Report of the Review of the Role and Functioning of Institutional Ethics Committees* concluded that the appropriateness of payment to IEC members was an issue to be determined by individual institutions.⁶²

Advice for HRECs on review of human genetic research proposals

14.65 Some submissions suggested that HRECs need further sources of advice on ethical considerations related to human genetic research. The Australian Academy of Science stated that

there are many HRECs that are facing new challenges in areas such as genetics. Each HREC has the responsibility to consider each proposal on its merits, but we recommend that there should be a system in place where HRECs can ask for advice from a central body. If a Standing Advisory Group on Human Genetics is established, either it, or the Australian Health Ethics Committee, or the two together, could fill this role.⁶³

14.66 In this context, the NSW Genetics Service Advisory Committee suggested that it should be explicitly stated that AHEC membership must include a member with experience in human genetics.⁶⁴

62 D Chalmers, *Report of the Review of the Role and Functioning of Institutional Ethics Committees: Report to the Minister for Health and Family Services* (1996), Commonwealth of Australia, Canberra, para 6.2.

63 Australian Academy of Science, *Submission G097*, 21 January 2002.

64 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

Research compliance costs

14.67 In consultations and submissions, medical researchers expressed concern about the costs involved in complying with ethics review and other requirements. For example, Professor Nick Martin, Head of the Queensland Institute of Medical Research stated:

We receive no extra budget to cope with compliance costs, and inevitably this means less research gets done. For example, simply to comply with ethical requirements for my own projects requires 1.5 FTE positions. In the US, the National Institutes of Health have now recognised this and now add 8% for compliance costs to all successful grants. I hope that your report will recommend a similar measure here. The government and community have to recognise that they simply cannot have this degree of regulation without paying for it. Furthermore, the amount of time now required to look after compliance issues greatly decreases job satisfaction for scientists and I know many who are now actively avoiding tackling important clinical problems for this reason. I don't believe this is in the community's best interest.⁶⁵

Conclusion

14.68 The Inquiry is concerned not to 're-invent' the present regulatory framework for review of research proposals by HRECs, the development of which followed a period of extensive consultation prior to the publication of the National Statement in 1999.

14.69 The Inquiry observes that many of the reforms relating to the operation of HRECs proposed in submissions and in consultations do not relate solely to issues connected with human genetic research, as compared to the conduct of medical and other human research generally.

14.70 Many of the issues raised were the subject of recommendations made by the 1996 *Report of the Review of the Role and Functioning of Institutional Ethics Committees*⁶⁶ and have been, or are currently under, active consideration by AHEC.

14.71 Nevertheless, the Inquiry remains interested in further comment on the implications of human genetic research for the operation of HRECs and the system of ethics review generally.

⁶⁵ Queensland Institute of Medical Research, *Submission G036*, 14 January 2002.

⁶⁶ D Chalmers, *Report of the Review of the Role and Functioning of Institutional Ethics Committees: Report to the Minister for Health and Family Services* (1996), Commonwealth of Australia, Canberra.

Question 14–1. Are any changes needed to the reporting obligations of HRECs under the National Statement in order to enhance the operation of the current system of ethical review?

Question 14–2. Should HRECs be required to report to AHEC specifically on commercial arrangements relating to human genetic research proposals?

Question 14–3. Are the current minimum monitoring requirements adequate for human genetic research projects? Are there certain categories of human genetic research that require more active scrutiny by HRECs? If so, what changes should be made to the National Statement?

Question 14–4. How else might the role of HRECs in ethical review be strengthened? For example, should HRECs be accredited or should there be changes to their structure, composition or resourcing?

Part E. Human Genetic Databases

15. Human Genetic Research Databases

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Introduction

15.1 This chapter is concerned with the collection, use, storage and disclosure of genetic samples and genetic information, which have been collected primarily for use in research and are held in collections by hospitals, public and private research organisations, and in the archives of pathology laboratories (referred to in this Chapter as ‘human genetic research databases’).

15.2 Increasingly, researchers are compiling collections of genetic samples and related genetic and other health information to aid studies into the causes of disease, drug reactions and environmental interaction with genetic status.

Genetic databases are now helping elucidate gene function, estimate the prevalence of genes in populations, differentiate among subtypes of diseases, trace how genes may predispose to or protect against illnesses, and improve medical intervention.¹

15.3 The importance of human genetic databases has come in part as a result of developments in the field known as ‘bioinformatics’. Bioinformatics combines computer science, biology and mathematics to produce tools that enable the storage and analysis of large quantities of biological, particularly genetic, information.² The advent of this science has lent new value to large collections of genetic material and information, allowing researchers to perform studies on a scale impossible previously.

15.4 This chapter begins by explaining what we mean by the terms ‘human genetic database’ and ‘human genetic research database’ and describes (with reference to Australian and overseas examples) how these databases are comprised and how they are used in research.

15.5 The chapter then examines aspects of the existing regulatory framework that applies to the operation of human genetic research databases. As with other aspects of research involving humans, the relevant regulatory framework is currently centred on the National Health and Medical Research Council’s (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement)³ and relevant statutory restrictions on dealing with personal information, including genetic information, under the *Privacy Act 1988* (Cth) (*Privacy Act*)⁴ and similar state and territory legislation.

15.6 The central question for the Inquiry is whether, in addition to the reforms suggested elsewhere in this Discussion Paper that relate to human genetic research more generally (see Chapters 11–14), there should be additional regulation of the operation of human genetic research databases. In this context, issues and concerns raised by such databases are examined and options for reform, including the implementation of a licensing or registration scheme, canvassed.

What are human genetic research databases?

15.7 The term ‘human genetic database’ may be used to refer to many kinds of collections of genetic samples and genetic and other health information in various combinations.

1 W Lowrance, ‘The Promise of Human Genetic Databases’ (2001) 322 *British Medical Journal* 1009.

2 K Dearne, ‘Biotech Industry Booming’, *The Australian*, 14 May 2002, 3.

3 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

4 And related guidelines: National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra; National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (2001) National Health and Medical Research Council.

15.8 Genetic samples contained in collections can include any of a wide range of human biological materials such as extracted DNA, body fluids, cells and sections of tissue. The information in a human genetic database may include molecular genetic data, standardised clinical data, genealogical data, and information on the health, lifestyle and environment of an individual.⁵

15.9 The sorts of samples and information contained in a collection, as well as the uses to which they are put, define many of the ethical and legal issues raised by human genetic databases. Therefore, it is necessary to more closely examine the kinds of collections which may be described as human genetic databases.

15.10 As the Centre for Law and Genetics noted in its submission,⁶ there is currently no accepted definition of what is meant by a human genetic database. The Issues Paper⁷ referred to one definition, used by the House of Lords Select Committee on Science and Technology in its 2001 report.⁸ The report defined human genetic databases as:

[C]ollections of genetic sequence information, or of human tissue from which such information might be derived, that is or could be linked to named individuals.⁹

15.11 The House of Lords definition is very broad and anticipates that such databases may contain samples alone, information alone,¹⁰ or linked combinations of the two. Other definitions have emphasised the systematic nature of collections. The World Health Organization has defined a genetic database as

any methodical or systematic collection of data, structured in a fashion that allows accessibility to individual or collective elements of that database by electronic, manual or any other means.¹¹

15.12 Other terms such as 'biobank', 'gene bank' and 'tissue bank' have also been used to denote what this chapter refers to as 'human genetic research databases'. These additional terms demonstrate the lack of consensus over what is meant by a genetic database, which itself stems from the diversity of the collections that exist.

5 W Lowrance, 'The Promise of Human Genetic Databases' (2001) 322 *British Medical Journal* 1009.

6 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

7 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 7.1.

8 House of Lords Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2001), The Stationery Office Limited, London.

9 Ibid, para 3.3.

10 W Lowrance, *Privacy and Health Research: A Report to the US Secretary of Health and Human Services*, Department of Health and Human Services (US), <<http://aspe.os.dhhs.gov/datacncl/phr.htm>>, 8 July 2002.

11 F Dekkers and others, *Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights* (2001), World Health Organization, Geneva, 6.

15.13 For example, the term ‘biobank’ has been used in Sweden and the United Kingdom. In the United Kingdom, the ‘BioBank UK’ project encompasses the collection of blood samples and health and lifestyle information.¹² In Sweden the term has been used more restrictively to mean:

collections of tissue specimens which have been taken from human beings, which are collected and preserved for an indefinite or a definite period for a certain specified purpose and whose origin is traceable.¹³

15.14 Legislation establishing the Estonia Genome Project defines a ‘gene bank’ as:

a database established and maintained by the chief processor consisting of tissue samples, descriptions of DNA, descriptions of state of health, genealogies, genetic data and data enabling the identification of gene donors.¹⁴

15.15 In Australia, the term ‘tissue bank’ is often used to denote collections of genetic material that may be used in human genetic research — for example in the case of the West Australian Tissue Bank and the Peter MacCallum Cancer Institute tissue bank.

15.16 For the purposes of this Chapter, the Inquiry has chosen to use the term ‘human genetic research databases’. This term is used to refer broadly to collections of genetic samples and information (including genetic information, medical and other health records, genealogical information and environmental information) in any of the various possible combinations. The unifying element is that the databases have been created primarily for the purposes of medical or other human research.¹⁵

Other human genetic databases

15.17 Other types of collections that could be used as human genetic research databases exist, though they were not collected for that purpose. These include pathology collections, Guthrie cards (and other collections maintained as part of a newborn or population screening program). Collections of this kind may have great value for research as they include samples taken over a long period of time, or

12 People Science and Policy Ltd, *BioBank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust* (2002), Medical Research Council and the Wellcome Trust, London, 8.

13 Swedish National Board of Health and Welfare, *Biobanks in Medical Care*, <www.sos.se/sos/publ/refereng/0077011e.htm>, 9 July 2002.

14 *Human Genes Research Act 2000* (Estonia) s 2(10).

15 Such databases may differ in their intended uses. Some may be maintained for the study of a specific genetic condition, such as Tay-Sachs disease. Others will be used in many different types of genetic research.

from a unique class of patients. These databases and issues related to their regulation are examined in Chapter 16.¹⁶

Research value

15.18 Much of the research value of human genetic research databases is derived from the linkages created between clinical, personal and genetic information. Examining these linkages is an important tool in identifying the genetic causes of disease and other forms of human genetic research.

15.19 For example, databases are particularly valuable for pharmacogenetics — the study of genetic causes of variable drug responses. By linking clinical records with genetic information, genetic databases enable researchers to correlate the effects of medication and variations in genetic makeup on a scale large enough to produce statistically significant results. As a result, many pharmaceutical and biotechnology companies are seeking access to human genetic databases or building their own collections.

15.20 A number of different forms of genetic research can be conducted using human genetic databases. These include:

- linkage studies to identify the gene sequences associated with inherited diseases;
- association studies to find a correlation between a disease and a genetic change where there is no obvious pattern of inheritance;
- genetic epidemiology studying the interaction between genes and the environment; and
- pharmacogenetic studies to determine if there is a genetic basis for certain adverse reactions to drugs.¹⁷

15.21 Each of these studies requires access to a different type of human genetic database, or uses such databases in a different way, and may raise different issues.¹⁸ Some linkage studies involve mapping genetic sequences to identify the genetic changes linked to the existence of a particular inherited disorder. Such studies are carried out where a distinct familial pattern of disease inheritance can be seen. They require collections of tissue taken from family members and information as to which members suffer from the disorder.¹⁹

16 Human genetic databases created for law enforcement and forensic purposes are discussed in Part J.

17 J Kaye and P Martin, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (1999), Wellcome Trust, London, 9–13.

18 Ibid, 11 and following.

19 Ibid, 10–11.

15.22 By contrast, association studies require large collections of samples from people with a given condition, combined with detailed medical histories of symptoms. These studies examine the genetic causes of diseases that do not follow a clear inheritance pattern, and attempt to make statistical correlations between particular gene sequences and that disease. It is necessary to study large populations because such diseases may show a marked genetic cause in only some individuals, or a weak genetic cause in many individuals. Large populations also increase the accuracy of statistical correlations.²⁰

15.23 Epidemiological genetic studies examine the interaction between genetic and environmental factors in causing diseases and susceptibilities. Studies of this type require access to very large population collections that include detailed medical histories.²¹

15.24 Pharmacogenetic studies are a form of study that examines possible associations between adverse drug reactions (and other forms of variable drug response) and genetic factors. These studies require access to collections of samples taken from people who have displayed adverse reactions to the drug in question, linked with medical information about previous drug therapy and their reactions to it.

Examples of human genetic research databases

15.25 In some cases, human genetic research databases have been built up by research organisations for use in their own studies. Genetic samples and information may be collected from a specific type of patient for a group of related research projects to be carried out by the organisation that controls the sample collection. Other researchers may be granted access to the database.

15.26 One such example is the tissue bank maintained by the Peter MacCallum Cancer Institute, which was established in 1998 to permit a number of molecular genetic studies in cancer.²² Cancerous tissue is obtained from patients via surgical and pathology staff, who liaise with the tissue bank. Patients give broad consent to the storage and use of their tissue in research, and the tissue remains identified to allow continued collection of clinical information that will be used in conjunction with the tissue sample as part of ongoing research.

15.27 Another Australian human genetic research database is that maintained by the Menzies Centre for Population Research. The Menzies Centre combines extensive genealogical data, genetic samples, and health information supplied by donors, to search for genetic causes of disease. The Menzies Centre is a division of

20 Ibid, 11–12.

21 Ibid, 12–13.

22 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

the University of Tasmania and all material is donated by volunteer research participants specifically for the Centre's research projects.²³

15.28 Human genetic research databases may also be created on a much larger scale to encompass genetic samples and information from very large sections of the population. They may also be used for a wide variety of research projects by different groups of researchers. The Estonian Genome Project, the Iceland deCODE project and BioBank UK are examples of such databases.

15.29 In Estonia, a non-profit government project to form a database of the genetic information from three-quarters of the country's population is underway. The centralised electronic database will contain blood samples and health data information, each collected and stored separately, to be used for large-scale association studies. Control of the database is split between the Estonian Genome Project Foundation (the government body that will own the database) and Egeen (the exclusive commercial licensee that also finances the project). Egeen will have access to the database for research into the causes of disease and to develop drugs and treatments.²⁴

15.30 A similar project has already been undertaken in Iceland, by deCODE, a company that holds an exclusive licence to create and operate a database of genetic and other health information, known as the Iceland Health Sector Database. The project brings together three types of information — coded health information taken from Iceland's national health care system records; genealogical data; and genetic information from samples taken obtained and analysed with the consent of Icelandic donors.²⁵

15.31 These two projects both involve an exclusive licence for access to medical and genetic information, as well as to the genetic samples. They demonstrate the commercial and national economic interest in databases that has developed, as the importance of such databases for research has grown. In each case, genetic information is not publicly available, but is controlled in part by commercial entities.

15.32 A different approach to the development of a major genetic research database has been taken in the United Kingdom. BioBank UK is a publicly funded project to collect samples and health information from 500,000 volunteers in

23 Menzies Research Institute, *Home Page*, <<http://www.menzies.utas.edu.au/>>, 23 July 2002.

24 Estonian Genome Foundation, *Genome Project*, <<http://www.genomics.ee/index.php?lang=eng&show=20>>, 23 July 2002; Guardian Unlimited, *Estonia Sells its Gene Pool*, <<http://www.guardian.co.uk/science/story/0,3605,394691,00.html>>, 23 July 2002.

25 DeCODE Genetics, *Home Page*, <www.decode.com>, 23 July 2002. See also H Rose, *The Commodification of Bioinformation: The Icelandic Health Sector Database* (2001) Wellcome Trust; H Greely, 'Iceland's Plan for Genomics Research: Facts and Implications' (2000) 40(2) *Jurimetrics* 153; H Jonatansson, 'Iceland's Health Sector Database: A Significant Head Start in the Search for the Biological Grail or an Irreversible Error?' (2000) 26(1) *American Journal of Law and Medicine* 31.

Britain. The project aims to provide sufficiently comprehensive health information and a large enough sample size to enable more effective studies of the interaction between genotype and environment. Participants will also supply updated medical and environmental exposure information every five years.²⁶

15.33 Researchers will be given access to the central database following application and approval from an oversight body. The project differs from the deCODE and Estonian projects, both of which involve an exclusive commercial partner, as BioBank UK is funded entirely by public funds and its information is made publicly available to researchers.²⁷

Regulation of human genetic research databases

15.34 The collection, storage, use and disclosure of genetic samples and information held in human genetic research databases is regulated by a mixture of legislation, guidelines and standards. These include:

- the legislative framework for the protection of information and health privacy based on the *Privacy Act* and similar state and territory legislation (see Chapter 7);
- State and territory Human Tissue Acts, which require varying forms of consent for donation of human tissues for research; and
- ethical guidelines, particularly the National Statement²⁸ (see Chapters 12–14), and the Human Genetics Society of Australasia's *Guidelines for Human DNA Banking* (the HGSA Guidelines).

Information and health privacy legislation

15.35 Chapter 7 briefly summarised the existing legislative framework for the protection of information and health privacy based on the *Privacy Act* and similar state and territory legislation,²⁹ and its application to the privacy of genetic samples and information.

26 Wellcome Trust, *Biobank UK: A Study of Genes, Environment and Health*, <www.wellcome.ac.uk/en/1/bioenpop.html>, 23 July 2002; K Staley, *Giving Your Genes to BioBank UK: Questions to Ask* (2001), GeneWatch UK, Buxton.

27 Medical Research Council and the Wellcome Trust, *Draft Protocol for BioBank UK: A Study of Genes, Environment and Health*, 1 February 2002, 2.3.1.

28 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

29 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Information Privacy Act 2000* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT).

15.36 The *Privacy Act*, and similar state and territory legislation, is intended to protect the personal information of individuals and to give them control over how that information is collected, used and disclosed. Such legislation sets out certain safeguards that organisations must observe in collecting, storing, using and disclosing personal information. It also gives individuals rights to access and correct their own personal information.

15.37 The protection provided by information and health privacy legislation extends to genetic information and is an important element in regulating the operation of human genetic research databases. An organisation covered by information or health privacy legislation must handle genetic information (including that in a human genetic research database) in accordance with legislative privacy principles.

15.38 A range of threshold issues relevant to the adequacy of the privacy protection extended to genetic samples and information held in human genetic research databases are discussed below.

Harmonisation of health privacy law

15.39 Chapter 7 highlighted problems that arise from the absence of a comprehensive framework for consistent national regulation of health information (including genetic information) across public and private sectors, state and federal. In response, the Inquiry proposed that Commonwealth, state and territory governments should vigorously pursue the harmonisation of information and health privacy legislation as it relates to human genetic information (Proposal 7–1).

15.40 The fact that health information is subject to different protection depending on whether it is held by a Commonwealth agency, state agency or private sector organisation has particular implications for the regulation of human genetic research databases.

15.41 The federal *Privacy Act* applies to genetic information in databases maintained by federal and ACT government agencies and private sector organisations,³⁰ including private hospitals. In general, commercial organisations will be covered by the *Privacy Act* unless they are established for a public purpose by state or territory law (other than as incorporated companies).³¹

15.42 Major human genetic research databases are generally maintained by public hospitals, universities or research institutes. In most cases, as State or Territory authorities,³² these types of organisation are not covered by the *Privacy*

30 *Privacy Act 1988* (Cth) s 6C(1).

31 See *Ibid* s 6C(3)(c).

32 *Ibid* s 6C(1)–(3).

Act.³³ Instead, they may be covered by state or territory information and health privacy legislation, where it exists.

15.43 At present only New South Wales, Victoria and the ACT have privacy legislation which protects health information held in their public sectors.³⁴ Some human genetic research databases are not covered by any information or health privacy legislation. For example, the database held by the Menzies Centre for Population Research, an organisation within the University of Tasmania, is not subject to privacy legislation, because no such legislation has been enacted in Tasmania.

15.44 It may not be clear which, if any, privacy legislation will apply where researchers affiliated with hospitals or universities are funded by an external source or work in collaboration with private sector organisations. In such instances, the application of legislation may need to be considered on a case-by-case basis taking into account factors like the nature of the contract, if any, between the researcher and funding body, and the impact of the funding on the relationship between the university or hospital and the researcher.³⁵

15.45 For example, the Murdoch Children's Research Institute carries out genetic research using samples and information obtained from the Royal Children's Hospital and is affiliated with the University of Melbourne. Researchers are employed by the Institute, an incorporated company covered by federal *Privacy Act*. The hospital and university are covered by the Victorian legislation. Researchers may therefore have access to genetic samples and information held by a public hospital, covered by state health privacy legislation, but themselves be covered by the federal *Privacy Act*.³⁶

15.46 Concerns about the lack of uniform, national guidelines for storage and access to genetic information were expressed in submissions.³⁷ In relation to databases, the Centre for Law and Genetics submitted that:

33 Eg most universities in Australia are State or Territory authorities eg *University of Sydney Act 1989*; *University of Tasmania Act 1992* (Tas). However, three private universities, Bond University, the University of Notre Dame, and Melbourne University Private may be covered by the federal *Privacy Act*.

34 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Privacy Act 1988* (Cth).

35 M Otlowski, 'Protecting Genetic Privacy in the Research Context: Where to From Here?' (2002) 2 *Macquarie Law Journal* 87.

36 The situation may become even more complex where public sector organisations become incorporated companies, a process which the Menzies Centre for Population Research has commenced. The Centre will continue to hold materials collected while part of the University of Tasmania.

37 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

The lack of uniform privacy legislation throughout the country remains a major issue in this area. Were the states and territories to introduce complimentary privacy legislation to the Commonwealth legislation there would be an improved framework for the protection of human genetic databases.³⁸

15.47 The discussion above highlights the potential uncertainties, in relation to the regulation of human genetic research databases, which can arise from lack of harmonisation in health privacy legislation. It constitutes additional reason for Commonwealth, state and territory governments to pursue harmonisation.

Coverage of genetic samples

15.48 In Chapter 7, the Inquiry proposed that the *Privacy Act* should be amended to cover genetic samples, as well as the genetic information derived from them (Proposal 7–2). The reasons for this proposal included that there is a gap in the existing framework for protecting the privacy of genetic samples, genetic samples are closely analogous to genetic information and the *Privacy Act* appears capable of extending appropriate privacy protection to them.

15.49 Human genetic research databases often include genetic samples and genetic information derived from the analysis of the samples (along with other health information). The samples and information are used in close association to facilitate research. Applying the same (or very similar) privacy principles to the handling of genetic samples and the information derived from them makes intuitive sense. Excluding the samples themselves from the coverage of privacy legislation poses a problem because, as discussed in Chapter 7, individual privacy rights in respect of the samples may not be asserted by the individuals from whom the samples were taken.

Retrospective application

15.50 The Issues Paper³⁹ noted that the *Privacy Act* NPPs concerning the collection, use and disclosure of information only apply to information collected after 21 December 2001.⁴⁰ Therefore, the *Privacy Act* does not constrain the use of existing information stored in human genetic research databases by private sector organisations, even where fully informed consent has not been obtained. Privacy NSW stated:

This is a very serious concern with respect to information contained in human genetic databases, including human tissue samples, collected before the commencement of the *Privacy Act*'s private sector amendments. The use of such information for purposes

38 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

39 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 7.17.

40 *Privacy Act 1988* (Cth) s 16C.

other than which it was collected should be strictly regulated and consent should generally be required for such use.⁴¹

15.51 Research organisations have emphasised the problems involved in complying with new regulation in relation to the samples collected in the past.⁴² For example, the Queensland Institute of Medical Research stated:

we feel we can comply with pretty well any new regulations as they are introduced, and these have grown more demanding over the last 15 years. What we are quite unable to cope with is the idea that use of samples or data collected in the past should have to comply with new regulations.⁴³

15.52 The cost and time associated with obtaining subsequent consent from donors to future research was discussed earlier in Chapter 12. In this context, there is clearly a tension between the competing demands of privacy and the conduct of research. In the long term, the problem may best be addressed by allowing human genetic research databases to obtain broad consent to the use of the samples they collect in future research.⁴⁴

Human Tissue Acts

15.53 The Human Tissue Acts⁴⁵ were enacted in each State and Territory, largely in response to the recommendations made by the Australian Law Reform Commission's 1977 report on *Human Tissue Transplants*.⁴⁶ The Acts regulate aspects of the donation of tissue for use in research ('scientific or medical' purposes) as well as for transplantation or therapeutic uses.

15.54 The Acts lay down consent provisions for the donation of three classes of tissues — blood, regenerative tissue and non-regenerative tissue.⁴⁷ Regenerative tissue is any tissue that can be replaced by the body after removal, while non-

41 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

42 Peter MacCallum Cancer Institute, *Submission G028*, 20 December 2001; Queensland Institute of Medical Research, *Submission G036*, 14 January 2002.

43 Queensland Institute of Medical Research, *Submission G036*, 14 January 2002.

44 See Ch 12.

45 *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

46 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), AGPS, Canberra.

47 Sperm, ova and foetal tissue are expressly excluded from the ambit of the legislation: *Human Tissue and Transplant Act 1982* (WA), s 6; *Human Tissue Act 1985* (Tas) s 5; *Transplantation and Anatomy Act 1983* (SA) s 7; *Transplantation and Anatomy Act 1979* (Qld) s 7; *Human Tissue Transplant Act 1979* (NT) s 6; *Human Tissue Act 1983* (NSW) s 6; *Transplantation and Anatomy Act 1978* (ACT) s 6; *Human Tissue Act 1982* (Vic) s 5. It should be noted that in each Act the exclusion actually only applies to donations from living persons, but the legislation has generally been taken to exclude donations from the dead also.

regenerative tissue is any tissue other than regenerative tissue.⁴⁸ Distinctions are also made between donations from living and deceased persons.

15.55 Living persons may donate blood for transfusion, for therapeutic uses or medical or scientific purposes with verbal consent.⁴⁹ It is not clear whether consent to one use constitutes consent to the other uses, but the Acts would appear to require specific consent to each use. That is, consent to transfusion does not immediately entail consent to scientific or medical purpose.

15.56 Similar provisions apply to living donations of regenerative tissue; however, consent must be in written form and may require either certification from a doctor or witnessing by a family member.⁵⁰ Non-regenerative tissue only can be donated for transplantation.⁵¹

15.57 Any tissue may be donated from a deceased person where consent to do so was expressed during life. This tissue may be donated for transplantation or therapeutic uses, or for other medical or scientific purposes. Tissue also may be donated if the donor expressed no objections during life and the senior available next of kin gives consent. In the absence of next of kin, a designated officer may also authorise removal of tissue (except in Tasmania).⁵² Only the Western Australian Act explicitly requires that tissues be used only for the purpose for which they were removed,⁵³ but this appears to be the meaning of the provisions in the remaining Acts.

48 *Human Tissue and Transplant Act 1982* (WA) s 3(1); *Human Tissue Act 1985* (Tas) s 3(1); *Transplantation and Anatomy Act 1983* (SA) s 5(1); *Transplantation and Anatomy Act 1979* (Qld) s 5(1); *Human Tissue Transplant Act 1979* (NT) s 4(1); *Human Tissue Act 1983* (NSW) s 4(1); *Transplantation and Anatomy Act 1978* (ACT) s 4(1); *Human Tissue Act 1982* (Vic) s 3(1).

49 *Human Tissue and Transplant Act 1982* (WA) ss 18, 20; *Human Tissue Act 1985* (Tas) ss 18, 20; *Transplantation and Anatomy Act 1983* (SA) ss 18, 20; *Transplantation and Anatomy Act 1979* (Qld) ss 18, 20; *Human Tissue Transplant Act 1979* (NT) ss 14, 15; *Human Tissue Act 1983* (NSW) ss 19, 21; *Transplantation and Anatomy Act 1978* (ACT) ss 20, 22; *Human Tissue Act 1982* (Vic) ss 21, 23.

50 *Human Tissue and Transplant Act 1982* (WA) ss 8, 15; *Human Tissue Act 1985* (Tas) ss 7, 9, 14; *Transplantation and Anatomy Act 1983* (SA) ss 9, 15; *Transplantation and Anatomy Act 1979* (Qld) ss 10, 12, 13; *Human Tissue Transplant Act 1979* (NT) ss 8, 10, 11; *Human Tissue Act 1983* (NSW) ss 7, 9, 12; *Transplantation and Anatomy Act 1978* (ACT) ss 8, 10, 15; *Human Tissue Act 1982* (Vic) ss 7, 9, 10.

51 *Human Tissue and Transplant Act 1982* (WA) ss 9, 16; *Human Tissue Act 1985* (Tas) ss 8, 9, 15; *Transplantation and Anatomy Act 1983* (SA) ss 10, 16; *Transplantation and Anatomy Act 1979* (Qld) ss 11, 12, 14; *Human Tissue Transplant Act 1979* (NT) ss 9, 10, 12; *Human Tissue Act 1983* (NSW) ss 8, 9, 13; *Transplantation and Anatomy Act 1978* (ACT) ss 9, 10, 16; *Human Tissue Act 1982* (Vic) ss 8, 9, 11.

52 *Human Tissue and Transplant Act 1982* (WA) s 22; *Human Tissue Act 1985* (Tas) ss 23, 24; *Transplantation and Anatomy Act 1983* (SA) ss 21, 22; *Transplantation and Anatomy Act 1979* (Qld) ss 21, 22; *Human Tissue Transplant Act 1979* (NT) ss 19, 27; *Human Tissue Act 1983* (NSW) ss 23, 24; *Transplantation and Anatomy Act 1978* (ACT) ss 27, 28; *Human Tissue Act 1982* (Vic) s 26.

53 *Human Tissue and Transplant Act 1982* (WA) s 22(3).

15.58 The Human Tissue Acts do not comprehensively regulate the collection, storage and use of tissue samples as part of human genetic research databases. For example, there are no provisions requiring that consent be informed by information about the storage and future use of samples or regulating access to or storage of samples.

15.59 In relation to consent, while the Acts require that donors be informed of the nature and effect of the removal of tissue, they do not require donors to be informed that their tissue may be stored, accessed by other researchers or linked with health information. In this context, Dr Nikolajs Zeps of the West Australian Tissue Bank stated that the Human Tissue Acts needed amending to ensure patients were provided with sufficient information about what would be done with their tissue samples.⁵⁴

15.60 IP 26 asked whether the Human Tissue Acts should be amended to regulate the collection and use of human tissue samples for genetic research.⁵⁵ The Acts could be amended to include new provisions to cover collection, storage, access to, and use of samples (including those held in human genetic research databases). There are both benefits and disadvantages to amending the Human Tissue Acts in this way, which are addressed in Chapter 17.

National Statement

15.61 The National Statement⁵⁶ does not contain any provisions dealing specifically with human genetic research databases.⁵⁷ However, many of its provisions are relevant to the operation of such databases. These provisions are briefly discussed below.

15.62 The National Statement requires that researchers ensure the confidentiality and privacy of stored genetic information, where identified or potentially identifiable.⁵⁸ Research protocols must also make clear whether information is to be stored and whether it is to be stored in identified, potentially identifiable (coded), or de-identified (not identifiable, anonymous) form.⁵⁹

54 N Zeps, *Submission G047*, 14 January 2002.

55 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 7–4.

56 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

57 With the possible exception of para 15.7, which relates to consent to the use of tissue samples held in 'banks'.

58 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.3.

59 *Ibid*, para 16.5.

Individuals should also be informed of any intention to store genetic samples or information.⁶⁰

15.63 The National Statement also provides that where research involves linkage of data sets (as would typically be the case if a research database is being used), an HREC may approve the use of identifiers to ensure that the linkage is accurate, but once the linkage has been completed the HREC should require that the resulting data be coded or de-identified.⁶¹

15.64 In the context of human genetic research databases, the requirements of the National Statement effectively mean that genetic samples and information should be placed in such a database only when the individual is aware that they will be stored.

15.65 In addition, the National Statement generally requires consent to the use of human tissue samples, genetic material and genetic information in medical research, but these consent requirements can be waived by a Human Research Ethics Committee (HREC). The provisions of the National Statement relevant to consent were discussed in detail in Chapter 12.

15.66 The National Statement lays down some ethical principles that help to regulate the operation of human genetic research databases. However, there are some specific issues that arise from the establishment and operation of large-scale research databases that might usefully be addressed by new provisions of the National Statement.

15.67 An issue of particular relevance to the operation of standing human genetic research databases is the extent to which researchers are effectively able to obtain consent for as yet unspecified future research. This issue was examined in detail in Chapter 12, in which the Inquiry proposes that the National Statement should establish new guidelines dealing specifically with obtaining consent to as yet unspecified future research (Proposal 12–2).

15.68 It was noted that some tissue banks in Australia already operate by obtaining consent to as yet unspecified future research and that there is support for mandating procedures to facilitate this process. Major human genetic research databases may not be able to operate effectively without the ability to seek broad and durable consent to the use of genetic samples and information in research, given the cost and time involved in obtaining specific consent from large numbers of donors.

60 Ibid, para 15.5(c), 16.10(j), 18.4.

61 Ibid, para 14.8. In certain circumstances, an HREC may permit personal information to be used to enable record linkage without consent: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 18.5.

15.69 There is a range of other matters relating to the operation and governance of human genetic research databases that might usefully be dealt with in a new chapter of the National Statement. For example, the chapter might deal with:

- the establishment of appropriate ethical approval processes where external researchers are seeking access to samples and information stored on the database;
- guidance on the appropriate use of independent intermediaries to hold codes linking genetic samples or information with identifiers;⁶² and
- appropriate governance structures for the operation of human genetic research databases.

15.70 Whether or not additional regulation of major human genetic research databases is recommended (see below), the National Statement should deal specifically with the ethical issues raised by the operation of standing research databases.⁶³

Proposal 15–1. The National Statement should be amended to include a new chapter providing ethical guidance on the operation of human genetic research databases.

HGSA Guidelines for Human DNA Banking

15.71 The Human Genetics Society of Australasia (HGSA) has established *Guidelines for Human DNA Banking* (the HGSA Guidelines).⁶⁴ The guidelines use the term ‘DNA bank’ and refer to collections of genetic material maintained by both clinical service groups and researchers.⁶⁵ The HGSA Guidelines set standards for banking of DNA and are directed, in part, to ensuring that possible future service needs of families will be met where DNA is stored.

⁶² W Lowrance, *Privacy and Health Research: A Report to the US Secretary of Health and Human Services*, Department of Health and Human Services (US), <<http://aspe.os.dhhs.gov/datacncl/phr.htm>>, 8 July 2002, 35–36.

⁶³ The National Statement is scheduled for formal review by AHEC during the 2003–2005 triennium, consistent with NHMRC policy to revise guidelines on a five year cycle.

⁶⁴ Human Genetics Society of Australasia, *Guidelines for Human DNA Banking*, Guidelines, 1 July 1990. The guidelines do not contain sanctions and they have no binding force. Rather, they are designed to act as guides to correct storage of DNA, and to leave regulation to any relevant NHMRC publications, including the National Statement.

⁶⁵ *Ibid.*

15.72 While the HGSA Guidelines mainly address storage of DNA in the context of clinical service, they also consider the situation where gene-mapping research of serious disorders will take on a service aspect. In recognition of this, the Guidelines state that researchers have obligations to the families they are studying. The Guidelines recommend that proper documentation should be kept and made available to whoever will be providing for the service needs of the families. Where the subject is elderly and has a reduced life expectancy, there should be a clear policy about how much of any DNA sample is used, to allow some to be set aside for future service needs. Once research has been completed, proper consideration should be given to the future service needs of families.⁶⁶

15.73 Beyond this, the Guidelines offer no further recommendations specifically relating to research, but direct that research using DNA samples should be regulated by the NHMRC through its guidelines and ethics approval mechanisms.⁶⁷

15.74 The Guidelines recommend the establishment of a central directory of DNA banks storing material for both clinical and research purposes, with the register to be maintained by one centre in each region. Any persons storing DNA would be under obligation to notify the appropriate centre in their region, and any extraction and storage of DNA should be reported to the centre. It is recommended that the centre be a regional clinical genetics service.⁶⁸

New regulation of human genetic research databases

15.75 The Inquiry proposes that the National Statement provide further ethical guidance on the operation of human genetic research databases, notably in relation to consent to as yet unspecified future research. The next question is whether, in addition to this proposal (and the reforms suggested elsewhere in this Discussion Paper that relate to human genetic research generally),⁶⁹ there should be additional regulation of human genetic research databases.

15.76 IP 26 noted that privacy concerns about the use of genetic samples and information may be magnified by the volume of information that may come to be held in some human genetic research databases.⁷⁰ Submissions specifically referred to concerns about the possible uses of information on genetic databases.

66 Ibid, 2.5.

67 Ibid, 2.7.

68 Ibid, 4.7.

69 See Ch 11–14.

70 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 7.19.

Is there any doubt that were the genetic information currently available [on databases] that those involved in “ethnic cleansing” would use it to identify members of ethnic groups for appropriate treatment; that adopted children would use it to trace their real parents and *visa versa*; that those with a grudge or other reason would use it to stigmatise another as inherently schizophrenic or homosexual or having criminal tendencies or potentially alcoholic or likely to die of a particularly nasty disease in a few years ...⁷¹

15.77 Genetic databases raise privacy concerns because they store large quantities of genetic samples and information that may be accessed by many different researchers, over many years and for many different research purposes. These concerns include questions about consent to storage of genetic samples and information, consent for re-use, linking of information to genetic samples, and the extent of use and disclosure of this information and material.

15.78 In particular, the potential for linkages creates privacy concerns, as the combination of types of samples and information can yield new information in itself. Collections may build up a more comprehensive picture of an individual's health than is held in any other form, such as by linking detailed genealogical information with the health records of a number of family members and data derived from testing of genetic samples.

15.79 The existence of human genetic research databases may increase the chances that genetic samples or information may be able to be re-identified through links with other information. That is, while genetic samples, medical records, and lifestyle information may all have been coded or de-identified,⁷² bioinformatics technologies may allow links to be drawn that reveal the identity of the individual to whom they relate.⁷³ By combining large quantities of information about an individual, databases provide opportunities for information to be re-identified.

Is existing regulation adequate?

15.80 The existing regulation of human genetic research databases is limited. As discussed above, while some aspects of the operation of research databases are covered by information and health privacy legislation, the Human Tissue Acts and ethical guidelines respectively, there are significant gaps.

⁷¹ I Turnbull, *Submission G059*, 14 January 2002.

⁷² Under the National Statement, information or material is ‘de-identified’ only if the process of de-identification is ‘irreversible’ — for example because the identifiers have been removed permanently or because the data have never been identified: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 9.

⁷³ See further on linkage of medical information, R Magnusson, ‘Data Linkage, Health Research and Privacy: Regulating Data Flows in Australia’s Health Information System’ (2002) 24(1) *Sydney Law Review* 5.

15.81 Some of these gaps relate to the absence of rules governing the collection, storage, use and disclosure of genetic samples and information. For example, the *Privacy Act* and most other state and territory information and health privacy legislation do not cover genetic samples. Further, the *Privacy Act* and other state and territory information and health privacy legislation do not cover information that has been de-identified in such a way as to fall outside the definition of ‘personal information’.⁷⁴ Relevant regulation provided by the Human Tissue Acts is limited to aspects of the collection of research samples.

15.82 Perhaps more significantly, there is no regulation directed specifically at human genetic research databases to ensure, for example, that major collections of genetic samples and information are subject to appropriate governance and accountability or processes for the ethical review of research proposals. The issues raised by large-scale and long-term storage of linked genetic samples and information are distinct. A genetic database is both a collection of samples and information, and a thing in itself. Merely applying regulation to samples and information held by it, instead of to database operations as a whole may fail to take account of these issues.

Regulation of databases in other jurisdictions

15.83 These concerns have been recognised overseas.⁷⁵ While there remains little specific regulation of human genetic research databases, the issue is being discussed in many jurisdictions.

15.84 Some overseas regulation is directed at regulation of databases established on a nation-wide scale, rather than at regulating a variety of disparate research databases. For example, in 1998, Iceland passed the *Act on a Health Sector Database*,⁷⁶ which authorised the creation of a national database containing genetic, genealogical and medical history data from all inhabitants of Iceland. Information is included in the database with consent from health institutions and practitioners unless inhabitants request that their information be excluded.⁷⁷ This opt-out system has been criticised as being contrary to international ethical standards of consent.⁷⁸

⁷⁴ Eg *Privacy Act 1988* (Cth) s 6(1).

⁷⁵ See House of Lords Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2001), The Stationery Office Limited, London.

⁷⁶ *Act on a Health Sector Database 1998* (Iceland).

⁷⁷ Ibid, Art 8.

⁷⁸ M Smith, ‘Population-Based Genetic Studies: Informed Consent and Confidentiality’ (2001) 18 *Santa Clara Computer & High Technology Law Journal* 57, 80. As discussed earlier in this chapter, the Icelandic Act also allows for the database to be operated by a licensee for a term of no more than twelve years subject to the Act and special licence agreements.

15.85 Legislation has also been enacted in Estonia to regulate the Estonia Gene Bank. The *Human Genes Research Act 2000* contains several provisions focusing on the rights of research subjects and the need for consent to the collection of data to be fully informed. The Act also excludes commercial licensees from controlling the database, and instead it is to be maintained by a non-profit foundation.⁷⁹ Commercial licensees are allowed access to the database only to undertake research as authorised by the controlling organization. Coding of information is to be performed by this foundation and not commercial organisations, which will only have access to samples and information once identifying information has been removed.⁸⁰

15.86 The Estonian legislation takes account of the need to link samples and information and the problems for privacy that this may raise. Under the Act, any linked samples and information must be released only in batches containing material from at least five different donors.⁸¹ Further privacy protection is provided by a prohibition on researchers having access to genealogies. These may only be used to link and organise samples and information within the gene bank, but cannot be accessed by researchers.⁸²

15.87 No specific legislation has as yet been enacted in the UK to regulate research databases in general, or BioBank UK in particular. However, the Human Genetics Commission has recommended that genetic research databases and DNA collections should be subject to the oversight of an independent body that is separate from the owners and users of the database.⁸³

15.88 Two models for an oversight body were proposed in a report on BioBank UK prepared by the United Kingdom Medical Research Council and the Wellcome Trust. In the first model, the body would be comprised of BioBank stakeholders, including users and funders of BioBank, volunteers, the medical profession, lawyers and clerics. It would be headed by a well-known person such as a retired judge.⁸⁴ Under the second model, the body would be made up of lay members with no vested interest in BioBank. It would be supported by professional staff and would consult widely on relevant issues.⁸⁵

79 *Human Genes Research Act 2000* (Estonia) s 3.

80 *Ibid.*, s 3(3).

81 *Ibid.*, s 22(4); M Smith, 'Population-Based Genetic Studies: Informed Consent and Confidentiality' (2001) 18 *Santa Clara Computer & High Technology Law Journal* 57, 87.

82 *Human Genes Research Act 2000* (Estonia) s 17.

83 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 103.

84 People Science and Policy Ltd, *BioBank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust* (2002), Medical Research Council and the Wellcome Trust, London, 4.

85 *Ibid.*

15.89 Under either model, the oversight body would have the task of ensuring compliance with standards of behaviour and ethics, which should be developed in accordance with public consensus.

Licensing or registration of research databases

15.90 Protection of privacy must be balanced against the need to promote research and ensure that Australian research remains internationally competitive. However, maintaining public confidence in genetic research is also important, because much of the tissue used in research in this country is obtained through altruistic donations from the public. Such altruism may be adversely affected where there is a lack of community trust in what will be done with genetic samples and whether information derived from them will be adequately protected.

15.91 At this stage, the Inquiry does not have sufficient evidence to make any detailed proposal for the regulation of human genetic research databases. The Inquiry would welcome further comment, for example, on whether new legislation specific to the operation of such databases is needed.

15.92 Chapter 10 noted the need, in considering reform, to be sensitive to the dynamic environment in which medical, scientific and technological developments are taking place in the field of human genetics and, in particular, to consider forms of regulation that are flexible and quick to adapt to changing circumstances. These comments are particularly pertinent to the possible regulation of human genetic research databases. For this reason, the Inquiry has been examining the option of a licensing or registration scheme for human genetic research databases.

15.93 A licensing scheme would require that all human genetic research databases maintained in Australia have to obtain a licence to operate. Such a scheme would establish a specific relationship between the regulator and the licence-holder. Organisations maintaining databases would be subject both to the general rules applying to licence-holders, as well as any specific conditions of the licence itself.

15.94 This approach would have a number of benefits. Criminal sanctions could apply to deter the creation of unauthorised collections of genetic samples and information or their unauthorised use. Sanctions could apply for non-compliance with licence conditions, including withdrawal or non-renewal of the licence, or the imposition of fines.

15.95 The licensing body could have powers of inspection to ensure compliance, which would enable the body to review security procedures and examine privacy protection policies. Reporting could also be made a licence condition. The licensing body could be required to report to Parliament on the

number and kind of licences given, which would add to public awareness of what kinds of databases exist. This could address some of the current community concerns about storage of samples and information, making the process more transparent to the public.

15.96 As a condition of licensing, those maintaining databases could be required to comply with the National Statement. This would help ensure compliance with the National Statement, including the proposed new chapter providing ethical guidance on the operation of human genetic research databases (Proposal 15-1), by all research database operators (including private sector organisations).

15.97 Licence conditions could be used to impose specific limitations on how databases are maintained, and could be adapted for different types of databases. Restrictions on use and disclosure of information, like those in the Estonian legislation discussed above, could be implemented. Different databases will contain different combinations of samples and information. Particular licensing conditions to deal with specific privacy and other issues arising from specific databases could be imposed, facilitating tailored regulation.

15.98 Renewal of licences at various times would allow for changed conditions to be included to allow for developments in technology, which may create new issues in relation to databases.

15.99 It is easier to propose the establishment of a licensing scheme in principle than to determine how it should be implemented, especially given constitutional limits on the legislative powers of the Commonwealth Parliament, or the precise form it should take. The implementation of such a scheme would require careful definition of the human genetic research databases to be subject to licensing requirements. In particular, the size and permanence of research databases may be relevant. The benefits of any licensing scheme have to be weighed against administrative and other costs. There may be limited benefit, for example, in licensing small or transitory collections of genetic material. In addition, careful consideration would have to be given to how the scheme would be administered and by what body.

15.100 An alternative, 'light touch' approach would be to implement a system of registration. A registration scheme could be modelled on the existing processes for the registration of HRECs with the Australian Health Ethics Committee (AHEC). Operators of human genetic research databases (or their HREC) could be required to report to AHEC on their activities, including on their consent procedures and on the nature of research undertaken using the database during the reporting period.

AHEC could have authority to audit the activities of research databases to ensure compliance with the National Statement.⁸⁶

Question 15–1. Should human genetic research databases be subject to a licensing or registration scheme? If so:

- would a licensing or registration scheme be preferable?
- how should human genetic research databases be defined for the purposes of licensing or registration?
- what conditions should attach to licensing or registration?
- what form of independent scrutiny of database operations should be involved?

Question 15–2. Should the proposed HGCA have any role in the regulation of human genetic research databases?

The gene trustee

15.101 A concept relevant to the regulation of human genetic research databases is that of the ‘gene trustee’. This concept was briefly described in Chapter 13, in which the Inquiry proposed that AHEC should issue a model research protocol for human genetic research to give guidance on, among other things, the appropriate use of independent intermediaries to hold codes linking genetic samples or information with the identifiers (Proposal 13–1).

15.102 The use of a gene trustee could be required, in appropriate situations, as a condition of the licensing or registration human genetic research databases, or as a stand alone reform. A gene trustee system might be able to operate with a single body administering both licensing or registration, and acting as trustee. Persons or bodies taking on the role of gene trustee could also be subject to some system of scrutiny to ensure their integrity and independence from research organisations.

15.103 The model discussed here is based on the gene trustee approach developed for the Sydney Tay-Sachs disease-screening program within the Jewish community as outlined in a submission made by the Institute of Community Genetics.⁸⁷

⁸⁶ In addition, the National Statement might be amended to state that an HREC should not approve research using unregistered genetic databases.

⁸⁷ Institute of Community Genetics, *Submission G156*, 19 April 2002.

15.104 The scheme is based around an independent third party, which controls information used to identify data and samples held within a database. The gene trustee acts as an intermediary between the persons maintaining the database and the individuals who supply their tissues and information.

15.105 Consent to donation of samples and information is given using a three-part consent form. The donor fills out Part A with his or her personal details and provides consent to the storage and use of the samples and information. Part A is marked with a unique personal identification number (PIN) and a unique database control identification number. Part B of the form contains only the database control identification number while Part C contains only the PIN.

15.106 Part A is then separated from the consent form and held by the gene trustee. Samples and information, along with Part B, are supplied to the persons maintaining the database and stored using the database identification number as the only identifier. The donor of the samples and information is given Part C of the consent form, containing the PIN and contact details of the gene trustee.

15.107 Only the gene trustee can link the donor's personal information with any samples or information held by the database. If further consent to research is required, the holders of the database must pass the request to the gene trustee who will then contact the individual. Re-consent to future use could be obtained through the trustee, which would hold contact information for donors and details of the consent they have given. Destruction of the linking information held by the gene trustee (that is, Part A of the form) will permanently de-identify all samples and information held on a person in the database.

15.108 The gene trustee could act as a central body that holds linking information from materials held in numerous databases. Alternately, large databases could be required to establish their own gene trustee system. In either case, gene trustees would have to handle linking information in accordance with regulatory requirements.

15.109 The value of this approach lies in the separation of any identifying information from all sensitive data and material held in a database. No matter who accesses this material, they will be unable to identify it without contacting the gene trustee, who will be bound not to release any identifying information without consent from the individual.

15.110 There are, however, a number of problems with this approach. First, it would present significant administrative costs, particularly where re-consent was sought for numerous samples. It also does not take account of the means by which many research subjects are contacted and asked to donate tissues and information. Often this occurs in a clinical context, where sufferers of a genetic condition are

identified by their treating clinician and asked if they would like to participate in research. In other instances, researchers seek out participants through genetic counselling services and clinics. There may not be the initial degree of separation between the donor and researcher that would be necessary to make the gene trustee system workable in all situations.

15.111 The system may, however, be more workable where large research databases are established for broad purposes, like BioBank UK or the Estonian database. The system may also be appropriate where commercial organisations develop databases from patient samples and information acquired from hospitals — a practice that is common in the United States.⁸⁸

Question 15–3. Should the use of a gene trustee or other independent intermediary be a condition of the licensing or registration of human genetic research databases?

A new statutory restriction on the use of research databases?

15.112 In the United Kingdom, the Human Genetics Commission (HGC) has recommended that genetic databases established for health research should not be used for any other purpose and that this should be put beyond any doubt, by legislation if necessary.⁸⁹ The HGC referred, in particular, to ‘pressure for allowing police access for purposes of identification’.⁹⁰

15.113 In Australia, the *Privacy Act* allows personal information to be disclosed without consent where the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue.⁹¹ Some state and territory information privacy legislation contains similar provisions allowing disclosure for law enforcement purposes.⁹²

15.114 There may be good reasons to enact legislation specifically to protect genetic samples and information held on human genetic research databases from disclosure for law enforcement purposes. Such special protection might be justified, not solely on the basis that such disclosure constitutes an interference

88 See GenomeWeb Staff Reporter, *New Tissue Repository Firm to Close Microarray, IP Collaborations in 6 Months*, GenomeWeb, <www.genomeweb.com/articles/view.asp?Article=2002627173511>, 27 June 2002.

89 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 105.

90 Ibid, 105.

91 *Privacy Act 1988* (Cth) IPP 11.1(e); NPP 2.1(h).

92 Eg *Health Records Act 2001* (Vic) Health Privacy Principle 2.2(i), (j); *Privacy and Personal Information Protection Act 1998* (NSW) ss 18, 23(5).

with privacy, but also because people may be less willing to donate samples for research without such protection with adverse consequences for medical research.

Question 15–4. Do we need legislation governing the disclosure, for law enforcement purposes, of genetic samples and information held in human genetic research databases?

16. Human Tissue Collections

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Introduction

16.1 This Chapter is concerned with the collection, use, storage and disclosure of genetic samples and genetic information held in tissue¹ collections maintained by hospitals or pathology laboratories. These collections, which have not been collected primarily for use in research are referred to in this Chapter as human tissue collections to distinguish them from human genetic research databases (see Chapter 15).

16.2 Tissue samples are collected and stored in many medical contexts. Pathology laboratories receive blood and other tissues for testing and analysis. Blood banks take donations of blood for transfusion. Hospitals remove tumours during surgery that may be stored for later examination. Tissue repositories ‘bank’ bone marrow, skin and blood for use in treatment. Organs and tissues are also removed and retained following autopsy. In each of these cases, samples containing human genetic material are stored (that is, genetic samples).

¹ In this Chapter the term ‘tissue’ includes blood and other bodily substances.

16.3 In some instances, tissue is only stored for a short while and then disposed of. Other tissue is archived and retained for a significant period of time, whether for teaching purposes, to meet quality assurance requirements or to allow future re-testing. Retention with no single, defined purpose also occurs, as is the case with Guthrie cards created as part of newborn screening programs.

16.4 Developments in genetic technology have made it possible to perform almost all available genetic tests on stored tissue, provided it has been adequately preserved. Large amounts of potentially sensitive information, about both the person from whom the tissue was taken and their family, can be obtained from archived tissue.

16.5 As a result, archives of preserved human tissues have taken on a new importance as both a scientific and economic resource, particularly where they can be linked with an individual's medical history. Genetic testing of stored tissue samples has potential uses in other contexts, including in criminal or police investigations, as evidence in court proceedings and for parentage or other kinship testing. These potential secondary uses raise issues of privacy and consent.

16.6 The Chapter examines aspects of the existing regulatory framework that apply to human tissue collections and, in particular, to Guthrie cards. The Inquiry has concluded that there is a need for nationally consistent policies and practices in relation to Guthrie cards and other human tissue collections.

Archived pathology samples

16.7 Pathology laboratories receive samples of blood, body fluids and tissue from doctors and hospitals for testing. Such tissues may have been removed during surgery, such as tumours, or via a medical examination. Pathologists with special skills examine test results to aid in determining the cause of a condition and how it should be treated.²

16.8 The pathologist's findings and analysis are reported to the doctor who ordered the tests. However, the laboratory will retain any remaining portion of the sample once testing has been completed. These samples are archived and may be kept for some time. Samples may be retained to fulfil laboratory accreditation requirements or to meet laboratory standards. There also may be legal reasons for keeping samples, and a laboratory may wish to be able to re-test samples to confirm results at a later stage.

2 For example, a general practitioner who suspects a patient has anaemia may take a blood sample and send it to a pathology laboratory for analysis. The sample will be tested for haemoglobin levels and examined under a microscope to look for signs of iron deficiency like abnormally small cell size.

16.9 In its submission, the New South Wales Genetics Service Advisory Committee made the point that, although tissue is often left over after diagnostic tests or therapeutic procedures, this does not mean that excess tissue was taken. Rather, it is generally difficult to take the precise amount required for a test and some tissue invariably will be left over once tests or treatments are complete.³ This material may be banked, as well as the samples retained after testing.

16.10 Samples are stored in a variety of forms. Some are frozen and kept refrigerated. Others, like sections of tissue, may have been embedded in paraffin to enable slides to be made. These blocks of tissue can be stored for a long time without significant deterioration.

16.11 Sometimes, samples are disposed of once they have no further use. Usually this involves steam-heating samples to melt containers and destroy the contents. The heat at which they are melted is sufficient to denature any DNA contained in samples, while the process prevents separation of individual containers. Once cooled, destroyed samples are generally deep-buried.

16.12 Samples that are not destroyed may be archived. Collections of pathology samples are, therefore, comprised of residual tissue taken primarily for therapeutic and diagnostic purposes. Though generally samples are coded when a pathology laboratory receives them, the laboratory would retain the means to unite samples with their identifying information.

Guthrie cards

16.13 In hospitals around Australia, blood samples have been taken from newborns, identified and stored for the past thirty years. Between three and five days after birth, virtually all children in Australia are screened for a variety of conditions. Practice varies somewhat among the Australian states and territories, but as a general matter, samples are tested for phenylketonuria, hypothyroidism, galactosaemia, cystic fibrosis and other conditions.

16.14 A small sample of blood is taken and placed on a piece of blotting paper called a Guthrie card. The child's name, date of birth, hospital of birth, birth weight and their mother's name and date of birth are also recorded on the card. (See Appendix A for a sample Guthrie card.)

16.15 Given the nature of many of these genetic conditions, testing cannot be delayed until the child is older (or new parents less distracted) as the conditions require immediate medical or dietary intervention to preserve the life and health of the infant.

3 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

16.16 All newborns are tested unless parents express refusal. Parents are provided with leaflets and other information about the nature and value of the test for neonatal health and consent is rarely refused.⁴ The Human Genetics Society of Australasia has referred to the consent procedure as one of 'informed refusal or dissent ... rather than informed consent'.⁵

16.17 Guthrie testing and storage of cards has been routine practice for more than thirty years. In 1999, the Senate Legal and Constitutional Legislation Committee referred to Guthrie card collections as 'inadvertent DNA sample banks', noting that identified blood samples containing genetic material from almost all people under the age of 28 are currently stored in most states and territories.⁶

16.18 These samples could be used to derive genetic information about the person from whom the blood was taken. Due to the familial nature of genetic information, this may also reveal details about the genetic makeup of members of their family, including the parents named on cards.⁷ Other uses, such as in epidemiological studies may not require identifying information to be attached to samples and therefore would not reveal this kind of information.

16.19 Individuals occasionally seek to obtain their own or their child's Guthrie cards from the hospitals where the cards are stored. One such request was refused by the administrators of the NSW Newborn Screening Program on the basis that they were obliged to retain the cards in order to comply with National Pathology Accreditation Advisory Council (NPAAC) guidelines, New South Wales Department of Health directives and the *Privacy and Personal Information Act 1998* (NSW).⁸ Cards have been returned on request in other cases.⁹

Tissue banks

16.20 A variety of tissue banks have been established in Australia to hold tissues for transplantation and therapeutic uses. Unlike the human genetic research databases discussed in Chapter 15 (which are also sometimes referred to as tissue

4 L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 138.

5 Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians, *Policy Statement on the Retention and Use of Sample Cards From Newborn Screening Programs*, 7 June 2001, 2. See also L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137.

6 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, 3.

7 C Lawson and R Smith, 'Protecting Genetic Materials and Genetic Information: A Case Study of Guthrie Cards in Victoria' (2001) 9 *Journal of Law and Medicine* 215, 217.

8 *Confidential Submission G051CON*, 14 January 2002.

9 C Lawson and R Smith, 'Protecting Genetic Materials and Genetic Information: A Case Study of Guthrie Cards in Victoria' (2001) 9 *Journal of Law and Medicine* 215.

banks), these banks have not been created for research purposes. They do, however, house large collections of human tissue that contain genetic material that may potentially be used in other contexts.

16.21 An example of a donor tissue bank is the Perth Bone and Tissue Bank, which receives donations of bone for transplantation and therapeutic use. Bones are received from living individuals who donate bone removed during hip replacement surgery, and also taken from deceased individuals. Sections of bone are sometimes used in research projects by the bank; however, these are obtained from failed grafts. New consent for this research use is always sought from donors.¹⁰

16.22 Although not yet a feature of the Australian research culture, donor tissue banks are being constructed on a commercial basis in the United States. Such banks collect tissues from hospitals and process them ready for research. The banks themselves do not conduct research, but sell processed tissues to researchers at other institutions. An example is Gene Logic, a US tissue repository containing more than 10,000 tissue samples that are made available to researchers and pharmaceutical companies. Samples are supplied by hospitals once consent has been given.¹¹

16.23 Human genetic samples are also banked commercially in the form of cord blood. Firms such as Cryosite, based in Sydney, store blood taken from the umbilical cords of newborn infants. Parents pay for storage so that they will be able to access the blood, which can be used in the treatment of some diseases, if their children become ill.¹²

16.24 Finally, some genetic registers also maintain banks of genetic samples. These may be used for testing of families for presymptomatic diagnosis and carrier detection. Sometimes, where a disorder has been identified but a reliable molecular test has not yet been developed samples are banked for testing once a reliable test becomes available.

Secondary use of human tissue collections

16.25 Many submissions noted various potential secondary uses of human tissue collections and referred, in particular, to the actual or potential use of Guthrie cards for forensic and law enforcement purposes.¹³ Some submissions

¹⁰ Anne Cowie (Perth Bone and Tissue Bank), *Consultation*, 2 July 2002.

¹¹ GenomeWeb Staff Reporter, *New Tissue Repository Firm to Close Microarray, IP Collaborations in 6 Months*, GenomeWeb, <www.genomeweb.com/articles/view.asp?Article=2002627173511>, 27 June 2002.

¹² D Teutsch, 'Born to be Insured', *Sun Herald* (Sydney), 30 June 2002, 27.

¹³ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

expressed concerns about possible secondary uses of human tissue collections,¹⁴ including those uses that may occur without the knowledge of the person from whom the samples were taken.¹⁵ Other submissions raised concerns about the storage of genetic samples taken from children and infants, who cannot give consent.¹⁶

16.26 Individuals often may not be aware that their genetic samples or information have been retained and could be used again for other purposes. The Neurofibromatosis Association of Australia presented the results of a survey of its members, which showed that few were aware that their tissue could have been stored after it was removed for diagnosis or treatment. Few members were aware of the uses to which it might have been put once stored.¹⁷ Women's Health Victoria noted that:

The thought that parts of our human tissue may be stored in a bank or laboratory, for some other research, without our knowledge, is abhorrent to some and feels like a violation.¹⁸

16.27 Secondary uses of genetic samples and information collected for other purposes raise privacy and consent issues. However, it should be recognised that some secondary uses are directly related to the primary purpose of collection and are uses that individuals should reasonably expect and, therefore, are of less concern.

16.28 This may apply, for example, to some research uses of material held in human tissue collections, where the dividing line between clinical care and research may be unclear.¹⁹ The Australian Academy of Science observed, in relation to the role of pathologists, research into the causes of disease is an intrinsic part of diagnosis for the pathologist, and the two roles cannot be regarded in isolation — in trying to diagnose a condition, the pathologist is also searching for the most effective cure.²⁰

16.29 The Australian Society for Medical Research noting that a crossover between pathological diagnosis and ongoing research is regarded as good clinical practice, particularly as tests on historical samples can help find treatments for family members.²¹

14 *Confidential Submission G023CON*, 29 November 2001; UnitingCare NSW & ACT, *Submission G052*, 14 January 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

15 National Council of Women Australia, *Submission G095*, 31 January 2002.

16 Eg T Struzina, *Submission G016*, 25 November 2001.

17 Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

18 Womens Health Victoria, *Submission G076*, 3 January 2002. See also *Confidential Submission G051CON*, 14 January 2002.

19 Australian Academy of Science, *Submission G097*, 21 January 2002.

20 Ibid.

21 Australian Society for Medical Research, *Submission G124*, 18 March 2002.

16.30 Where tissue has been stored for some time, consent may be hard to obtain because, for example, an individual's contact details may have changed. Requirements to seek new consent may constitute an unjustifiable administrative burden. Dr Nikolajs Zeps submitted that obtaining consent for each and every use of archival tissue would be 'a logistical problem that would effectively stymie the function of routine pathology'.²²

16.31 The Androgen Insensitivity Syndrome (AIS) Support Group Australia submitted that community attitudes frowned upon subsequent re-use for research purposes, without specific consent.²³ The AIS Support Group also submitted that use of samples stored previously without consent 'must surely fail any reasonable ethical or moral test'.²⁴ Issues concerning consent to the use of genetic samples in research, including archival tissue originally obtained for clinical purposes, are discussed at length in Chapter 12.

16.32 In practice, consent to possible future research uses may be difficult to obtain in clinical settings. Dr Rosemary Balleine noted:

Pre-operative consent is neither practical in the context of busy clinical practice nor considerate of the patient's emotional well-being. Approaching patients post-operatively may be considered by some as intrusive, especially as researchers are frequently not the clinicians responsible for care of the patient. A reasonable approach may [be] to ask the attending clinician to obtain consent from the patient post-operatively, however clinicians may be disinclined to undertake this complicated and time-consuming process in support of research that they are not directly involved with.²⁵

16.33 Some individuals from whom samples have already been taken may have died, or may be distressed at being reminded of a time when they were ill. On this issue, Dr Balleine stated that 'the propriety of contacting these patients in itself poses an ethical dilemma'.²⁶

Research value

In the post genome sequencing era, the ability to easily and extensively access the staggering amount of medical and biological information locked up within tissue archives is paramount — molecular pathology could play a pivotal role in unlocking the bases of multiple disease types, including infectious diseases, cancer and developmental disorders.²⁷

22 N Zeps, *Submission G047*, 14 January 2002.

23 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

24 Ibid.

25 R Balleine, *Submission G035*, 14 January 2002.

26 Ibid.

27 Confidential *Submission G051CON*, 14 January 2002.

16.34 As is the case with human genetic research databases (see Chapter 15), human tissue collections have great value as research tools. As the samples are generally collected in a clinical setting, the samples will often have identifying information attached to them that enables them to be linked to medical records.

16.35 This is one reason Guthrie card collections are very useful research tools. Guthrie cards have been used, for example, to look for genetic mutations that may cause Sudden Infant Death Syndrome (SIDS). The researchers were able to test genetic samples taken from the cards of children known to have died of SIDS. Such targeted research would have been impossible if the cards were not identified.²⁸

16.36 Guthrie cards collections have significant potential value for population studies, including those that may help government and health system administrators to plan for the future health needs of the Australian population.²⁹ The collections can be used to study the interaction of genetic and environmental factors in disease over time, to examine the causes of genetic diseases and to locate genetic mutations. Through such research, new diagnostic tools and treatments can be developed that will have economic as well as medical value.

16.37 Other human tissue collections can be used to confirm diagnoses to facilitate research on familial disorders:

[T]here are circumstances where it is essential to review, for clinical and research purposes, the pathology on samples collected for diagnosis. For example, in many large molecular-epidemiology studies, confirmation of diagnosis is critical for substantiating apparent familial histories of specific cancers.³⁰

16.38 Tissue collections created over long periods of time have unique value for researchers. Access to historical collections can enable research that otherwise would have been logistically very difficult and time-consuming, if not impossible, given the problems of establishing such databases from scratch. Many studies require access to large sample sets, and in some cases collections created for research are not sufficiently large. They can be supplemented with archived material.

16.39 In its submission, the Australian Academy of Science emphasised the need to recognise the research uses of archived pathology material and submitted that research utilising these materials should be encouraged in the interests of the community. The Academy argued that restricting access to samples would be a major impediment to research.³¹ The Peter MacCallum Cancer Institute stated that it

28 B Williamson, *Consultation*, 5 September 2001.

29 Advisory Committee members, *Advisory Committee meeting*, 31 May 2002.

30 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

31 Australian Academy of Science, *Submission G097*, 21 January 2002.

is 'hard to overstate the importance of controlled access to archival material'³² and other submissions emphasised that any new regulation of tissue use should not unnecessarily impact on research:³³

[T]he law should not be too rigid and demanding so as to exclude tissue obtained for a specific purpose either diagnostic or therapeutic being used later, possibly some years later for other research purposes.³⁴

Forensic use of human tissue collections

16.40 Genetic samples stored in human tissue collections may be sought for forensic and law enforcement purposes.³⁵ For example, Guthrie cards provide a useful resource in some criminal investigations. The cards contain sufficient DNA to enable matching with other samples collected in an investigation, and have reliable identifying information attached. Guthrie cards may be of use in identifying human remains and in providing samples for DNA profiling to obtain matches to suspects where no other samples aside from those collected from a crime site can be obtained.

16.41 Access to Guthrie cards for police investigations is not granted regularly. However, police do sometimes seek access to Guthrie cards and hospitals do comply with police requests for such access. For example, in New South Wales more than a dozen requests for cards have been made since 1996, mainly for use in murder inquiries and to identify bodies. Parental consent was given in almost all cases, and cards were released in all but a few cases.³⁶

16.42 Public concerns about police access to samples came to prominence when the Western Australian police took possession of some Guthrie cards held by the Princess Margaret Hospital in Perth. Although the police had a warrant to take possession of the cards, some parents were nevertheless disturbed by this action and sought the return of their children's cards. These events are said to have led to a decrease in participation in the screening program.³⁷

16.43 The increased use of police powers to compel the provision of DNA samples under forensic procedures legislation may decrease the need for police to access Guthrie cards, at least where samples may be obtained from living persons.³⁸

32 Peter MacCallum Cancer Institute, *Submission G071*, 7 January 2002.

33 I Surveyor, *Submission G024*, 18 December 2001; *Confidential Submission G051CON*, 14 January 2002.

34 I Surveyor, *Submission G024*, 18 December 2001; *Confidential Submission G051CON*, 14 January 2002.

35 *Confidential Submission G023CON*, 29 November 2001; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

36 NSW Privacy Commissioner, *Correspondence*, 4 June 2002.

37 Department of Clinical Biochemistry at Princess Margaret Hospital in Perth, *Consultation*, Perth, 3 December 2001.

38 The content of forensic procedures legislation is summarised in Ch 34.

Parentage and other kinship testing

16.44 In some instances, individuals may seek access to stored genetic samples for parentage and other kinship testing,³⁹ sometimes in the context of court proceedings.⁴⁰ Some genetic screening programs in Australia have been approached for access to samples for parentage testing. For example, in Western Australia a Guthrie card has been released for parentage testing, with the consent of both parents named on the card.⁴¹

Regulation of human tissue collections

16.45 Different aspects of the collection, use, storage, and disclosure of genetic samples and information held in human tissue collections are regulated by:

- information and health privacy legislation, including the federal *Privacy Act 1988* (Cth) (*Privacy Act*) and similar state and territory legislation (see Chapter 7);
- State and territory Human Tissue Acts, which require varying forms of consent for donation of human tissues for research;
- an evolving body of common law property rights in some human tissues in limited circumstances (see also Chapter 17);
- the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement);⁴²
- the Human Genetics Society of Australasia (HGSA) and Royal Australasian College of Physicians *Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs*;⁴³
- standards and guidelines released by the National Pathology Accreditation Advisory Council (NPAAC), which apply to pathology laboratories accredited in Australia;

39 Parentage and other kinship testing is discussed in Ch 31.

40 Eg *Roche v Douglas* [2000] 22 WAR 331.

41 Department of Clinical Biochemistry at Princess Margaret Hospital in Perth, *Consultation*, Perth, 3 December 2001.

42 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

43 Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians, *Policy Statement on the Retention and Use of Sample Cards From Newborn Screening Programs*, 7 June 2001.

- professional ethical standards that apply to medical practitioners and pathologists, including policy and position statements released by the Royal College of Pathologists of Australasia (RCPA).

Information and health privacy legislation

16.46 Chapter 7 briefly summarised the existing legislative framework for the protection of information and health privacy based on the *Privacy Act* and similar state and territory legislation,⁴⁴ and its application to the privacy of genetic samples and information.

16.47 Chapter 15 discussed aspects of the application of information and health privacy legislation to human genetic research databases. This discussion is also relevant to the regulation of human tissue collections. In particular, the Inquiry's proposals that the *Privacy Act* should be amended to cover genetic samples, as well as the genetic information derived from them (Proposal 7–2) are especially relevant to human tissue collections.

16.48 Where it is held by public hospitals, pathology-related personal information will be subject to state and territory information and health privacy legislation, where it exists.⁴⁵ The handling of personal information related to genetic material in tissue banks maintained by universities or public hospitals is generally also subject to state and territory legislation. Personal information held by private pathology laboratories and tissue banks is governed by the federal *Privacy Act*. Guthrie cards are held by state public hospitals⁴⁶ and screening is done in public laboratories. Therefore, the cards are subject to state and territory information and health privacy legislation.

16.49 In relation to *Privacy Act* coverage of genetic samples, it is relevant to note that Guthrie cards, despite containing blood and constituting a genetic sample, are clearly covered by the Act. Guthrie cards are 'personal information' for the purposes of the Act as the cards also contain identifying information. Furthermore, unlike a test tube of blood, a Guthrie card is clearly a 'document' for the purposes of the Act.⁴⁷ However, once a section of the blood spot is punched out, and physically detached from the personal information and the record on which it was stored, the *Privacy Act* no longer governs how the genetic sample is dealt with.

44 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Information Privacy Act 2000* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT).

45 At present, only New South Wales, Victoria and the ACT have privacy legislation which protects health information held in their public sectors: *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Privacy Act 1988* (Cth).

46 Victorian cards are held by the Murdoch Childrens Research Institute, part of the Royal Children's Hospital; Tasmanian, South Australian and some Northern Territory cards are held by the Women's and Children's Hospital in Adelaide; NSW and ACT cards are held by the Westmead Children's Hospital; Western Australia cards are held by the Princess Margaret Hospital in Perth; Queensland cards are stored at the Prince Charles Hospital.

47 *Privacy Act 1988* (Cth) s 6(1).

16.50 In Chapter 15, the Inquiry referred to provisions in federal, state and territory information privacy legislation that allow disclosure of information held on human genetic research databases for law enforcement purposes. The Inquiry asked whether legislation should be enacted to protect genetic samples and information held on human genetic research databases from disclosure for law enforcement purposes. The same question also needs to be asked in relation to Guthrie cards, given the existing and future public health importance of genetic population genetic screening programs.

Question 16–1. Do we need legislation governing the disclosure, for law enforcement purposes, of the genetic samples or information held on Guthrie cards?

Human Tissue Acts

16.51 Human genetic samples collected for diagnostic or therapeutic purposes are expressly excluded from the ambit of the Human Tissue Acts.⁴⁸ Therefore, samples collected for pathology purposes and Guthrie cards are not covered by the Acts.

16.52 Tissues, body parts and organs donated to tissue banks are covered by the Acts under provisions outlined in Chapter 15. Under these provisions consent to donate tissue for one purpose, for example transplantation, probably does not constitute consent to other uses, such as research.

16.53 IP 26 asked whether the Human Tissue Acts should be amended to regulate the collection and use of human tissue samples for genetic research.⁴⁹ This issue is dealt with in Chapter 17.

Ownership

16.54 Pathology samples may be regarded as property under the common law, though there is little consensus on this issue at present. If so, they may be the property of the laboratory that holds them. This issue has wide implications, including for human genetic research databases and is discussed in Chapter 17.

⁴⁸ *Human Tissue and Transplant Act 1982* (WA) s 32(1); *Human Tissue Act 1985* (Tas) s 28(1)(a) and (b); *Transplantation and Anatomy Act 1983* (SA) s 37(1)(a) and (b); *Transplantation and Anatomy Act 1979* (Qld) s 47(1)(a) and (b); *Human Tissue Transplant Act 1979* (NT) s 26(1)(a) and (b); *Human Tissue Act 1983* (NSW) s 34(1)(a) and (b); *Transplantation and Anatomy Act 1978* (ACT) s 46(1)(a) and (b); *Human Tissue Act 1982* (Vic) s 42(1)(a) and (b).

⁴⁹ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 7–4.

16.55 Guthrie cards may be regarded as a medical record. It is therefore likely that, according to common law and equitable principles, Guthrie cards are owned by the health authorities that create them.⁵⁰

The National Statement

16.56 The provisions of the National Statement dealing with consent to the collection and use of human tissue for research purposes, including human tissue samples that have been collected and stored after clinical procedures and held in tissue banks are discussed in detail in Chapter 12.

16.57 These consent requirements may be waived by a Human Research Ethics Committee after consideration of a range of factors, the most relevant of which in the context of archived pathology samples is the practical difficulty of contacting the donor for consent.⁵¹

HGSA policy statement

16.58 The Human Genetics Society of Australasia (HGSA) *Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs* (HGSA policy statement) states that sample cards should be stored in a manner appropriate to their intended future uses, noting that the primary purpose of retaining cards is to enable confirmation of test results.⁵² Cards also may be used to improve and to check testing methods as part of screening program development, on request by health professionals where a person has died, for research studies and in coronial and forensic investigations.⁵³ Requests from individuals for the return of their cards are sometimes granted.

16.59 In each of these cases the HGSA policy statement recommends particular consent or approval requirements for the release or use of Guthrie cards:

- **Screening program development:** No consent is required where cards have been anonymised; however, ethics committee approval is necessary if cards are to be used outside the screening laboratory or where the samples remain.

50 *Breen v Williams* (1996) 186 CLR 71. See also C Lawson and R Smith, 'Protecting Genetic Materials and Genetic Information: A Case Study of Guthrie Cards in Victoria' (2001) 9 *Journal of Law and Medicine* 215, 223; L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 140. There may be some disagreement with this view, as *Breen v Williams* did not deal with records which included blood or tissue samples.

51 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.8.

52 Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians, *Policy Statement on the Retention and Use of Sample Cards From Newborn Screening Programs*, 7 June 2001, 4.1, 4.3.1.

53 *Ibid.*, 4.3.4–4.3.6.

- **New health information about the person from whom the sample was obtained is generated:** The approval must specify who should be informed of abnormal test results, what they will be told and the nature of any follow-up that may be necessary.⁵⁴
- **Individual requests:** Test information should not be released to anyone other than the person whose blood is on the card, or parents where that person is a minor. Release should be discouraged if the person is still living and could give another sample. If a card is returned, the family should be encouraged to retain it, or if they will not, then destruction of the card at an agreed time is to be sought.⁵⁵
- **Requests from health professionals:** A card may be released to determine cause of death or to gain genetic information for family reasons, but only where parental consent has been given.⁵⁶
- **Research studies:** Cards may be used in research studies where approval has been obtained from both an ethics committee and the screening program advisory committee (if one exists). Research should be conducted in accordance with NHMRC guidelines and follow any other requirements placed on it by the screening program committee.⁵⁷
- **Coronial and forensic:** Cards may be released with parental or next of kin permission or in accordance with a legal requirement.

National Pathology Accreditation Advisory Council

16.60 NPAAC produces guidelines and standards for the accreditation of pathology laboratories and services. The quality assurance and accreditation standards that regulate genetic testing laboratories are discussed in Chapter 5.

16.61 NPAAC accreditation recommendations for pathology collections are currently under review. The Inquiry understands that new standards for the operation of pathology laboratories, including for the retention of laboratory records and diagnostic material are in draft form and will be finalised in September 2002.

16.62 Under the present guidelines, released in 1998, many types of samples including slides, frozen tissues, blocks and specimens taken at autopsy are to be retained for twenty years. Others, including blood samples, blood films, serum and

54 Ibid, 4.3.2.

55 Ibid, 4.3.3.

56 Ibid, 4.3.4.

57 Ibid, 4.3.5.

plasma need not be retained more than one week. Pathology reports must be retained for periods ranging from one to twenty years, dependent on their subject.⁵⁸

16.63 Different requirements exist for laboratories involved in biochemical genetics, molecular genetics and newborn screening. DNA extracts and tissue samples must be stored indefinitely; plasma, serum and urine for two years; and dried blood spots, including Guthrie cards, for fifty years.

16.64 The new guidelines require similar retention periods in most cases. Samples taken during autopsy will need to be retained for three months following removal unless samples are to be returned to the body for burial at the direction of next of kin. Samples used for genetic analysis will need to be retained for at least one month, and longer if the laboratory regards retention as necessary. Pre-natal samples must be retained for twenty-five years, while slide, plasma and urine need only be kept for three months after a report is completed.⁵⁹

16.65 The Inquiry understands that, under the new guidelines, Guthrie cards effectively will have to be stored for 25 years — being seven years after the child has reached 18 years of age.⁶⁰

16.66 The new guidelines also require that samples used for quality assurance and validation of laboratory methods be de-identified.⁶¹ Other existing NPAAC guidelines state that laboratory officers and staff shall not disclose information on patients, except in the performance of their duties.⁶²

RCPA policy statement

16.67 The Royal College of Pathologists of Australasia (RCPA) has released a policy statement on the secondary use of human tissue samples collected for diagnostic purposes.⁶³ The RCPA policy statement includes guidance on the re-use of samples for education, research, commercial, medico-legal, insurance, employment and legal determinations.⁶⁴ The statement works alongside the requirements of other bodies, adding to the complex patchwork of regulation and guidance on access to and disclosure of samples and information.

58 National Pathology Accreditation Advisory Council, *Retention of Laboratory Records and Diagnostic Material* (1998), Commonwealth of Australia, Canberra.

59 National Pathology Accreditation Advisory Council, *Draft Guidelines for the Retention of Laboratory Records and Diagnostic Material* (2002), Commonwealth of Australia, Canberra.

60 B O'Connor (National Pathology Accreditation Advisory Council), *Correspondence*, 20 May 2002.

61 National Pathology Accreditation Advisory Council, *Draft Guidelines for the Retention of Laboratory Records and Diagnostic Material* (2002), Commonwealth of Australia, Canberra.

62 National Pathology Accreditation Advisory Council, *Standards for Pathology Laboratories* (1998), Commonwealth of Australia, Canberra, Standard 9.

63 Royal College of Pathologists of Australasia, *Provision of Second Opinions with Particular Reference to Histopathology Cytology and Specimens for Morphological Examination*, 1 March 2001.

64 *Ibid.*, 3.3–3.6.

16.68 For educational and quality review purposes, consent is generally considered to be an implied part of patient care while the individual is still a patient at the institution where the review is taking place.⁶⁵ Research use of pathology samples requires consent unless HREC approval for a waiver of consent has been acquired in accordance with the National Statement. Otherwise samples should be used only for the purpose for which consent was obtained.⁶⁶

16.69 The RCPA policy statement provides that samples should not be released for insurance, employment or medico-legal purposes unless a subpoena or warrant has been acquired or where the individual has consented to the sample's use in this manner. Once the use has been completed, samples should be returned to the laboratory where they were held.⁶⁷ This would include police access to samples. Generally an individual's request for the return of his or her own material will be refused.⁶⁸

16.70 The RCPA has not at this point issued any policy statement on the retention and use of Guthrie cards specifically. However, in the United Kingdom, the Royal College of Pathologists has stated that newborn screening cards should be retained for 20 years.⁶⁹

Health authority policies

16.71 In some cases, health authorities have developed their own policies in relation to storage, access and disposal of samples and information held in their human tissue collections. For example, in relation to Guthrie cards, the Western Australia Newborn Screening Program has slightly different policies to those adopted in most other Australian programs, most notably the requirement that cards be destroyed after 2 years. In other states and territories cards are generally stored for much longer periods.

16.72 In Western Australia, cards will not be released for law enforcement purposes unless a subpoena has been acquired, and even then release will be restricted unless the requesting party can demonstrate that no alternative sample can be found.⁷⁰

65 Ibid, 3.3.

66 Ibid, 3.4.

67 Ibid, 3.5, 3.6.

68 Ibid, 3.7.

69 Working Party of the Royal College of Pathologists and the Institute of Biomedical Science, *The Retention and Storage of Pathological Records and Archives*, 2nd Edition (1999), Royal College of Pathologists, London.

70 WA Newborn Screening Program, *Policy for the Retention, Storage and Use of Dried Blood Spot Samples Collected by the Western Australian Newborn Screening Program*, Policy Guidelines, 1 January 2001.

16.73 In Victoria, cards are held at the Murdoch Childrens Research Institute and access is granted on a case-by-case basis. It is rare that cards are released to police. When they are it is generally only with a court order to identify deceased persons.⁷¹

16.74 In NSW, Westmead Hospital releases cards only with written parental consent and authorisation from the Director of the Screening Program.⁷² Cards may be released to the police under the terms of a Memorandum of Understanding between the program and the NSW police.⁷³ Cards may be released for certain forms of research.⁷⁴

16.75 In Western Australia, cards may be released for research, but only after the removal of identifiers. Demographic information may be provided if deemed necessary. Only one blood spot from each card will be released and the research project should aim to make some contribution to public or family health, or to the goals of public health screening.⁷⁵ Cards are sometimes released for research in Victoria, again through the Murdoch Childrens Research Institute, although the process of ethics approval is said to be much more stringent.⁷⁶

Options for reform

16.76 The Inquiry considers that there is a need for nationally consistent policies and practices in relation to the collection, storage, use of and access to pathology samples, banked tissue and Guthrie cards.

16.77 In relation to Guthrie cards, participation in screening programs is vitally important for detecting some treatable genetic conditions at an early stage and full participation in these programs should be encouraged. Lack of clarity about retention periods and permissible secondary uses, such as for research and law enforcement, may undermine newborn screening programs. For this reason, clear policies and practices should be developed and implemented. These policies and practices need to be consistent with the provisions of federal, state and territory health and information privacy legislation.

⁷¹ B Williamson, *Consultation*, 5 September 2001.

⁷² B Wilken, *Consultation*, 6 June 2001; The Children's Hospital at Westmead, *NSW Newborn Screening Programme*, <<http://www.chw.edu.au/prof/services/newborn/>>, 13 June 2001.

⁷³ B Wilken, *Consultation*, 6 June 2001.

⁷⁴ These are: special studies for families where the child is deceased; other special studies for families; forensic studies as directed by the Director General of Health/Department Head of the Newborn Screening laboratory; and when de-identified, for epidemiological studies approved by the hospital ethics committee: Children's Hospital at Westmead, *Sample Manual — NSW Newborn Screening Manual*.

⁷⁵ NSW Newborn Screening Programme, *Newborn Screening in NSW: Storage of Samples* (2000) NSW Department of Health.

⁷⁶ B Williamson, *Consultation*, 5 September 2001.

16.78 As discussed in Chapter 7 (see Proposal 7–2), there may also be advantages in extending the *Privacy Act*, and other state and territory privacy legislation, to cover identifiable bodily samples, as is the case in New South Wales under the *Privacy and Personal Information Protection Act 1998* (NSW).⁷⁷ Such a reform could provide important privacy protection in relation to the handling of genetic samples that are consistent with the principles that apply to information derived from these samples. In general, information and health privacy legislation is designed to co-exist with codes of practice that apply general privacy principles to specialised contexts.⁷⁸

Proposal 16–1. The Australian Health Ministers’ Advisory Council, in collaboration with key professional bodies, should develop nationally consistent policies and practices in relation to the collection, storage, use of and access to pathology samples, banked tissue, Guthrie cards and other samples collected and stored as part of a population genetic screening program.

⁷⁷ *Privacy and Personal Information Protection Act 1998* (NSW) s 4.

⁷⁸ Eg approved privacy codes under the federal *Privacy Act*: s 16A.

17. Ownership of Samples and the Human Tissue Acts

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Introduction

17.1 The existing regulatory framework to protect the privacy of human genetic samples and information focuses on the rights of individuals to control the collection, use and disclosure of their genetic information. The Inquiry proposes that the *Privacy Act 1988* (Cth) (*Privacy Act*), and similar state and territory health and information privacy legislation, should be amended to cover genetic samples, as well as the genetic information derived from them (Proposal 7–3).

17.2 Part of the reason for making this proposal is that if genetic samples are not to be covered by the *Privacy Act*, even where identifiable, there would be a major gap in the framework for protecting the privacy of the individuals from whom genetic samples are taken. Some other regime may have to be developed to fill the gap. This chapter presents other possible approaches to regulating the handling of genetic samples and to providing the individuals from whom genetic samples have been taken with rights to exercise more control over what happens to the samples.

17.3 The chapter discusses property rights in genetic samples and, in particular, whether the privacy of genetic samples and information could be more adequately protected by allowing some property rights other than possession to be exercised over genetic samples. The chapter then examines whether the Human

Tissue Acts¹ should be amended to comprehensively regulate the collection, storage, use of, and access to, genetic samples.

Ownership of human genetic samples

17.4 IP 26 briefly considered whether reform of property law could provide individuals with means to better protect the privacy of their genetic information. It was noted that the exercise of information privacy rights and any property rights that may exist in human genetic samples need not conflict.²

17.5 The idea of according property rights in human tissue, which includes the genetic material that may be extracted from almost all human cells, is not entirely novel. In the United States, property rights have been suggested as a possible means of protecting the privacy of genetic samples and information. For example, s 104(a) of the model Genetic Privacy Act (GPA) provides that 'an individually identifiable DNA sample is the property of the sample source'.³ The authors of the GPA explain that:

By establishing an individually identifiable sample as the property of the sample source, the GPA serves not only the interest of those who would want to maintain exclusive control over their DNA, but also enables those who desire to share or transfer such control to do so. This ability is particularly important to individuals who are concerned with preserving their own samples for the future use and benefit of relatives and descendants ... Owning one's own DNA sample allows transfer of control in accordance with property law principles.⁴

17.6 A version of the GPA was introduced into the United States Congress in 1995. However, although it identified a DNA sample as property, it did not assign ownership of that property to anyone.

17.7 In 1995, Oregon became the first state in the United States to grant ownership rights in genetic samples to the individual from whom it was obtained and to that person's children.⁵ However, the Oregon law was amended in 2001 to specify that genetic samples were *not* property, but that both genetic samples and

1 *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

2 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 7.41.

3 P Roche, L Glantz and G Annas, 'The Genetic Privacy Act: A Proposal for National Legislation' (1996) 31(1) *Jurimetrics* 1. In Australia, this would be known as a Model Bill, since it has not passed through the parliamentary process.

4 G Annas, L Glantz and P Roche, 'Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations' (1995) 23(4) *The Journal of Law, Medicine and Ethics* 360, 363.

5 *Oregon Genetic Privacy Act 1995* (US), §4(1).

information were private and must be protected.⁶ The amendments were made after the property approach was criticised as a disincentive to research — an argument that also was put to the Inquiry in the submissions.⁷

17.8 At present, no Australian legislation makes any determination on the property status of genetic samples. Instead, the status of such samples is covered by the common law.

Consequences of property rights

17.9 Property is often described as a ‘bundle of rights’, which includes the rights to use, transfer, manage and possess that object. This bundle of rights also normally includes the right to the income generated by the object and the right to its capital value — which may not be regarded as appropriate rights for individuals to have in respect of genetic material. For example, such rights would allow an individual to sell their genetic material. Where a person was found to have unique and valuable genetic material, he or she would be free to offer it to the highest bidder. In place of the current system of altruistic donation of samples for research, a situation could result whereby researchers would have to bid for access to genetic material.

17.10 There are other incidents of property that may be problematic in the context of human genetic information. Property normally can be subject to ‘execution’; that is, it can be seized to pay a debt pursuant to court order. However, it is unlikely that our legal system would countenance seizure of someone’s genetic material to satisfy a debt.

17.11 Property rights normally are alienable; that is, they can be transferred to others. For example, if a hospital had property rights in a sample, it could transfer them to a pharmaceutical company for a fee. That company would then have the right to use the samples to produce a product and would be entitled to any income that was generated by this use.

6 The provision was altered by §15 of Senate Bill 114 of 2001. Attempts were made to remove the property provision in 1999 through Senate Bill 937, but these measures failed. See further P Wentz, ‘Royal Flush’ (1999) 25(22) *Williamette Week*; A Onion, *Should You Own Your Own Genes?*, ABC News (USA), <abcnews.go.com/sections/scitech/DailyNews/geneprivacy010508.html>, 10 May 2001; Institute for Health Freedom, *Who Owns Your Genetic Information?*, <forhealthfreedom.org/Publications/Informed/WhoOwns.html>, 3 April 2001. The state of Georgia passed similar provisions which have also subsequently been repealed.

7 N Zeps, *Submission G047*, 14 January 2002.

Legal status of genetic samples

17.12 The traditional position under the common law was that a human corpse could not be an object of property. This rule gained support in a number of cases and was generally accepted throughout the 19th century.⁸

17.13 Over the last century, the common law has shifted away from the original rule against property in corpses towards recognising ownership interests. Body parts and sections of tissue also have been accorded property status in some cases. Samples of blood and urine, as well as blocked tissue sections, have been considered within the context of the rule, which is likely to be wide enough to encompass genetic samples of all kinds.

17.14 The shift away from the rule against property in corpses came at the start of the 20th century, when the High Court of Australia held that it was possible to have ownership rights over a corpse.⁹ Although the decision was not unanimous on this point, Griffith CJ took the view that the rule against property did exist, but that it was subject to an exception. His Honour held that it was possible for human bodies and parts to become the subject of property rights where work or skill have been exercised to preserve them.¹⁰

17.15 Two later cases concerned the taking of urine and blood samples that had been provided to the police. It was found in each case that the samples had been stolen,¹¹ with both decisions being regarded as support for the property status of tissue samples.¹² These cases did not expressly consider the rule noted above, but appear to have assumed that tissue can amount to property for the purposes of theft. Whether such an approach would be taken in other situations is unclear — in both cases the samples were provided to a law enforcement body, in accordance with legal requirements.

8 The major cases are *R v Sharpe* (1857) 169 All ER 959; *R v Price* (1884) 12 QB 247 and *Williams v Williams* (1881) 20 ChD 659. The rule against property in corpses was generally accepted until the 20th century.

9 *Doodeward v Spence* (1908) 6 CLR 406. The case concerned an action for the return of a two-headed foetus preserved in a jar of alcohol. Only Griffith CJ in the majority upheld the exception based on work or skill. Justice Barton held that the foetus could be the subject of property rights because it was not a human body awaiting burial, being instead a freak of nature that was not fit for Christian burial. Justice Higgins in dissent disagreed that a human body could be the subject of ownership rights. Despite the divergence of opinion in the decision, the case has been used as support for the 'work or skill' exception in a number of subsequent cases.

10 *Ibid*, 414 (Griffith CJ).

11 *R v Rothery* [1976] Crim LR 691; *R v Welsh* [1974] RTR 478.

12 R Magnusson, 'The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions' (1992) 18 *Melbourne University Law Journal* 601, 617; G Dworkin and I Kennedy, 'Human Tissue: Rights in the Body and its Parts' (1993) 1 *Medical Law Review* 291, 300; P Matthews, 'Whose Body: People as Property' (1983) 36 *Current Legal Problems* 193, 223.

17.16 By contrast, a 1996 decision of the English Court of Appeal rejected a claim that sections of a brain preserved in paraffin could be property. Although the court accepted the ‘work or skill’ exception propounded by Chief Justice Griffith in *Doodeward v Spence*, it found that merely fixing tissue to preserve it for medical purposes was not enough. Only processes meant to permanently preserve tissues, such as embalming and stuffing, were regarded as sufficient to meet the requirement of work or skill, and the tissue also must have been awaiting burial. This decision has been criticised and was not followed in later cases.¹³

17.17 The two most recent cases on ownership of tissue samples have upheld property rights. The 1998 case of *R v Kelly*¹⁴ held that preserved body parts taken from the Royal College of Surgeons were the property of the Royal College. The Court found that the exception to the rule was now accepted at law and that preservation for study and retention, as well as dissection, were enough to meet the criterion of work or skill. Whoever undertakes that work or skill becomes the owner of the tissue sample, as long as they have performed it with lawful authority.

17.18 In 2000, the Supreme Court of Western Australia considered a case in which a woman sought access to preserved tissue samples taken from a man whom she alleged was her father.¹⁵ The man had died and the applicant wished to have the samples tested to prove her entitlement to claim a portion of his estate.¹⁶ Master Sanderson found that the samples were property in the sense that they could be acquired for the purpose of the case, within the meaning of a Supreme Court rule allowing inspection of ‘property’.¹⁷

17.19 Claims for access to samples for genetic testing, whether to determine paternity or the presence of a genetic condition, are likely to become increasingly common as the sophistication and availability of genetic tests increases. The present state of the law suggests that preserved samples of tissue are the property of the hospital that holds them where its staff has exercised the work or skill required for preservation. This has implications for access, storage and use of such samples.

17.20 However, the cases to date have dealt with only very limited fact situations. The courts have not produced any clear ruling on the particular property rights that may be held over tissue samples, beyond a right to possess — the violation of which constitutes theft only in very specific circumstances. It is not clear how far other property rights could be said to exist in relation to tissue samples.

13 D Brahams, ‘Body Parts as Property’ (1998) 66(2) *Medico-Legal Journal* 45.

14 *R v Kelly and another* [1998] 3 All ER 741.

15 *Roche v Douglas* [2000] 22 WAR 331.

16 Parentage testing is discussed in more detail in Ch 31.

17 *Roche v Douglas* [2000] 22 WAR 331, [23]. A similar conclusion on similar facts was made in *Pecar v National Australia Trustees Limited* (Unreported, Supreme Court of NSW, Bryson J, 27 November 1996).

17.21 The question facing the Inquiry is whether the privacy of human genetic information could be more adequately protected by allowing some property rights other than possession to be exercised over genetic samples. This raises a number of associated issues. For example, should individuals be able to sell their genetic material? Should hospitals have a right to the income from the use or sale of samples? Would a right to manage samples protect unwanted access and use? Would such a right prevent others from accessing the genetic information contained within the sample and then using it to discriminate against the individual from whom it was taken?

Is a property approach appropriate?

17.22 Submissions made to the Inquiry on the question of ownership of genetic samples were divided in opinion. A number favoured property rights in genetic material as a means of protecting genetic privacy,¹⁸ with some also suggesting solutions to the drawbacks of taking a 'property approach' to protect genetic samples.

17.23 One of the major advantages associated with making genetic samples property is that once possessed, property rights can be asserted against all others who do not possess the requisite right to deal with the samples. For example, if only person A has a right to possess and use a genetic sample, there will be a corresponding duty on others not to interfere with that right and a correlative legal disability — they may not be allowed to use a sample as they do not have property rights in it.

17.24 As these rights can be asserted against others, where they have been violated, individuals would have the ability to bring actions for the destruction or return of their genetic samples where they were being used in a manner contrary to those rights. If these rights had not been alienated, then a claim could be brought against any person who interfered with the samples.

17.25 Such an approach overcomes one of the problems of the current consent-based approach, where it may be the case that only the person to whom an individual has given consent to use samples can be the subject of a legal claim. For example, if an individual gives consent for person A to use their tissue, and person A uses it in a manner inconsistent with that consent, the individual has a claim against that person. If however, person A transfers the sample to company B who misuses it, the individual is not in a legal relationship with company B and has no claim against it.

18 A Johnston, *Submission G042*, 13 January 2002; Caroline Chisholm Centre for Health Ethics, *Submission G061*, 26 December 2001; D Pawlukowski, *Submission G067*, 15 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Womens Health Victoria, *Submission G076*, 3 January 2002.

17.26 In many cases individuals have not explicitly transferred rights to genetic samples. Pathology samples held by laboratories, pieces of hair left on the hairdresser's floor and sections of tissue removed during surgery are all examples where samples have come into the possession of someone other than the individual from whom they were taken, yet there may have been no clear transfer of rights. In each case, a right of possession vested in the individual from whom the samples are taken might enable that individual to bring an action against the person holding the samples, regardless of whether they were misusing them, on the basis of interference with the individual's own right to possess the samples.

17.27 This problem might be overcome in some circumstances by a legal assumption that certain rights are transferred when samples are provided. For example, it could be assumed that in providing a blood sample to a pathology laboratory, the individual transfers a right of possession (perhaps with only limited scope). It also could be assumed that in some instances individuals have abandoned their rights over genetic samples, perhaps only on the condition that they are not misused. These problems demonstrate the clumsiness of a property approach in relation to the protection of genetic samples — by providing such strong rights and protections, the approach also produces some unwanted results.

17.28 The second advantage of a property approach is the ability to alienate rights over genetic samples. Rights to possess and use can be transferred by the individual to researchers, who will then be entitled to deal with the genetic samples in accordance with the right they have been accorded. Depending on the rights that have been transferred, they may be empowered to transfer those rights to other researchers and commercial bodies.

17.29 However, there are disadvantages to this approach. By allowing individuals to transfer rights over their tissue samples to someone else, they lose their interest in what is done with them. If a person transfers a right to use their tissue to a researcher, that person will have no claim against the researcher if the sample is used in a way that they find objectionable. In such a case, the person would be unable to prevent the sample being tested to generate genetic information. Again, it can be seen that property law may be a rather 'blunt instrument' for protecting a person's interest in his or her genetic samples.¹⁹

17.30 One submission proposed that property rights should enable an individual to control the use of their tissue, but that individuals should be prevented from transferring all rights. Doctors and researchers would be able to use tissue samples under some form of lease agreement, after the presentation of a research proposal.

¹⁹ R Magnusson, 'The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees' (2000) 7(4) *Journal of Law and Medicine* 390, 394.

It was suggested that lease agreements would be made publicly available and be overseen by an independent body.²⁰

17.31 Dr Nikolajs Zeps of the West Australian Tissue Bank suggested a model whereby tissue banks would be able to hold and use tissue as a custodian. The individual would retain the right to withdraw custodianship and could request the destruction or transfer of their samples as they wished:

Ideally the donor would delegate all responsibility for the use of their tissue to a Tissue Bank that distributes tissue under the auspices of [Human Research Ethics Committee] (HREC) approval for those wishing to use tissue.²¹

17.32 These approaches would deal with some of the problems of alienation of rights. However, they do not address the further issue of rights to income and capital of tissue that has been used for financial gain. Allowing people to exercise these rights over their genetic samples is regarded by some as allowing the human body to be commodified. This may alter community attitudes towards bodies and their parts, and as a result alter how we perceive and treat living human beings.

17.33 Commodification of genetic samples was identified as a concern in several submissions. One submission warned that property is often used to connote objects and things that are devoid of personal origins and significance.²² On this view, treating parts of human bodies, including genetic samples, as objects can have the flow-on effect of objectifying living people, or treating them as a source of valuable biological material, which is inconsistent with social understandings of the dignity of human beings.

17.34 As was noted in a submission from the Caroline Chisholm Centre for Health Ethics, in some circumstances, there is a need for private companies to have access to samples, and provision for reimbursement and profit sharing might be appropriate.²³ However, in Australia, altruistic participation in research is regarded as beneficial to the community as it reinforces a sense of unity and sharing.²⁴ Virtually all research participation, including the use of tissue samples, occurs without remuneration in this country.

20 A Johnston, *Submission G042*, 13 January 2002.

21 N Zeps, *Submission G047*, 14 January 2002.

22 Caroline Chisholm Centre for Health Ethics, *Submission G061*, 26 December 2001.

23 Ibid.

24 T Murray, 'On the Human Body as Property: The Meaning of Embodiment, Markets and the Meaning of Strangers' (1987) 20(4) *Journal of Law Reform* 1055.

17.35 Introducing a system of property rights could alter this situation by giving individuals the ability to sell the right to use their tissue. Altruistic participation could be eroded, although it is likely that a section of the community would still allow use of their tissue without seeking compensation.²⁵

17.36 Allowing individuals to request financial returns on the use of their tissue would allow them to share in the profits that are sometimes made from treatments that result from research. However, it also would burden research by increasing costs, which would likely then be passed on to consumers. As one submission stated:

to negotiate with a donor for a share in property rights would be a massive obstacle to medical research and the practice of medicine in general.²⁶

17.37 This possibility might be avoided by excluding the right to sell from the bundle of property rights held in a tissue sample. Limited property rights, in order to prevent commercial exploitation, was suggested by Uniting Care NSW&ACT. However, this suggestion was made on the proviso that those rights should not enable the individual to prevent sharing of non-identified samples for research as long as the samples were not collected in an unethical or discriminatory manner.²⁷

17.38 The Australian Academy of Science argued against individual property rights on the basis that genetic samples should be a community resource for health and also made the point that if genetic samples were the personal property of the individual from whom they were taken, all research use would be encumbered by this interest.²⁸ The Life Sciences Network concurred and submitted:

We believe that health samples and records (maintained within a system which assures confidentiality about individuals) should be seen as part of our community resource for health, rather than as a form of personal property of the individual receiving care or treatment. The aggregated results of this knowledge bank confer a substantial community benefit.²⁹

17.39 The recognition of property rights also would undermine the current system of ethical approval for research, where consent to use can be waived in some situations by a Human Research Ethics Committee (HREC).³⁰ It is questionable whether it would be lawful to waive consent where a person holds property rights over tissue.

25 Coercion of the poor and the unsatisfactory situation of the less wealthy selling parts of their bodies to the rich have also been raised as concerns. See T Murray, 'The Gift of Life Must Always Remain a Gift' (1986) (March) *Discover* 90.

26 N Zeps, *Submission G047*, 14 January 2002.

27 UnitingCare NSW & ACT, *Submission G052*, 14 January 2002.

28 Australian Academy of Science, *Submission G097*, 21 January 2002.

29 Life Sciences Network, *Submission G129*, 19 March 2002.

30 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, Ch 15; *Privacy Act 1988* (Cth), ss 95, 95A. See further on the waiver of consent to use tissue samples in research: Ch 12.

17.40 Further, if genetic samples were regarded as property, de-identification would not extinguish the rights of the person from whom the sample was taken. De-identification is one of the current mechanisms used by researchers, with the approval of HRECs, to enable important research to be carried out while still protecting the privacy of individuals.

17.41 Some submissions offered variations on the individual property model. Professor Loane Skene of the University of Melbourne felt that while individuals should not hold property rights in their own genetic material, hospitals and researchers should be able to have a proprietary interest in samples.³¹ This would circumvent problems with encumbrance and individual sale of tissues, while protecting and promoting important research and aspects of clinical practice.

17.42 Upholding the possessory rights of hospitals and researchers would maintain the integrity of their collections, and protect samples from arbitrary interference. The hospitals and researchers are not granted any stronger rights, such as rights to the income, they are still prevented from profiting from samples, and the culture of altruistic participation in research is maintained. This view also accords with the current common law situation and allows for regulation through principles of consent to be maintained. Privacy NSW agreed on the efficacy of using informed consent principles and protecting autonomy rights to protect privacy.³²

17.43 On balance, the Inquiry considers that the benefits of regarding genetic samples as property are outweighed by the drawbacks, and that the current status of genetic material should be maintained. While a property approach arguably has some merits, the Inquiry considers that other approaches would be more effective in protecting genetic privacy.

Proposal 17–1. The common law right to possession of preserved samples, which is currently enjoyed by hospitals and others, should continue to be upheld, but full property rights in genetic samples should not be granted.

Amendment of the Human Tissue Acts

17.44 In its 1977 report *Human Tissue Transplants* (ALRC 7), the Australian Law Reform Commission concluded that the common law was silent on property in human tissue removed during surgery or otherwise in the possession of a doctor

³¹ L Skene, *Submission G017*, 16 November 2001.

³² Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

or hospital. The Commission concluded that there was 'no reason to endow such tissue with the attributes of property'.³³

17.45 Following the recommendations of the *Human Tissue Transplants* report, the Human Tissue Acts were enacted in the various Australian jurisdictions. As outlined in Chapter 15, the Human Tissue Acts provide for the consensual donation of blood, tissues and organs for transplantation, and for scientific, therapeutic or medical purposes. The Acts did not anticipate the advent of genetic research, and do not contain any provisions dealing with the storage of samples, access to them, transfer to other researchers or the future use of samples.

17.46 IP 26 noted that the current uses of tissue samples in genetic research and bio-prospecting were not envisaged at the time the Human Tissue Acts were enacted³⁴ and asked whether the Human Tissue Acts should be amended to regulate the collection and use of human tissue samples for genetic research.³⁵ IP 26 stated that the Human Tissue Acts might constitute a useful starting point for new regulations dealing with the collection and handling of human tissue samples and, in particular, the use of clinical samples for genetic research.

17.47 At present, the donation of tissue removed as part of medical treatment, such as sections of tissue excised during surgery or blood leftover from testing, is excluded from the coverage of the Human Tissue Acts.³⁶ Therefore, there are no legislative requirements that consent be obtained to retain and use these samples. Consent to further research uses must be obtained when access to samples is sought, in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).³⁷

17.48 In his submission, Dr Roger Magnusson referred to this omission in the Acts as a 'loophole', and suggested that it had facilitated the development of tissue banks in Australian hospitals and research institutions.³⁸ In another submission, it

33 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), AGPS, Canberra, para 13.

34 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 7.37.

35 Ibid, Question 7–4.

36 *Human Tissue and Transplant Act 1982* (WA) s 32(1); *Human Tissue Act 1985* (Tas) s 28(1)(a), (b); *Transplantation and Anatomy Act 1983* (SA) s 37(1)(a), (b); *Transplantation and Anatomy Act 1979* (Qld) s 47(1)(a), (b); *Human Tissue Transplant Act 1979* (NT) s 26(1)(a), (b); *Human Tissue Act 1983* (NSW) s 34(1)(a), (b); *Transplantation and Anatomy Act 1978* (ACT) s 46(1)(a), (b). R Magnusson, *Submission G039*, 10 January 2002, National Council of Women Australia, *Submission G095*, 31 January 2002.

37 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, Ch 15. See further Ch 12.

38 R Magnusson, *Submission G039*, 10 January 2002.

was asserted that researchers obtain samples from tissue banks in order to avoid having to seek consent directly from research subjects.³⁹

17.49 One of the major concerns relating to protecting privacy in relation to genetic samples is the quantity of samples that are currently stored in research databases and laboratory sample collections. Many of these samples, especially those that were originally taken for therapeutic purposes, are stored without the knowledge and express consent of the person from whom they were taken. There are no legislative provisions governing how and for what purposes genetic samples removed during medical procedures may be stored or used.

Reform options

17.50 There are a number of ways in which the Human Tissue Acts could be amended. These include:

- the enactment of more comprehensive provisions dealing with consent to the storage and use of genetic samples in research;
- including tissue removed during medical procedures within the coverage of the Acts, making tissues subject to the Acts' consent and other requirements;
- the enactment of comprehensive provisions dealing with other aspects of the handling of tissues, including, for example rules for the storage, use of and access to such tissues.

17.51 The consent provisions in the Acts could be amended to require more comprehensive consent to the use of genetic samples in research. These provisions could require certain information to be provided for consent to be valid, including notification that samples may be stored and information on the kind of research for which they will be used. As samples are often re-used for a number of research projects, or used in projects that are not foreseen at the time of collection, the Acts could be amended to require future consent to subsequent re-use.

17.52 At present, tissue removed during medical procedures is excluded from the ambit of the Acts, however they could be amended to require that the same consent procedures be applied to tissue acquired in this manner. Consent to the storage and later research use of this kind of tissue would need to be obtained for that use to be lawful. This would avoid any problems associated with the omission of tissue removed during medical procedures. It also would ensure that all genetic samples were subject to the same requirements of consent to store and use.

39 Confidential Submission G051CON, 14 January 2002.

17.53 There some support in submissions for amending the Acts in these ways. The Centre for Law and Genetics stated:

The *Human Tissue Acts*...may be the appropriate legislation to regulate the collection, storage, release, use and access to human genetic samples. The *Human Tissue Acts* were intended to regularise the authorised use of human tissue for transplantation. Consistently these Acts could be used to regularise the authorised collection, storage, release, use and access to human tissue by providing that such dealings must be authorised. 'Authorisation' could define the proper medical, pathological and research use of human tissue. In addition, amendments to the *Human Tissue Acts* could include provision for restricting the use of human tissue to the purposes for which it was collected or stored as well as including a general requirement for the consensual collection, storage, release, use and access to the sample. By inclusion in legislation, criminal sanctions could attach to unauthorised use of human tissue. Inclusion in the *Human Tissue Acts* would represent at least a 'symbolic statement' about the national importance of the proper use of human tissue.⁴⁰

17.54 Other submissions supported the need to amend the consent provisions in the Human Tissue Acts. A number of submissions suggested that it would be beneficial to amend the Acts to require consent to research use of tissue removed for therapeutic purposes. Women's Health Victoria submitted that:

The Human Tissue Acts should require researchers to obtain patient consent as a precondition to using human tissue samples originally removed for therapeutic purposes. The simplest approach is to seek consent for further research at the time the sample is taken.⁴¹

17.55 The National Council of Women Australia stated:

The Human Tissue Acts should be amended to regulate the collection and use of human tissue samples for genetic research. When a sample of tissue is removed for therapeutic purposes, the patient should sign consent for the material to be used for research.⁴²

17.56 Similarly, both the Neurofibromatosis Association of Australia and Dr Nikolajs Zeps of the West Australia Tissue Bank suggested that the consent provisions in the Acts be amended to require that patients be informed that their samples may be stored for use in research.⁴³

17.57 Amending the Human Tissue Acts in these ways could place the use of all human tissue samples under one regulatory scheme, removing confusion and promoting a consistent approach to the use of tissue in research. It could give individuals a legal basis for complaint if they consider their tissues have been

40 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

41 Womens Health Victoria, *Submission G076*, 3 January 2002.

42 National Council of Women Australia, *Submission G095*, 31 January 2002. See also J Torrens, *Submission G029*, 11 January 2002 in support of this view.

43 Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; N Zeps, *Submission G047*, 14 January 2002.

misused, and those who do not comply with the consent requirements could be subject to criminal sanctions already provided for in the Acts.

Arguments against reform

17.58 Although the Human Tissue Acts might constitute a useful starting point for new regulation there are also problems with such an approach. The most fundamental objection is that the storage and use of genetic samples would be regulated differently to the storage and use of genetic information contained in the samples under information and health privacy legislation. This might also produce overlap or inconsistency between the Human Tissue Acts and privacy legislation.

17.59 Further, the Human Tissue Acts were intended primarily to deal with issues relating to donation of blood, tissues and organs for transfusion, transplantation, and other therapeutic purposes, the removal of tissue after death and to regulate commerce in human tissue. To amend the Acts to comprehensively regulate other aspects of the handling of human tissue may create unnecessary complexity and would be a difficult drafting exercise.

17.60 The Human Tissue Acts have been the subject of intensive review over the last few years, primarily to deal with issues relating to the retention and use of body parts after death (including in post mortem examinations). In this context, there may be practical reasons not to suggest further reform of the Human Tissue Acts until law reform processes dealing with these issues have run their course.⁴⁴ As each state and territory has enacted its own Human Tissue Act legislation, with relative uniformity in most major areas, any overhaul of the legislation might have adverse effects on harmonisation.

17.61 Another argument against amending the Human Tissue Acts is that the Acts require consent to be obtained prior to the removal of tissue. Extension of this requirement to include obtaining consent for research use of samples before collection of tissue samples removed during therapeutic procedures would be administratively onerous, potentially distressing to patients and inconsistent with the present regulatory framework for the ethical conduct of research, based on the National Statement and on review of research proposals by HRECs.⁴⁵

44 B Walker, *Inquiry into Matters Arising from the Post-Mortem and Anatomical Examination Practices of the Institute of Forensic Medicine* (2001), Department of Health, New South Wales; South Australia Solicitor-General, *Report into the Retention of Body Parts after Post-Mortems* (2001), Department of Health Services, South Australia, Adelaide; NSW Health Department, *Review of the Human Tissue Act: Organ and Tissue Donation and Use and Post Mortem Examination* (1999), NSW Health, Sydney; Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue Following Post-Mortem Examinations* (2001), Department of Health, Western Australia, Perth.

45 See Pt D.

17.62 The present regulatory framework provides for the waiver of consent where research would otherwise be unduly restricted and provides guidelines on the information that should be provided to individuals donating tissue for research. The system for ethical review of research proposals by HRECs allows a flexible approach to be taken on consent issues. The Human Genetics Society of Australasia stated in its submission that the Human Tissue Acts were not the appropriate mechanism by which collection of tissue for research should be regulated.⁴⁶

17.63 The Inquiry's preferred starting point for any comprehensive reform of the law relating to the collection, storage, use of, and access to, genetic samples is to build on existing information and health privacy legislation. As discussed in Chapter 7, this could be done by ensuring that privacy legislation, and basic privacy principles, cover the handling of genetic samples, as well as the genetic information derived from them. However, if this approach is not adopted, the Inquiry considers that it may be preferable to consider the enactment of new legislation to deal with privacy protection of genetic samples, rather than amending the Human Tissue Acts.

Proposal 17–2. The Human Tissue Acts should not be used as the vehicle for regulating collection, storage, access to, or use of genetic samples, whether for the purposes of human genetic research or otherwise.

⁴⁶ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

Part F. Health Services

18. Health Professionals and Family Genetic Information

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Introduction

18.1 IP 26 highlighted the familial or collective nature of genetic information.¹ Genetic information may allow inferences to be drawn about individuals other than the individual to whom the information most directly relates — most importantly about their blood (genetic) relatives.

18.2 Genetic information about one person may be relevant to the clinical treatment of that person's genetic relatives. This leads to questions about how individual patients and their doctors and other health professionals, including genetic counsellors, should collect and deal with genetic information about genetic relatives, derived in the course of diagnosis, treatment or counselling. These questions are the focus of this chapter.

¹ See Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.11; para 4.84–4.102.

18.3 The collection and disclosure of family genetic information, and rights of access to such information, are also central to the operation of genetic registers and to the conduct of genetic counselling. Issues raised by the use of genetic information in these particular contexts are specifically addressed in Chapter 19.

Collection of genetic information by health professionals

18.4 The collection of family medical history information is an established part of medical practice. When providing a health service, health professionals may need to collect information about an individual's family medical history in order to accurately diagnose a patient's condition.

18.5 This information may relate to the health, or cause and age of death, of individuals closely genetically related to the patient. It may also include social medical history — for example, information regarding marital status, health of spouse, children and other household members and what social support is available.²

18.6 Family medical history information takes on particular significance in the practice of genetic medicine.³ Genetic diagnosis is not always possible from a sample or information provided by one person and it may be desirable to test genetic relatives as well as the immediate patient. Such testing may be necessary to establish inheritance patterns correctly, to confirm the mutation in at least one other affected member of the family (as part of developing a 'family-specific' genetic test) or in conducting susceptibility testing for at-risk families.⁴

18.7 Even if genetic relatives are not actually tested, the verification of a genetic diagnosis usually involves the provision of information from or about relatives. This is often referred to as the compilation of a 'family pedigree'.

The information to construct the "family pedigree" may come from living relatives; death registers; autopsy results; cancer or other registers; medical records of relatives who have died; deposits of stored tissue; or other research studies.⁵

18.8 Information about the medical history of genetic relatives assists health professionals to provide effective health services to their patients. Such information may assist in diagnosis, the provision of medical advice about genetic risk (to the patient or to present or future children), the treatment or prevention options and in

² *Privacy Commissioner Temporary Public Interest Determination No. 2001-1 2001* (Cth), 3.

³ Many submissions referred to the clinical importance of collecting medical information about the genetic relatives of patients: eg G Suthers, *Submission G026*, 30 November 2001; *Confidential Submission G030CON*, 17 December 2001; Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

⁴ See L. Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6 *Medical Law Review* 1, 5-6.

⁵ *Ibid.*, 6.

genetic counselling generally. Conversely, if this information is not collected the medical care or advice provided to the patient may be compromised.

Application of privacy legislation to collection

18.9 IP 26 raised questions about whether the *Privacy Act 1988* (Cth) adequately recognises the ‘familial or collective nature’ of genetic information.⁶ One issue involves the constraints that the *Privacy Act* and other privacy legislation imposes on the collection of relevant genetic information by doctors and other health professionals about the genetic relatives of their patients.⁷

18.10 National Privacy Principle (NPP) 1 of the *Privacy Act* provides generally that an organisation must not collect personal information unless the information is necessary for its functions and must collect personal information only by lawful and fair means and not in an unreasonably intrusive way.⁸ Individuals must be informed about various matters such as their access rights, the purposes of collection and to whom the organisation usually discloses information of that kind.⁹ In general, an organisation must collect personal information about an individual only from that individual, rather than from any third party, unless it is not ‘reasonable and practicable’ to do so.¹⁰

18.11 Under NPP 10, an organisation generally must not collect sensitive information (including genetic and other health information) unless the individual has consented. This principle then sets out an extensive codification of circumstances in which an organisation may collect sensitive information without consent. Most relevantly, these include specified circumstances relating to the provision of health services. Under NPP 10.2, a health provider may collect health information without an individual’s consent when the collection is necessary to provide a health service to that individual and collection is carried out according to

6 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.84–4.88, Question 4–4.

7 Patients themselves need not comply with the *Privacy Act* NPPs in their collection, use and disclosure of information about their genetic relatives provided this is for the purposes of their ‘personal, family or household affairs’: *Privacy Act 1988* (Cth) s 16E; also *Health Records Act 2001* (Vic) s 13.

8 *Privacy Act 1988* (Cth) NPP 1.1–1.2.

9 Ibid, NPP 1.3.

10 Ibid, NPP 1.4. In order to determine whether it is ‘reasonable and practicable’ to collect information indirectly, the federal Privacy Commissioner has recommended balancing a number of factors. These include: whether it is possible to collect the information directly; whether a reasonable individual might expect information about them to be collected directly or indirectly; how sensitive the information is; the cost to an organisation of collecting directly rather than indirectly; the privacy consequences for the individual if the information is collected indirectly rather than directly; and what is accepted practice: Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), OFPC, Sydney, 22.

certain professional rules of confidentiality.¹¹ The Inquiry is not aware of any existing professional rules that comply with the requirements of NPP 10.2. Therefore, in some circumstances, the collection of family medical history information without the consent of family members by health professionals would breach these provisions of the *Privacy Act*.

18.12 This position was remedied by a Temporary Public Interest Determination (the Temporary PID), issued by the federal Privacy Commissioner on 21 December 2001 — the date the NPPs came into force under the *Privacy Amendment (Private Sector) Act 2000* (Cth).¹² The Privacy Commissioner recognised that informing third parties and seeking their consent to collection was not in line with the accepted practice of medical history taking because these activities would be time-consuming, may be impracticable, and would require additional resources.¹³

18.13 The Privacy Commissioner concluded that the public interest in medical histories taking outweighed to a substantial degree the public interest in full adherence to the NPPs because medical history taking, including in counselling and therapeutic settings, is central to good health care. Public health would be jeopardised by strict compliance with the NPPs, which would be an ‘unrealistic curtailment’ on the ‘core and essential practices’ of health providers.¹⁴

18.14 The effect of the Temporary PID is to ensure that organisations can continue to collect family medical history information without breaching the NPPs where the collection of health information from an individual about another individual (a third party) is

- necessary for the organisation to provide a health service directly to the individual and to diagnose, treat or care for the individual; and

11 The Privacy Commissioner has highlighted two key elements of the second part of the requirement. These are that professional rules dealing with obligations of confidentiality: must be binding on the health service provider, in the sense that breach will give rise to some sort of adverse consequence; and must be established by a competent health or medical body — such as medical boards recognised in federal, state or territory legislation: Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 3.

12 A Public Interest Determination (PID) or a Temporary Public Interest Determination may be issued by the Privacy Commissioner, on the application of an interested person, where an act or practice may breach the NPPs but the public interest in doing the act, or engaging in the practice, substantially outweighs the public interest in adhering to NPPs: See *Privacy Act 1988* (Cth) Part VI. In the present case, a Temporary Public Interest Determination was issued because an urgent decision was required and there was no time to conduct the consultation required before a permanent PID may be issued: *Privacy Act 1988* (Cth) s 80A. An extensive consultation process will be undertaken by the Office of the Federal Privacy Commissioner to gauge the merits of making the determination permanent: Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002. The Temporary Public Interest Determination will remain in operation until 20 December 2002.

13 *Privacy Commissioner Temporary Public Interest Determination No. 2001–1 2001* (Cth), 4.

14 *Ibid.*, 5.

- the third party is a member of the individual's family or household, or the third party's information is otherwise relevant to the individual's family medical history or social medical history.¹⁵

18.15 Issues concerning the collection of health information about genetic relatives will also arise under state and territory privacy legislation which contains privacy principles similar to those in the federal *Privacy Act*.

18.16 For example, the Victorian legislation, the *Health Records Act 2001* (Vic), which came into effect on 1 July 2002, contains provisions requiring an individual's consent to the collection of health information about that individual,¹⁶ organisations to collect health information about an individual only from that individual (if it is reasonable and practicable to do so)¹⁷ and requiring individuals to be informed about the circumstances of collection where health information about them is collected from someone else.¹⁸

18.17 Collection of family medical history information without the consent of family members by health professionals may breach some or all of these provisions of the new Victorian legislation. In response to this concern, the Victorian government is proposing to promulgate regulations to specify circumstances under Health Privacy Principle 1.1(i) under which a health service provider may collect health information from an individual about a family member of the individual.¹⁹ Such collection would be authorised only to the extent necessary to enable the individual who is attending the provider to receive safe and effective health, disability or aged care services.

18.18 While the Temporary PID and the proposed Victorian regulations allow collection practices that would otherwise breach legislative privacy principles, the need for such subordinate legislation to authorise the continuation of established and accepted medical practice may be criticised on grounds that the law should be discoverable and transparent.

18.19 Importantly, the Temporary PID and the proposed Victorian regulations only apply to situations where a health service is being provided directly to the individual (the patient) from whom family history information is sought. The information also must be collected directly from the individual being treated in order to come within the terms of the exemption provided by the Temporary PID.

15 Ibid.

16 *Health Records Act 2001* (Vic) Health Privacy Principle 1.1(a).

17 Ibid, Health Privacy Principle 1.3.

18 Ibid, Health Privacy Principle 1.5. See also Exposure Draft Health Records and Information Privacy Bill 2001 (NSW), Health Privacy Principle 3(1); 4(2).

19 Department of Human Services (Victoria), *Draft Proposals for Health Records Regulations*, <<http://healthrecords.health.vic.gov.au/propregs.pdf>>, 27 March 2002.

18.20 In some circumstances information about genetic relatives is collected in order to facilitate the diagnosis or treatment of other people — that is, to ensure that genetic relatives have an opportunity to become aware of their genetic risk and access genetic counselling and medical advice. Information collected from individual patients may then need to be verified through contact with other sources, such as the treating doctors of genetic relatives.

18.21 The Temporary PID and the proposed Victorian regulations do not authorise these forms of indirect collection of information about genetic relatives. These limitations are particularly relevant to the operation of genetic registers. The application of privacy legislation to the operation of genetic registers is discussed in more detail in Chapter 19.

Disclosure of genetic information to genetic relatives

18.22 Many submissions identified disclosure of genetic information to genetic relatives as an important topic for the attention of the Inquiry. For example, in what circumstances should the patient or their doctor inform other members of the family about genetic information relevant to their health or well-being? It is important that those tested should be advised to consider carefully with whom the test result should be discussed, before testing takes place.²⁰ However, following testing, if the patient is unwilling to inform his or her relatives, should the doctor take steps to inform them?

18.23 These issues have been referred to as ‘a looming area of medico-legal controversy’²¹ and have generated a great deal of comment both in Australia and overseas.²²

The overriding responsibility of the clinical geneticist remains with the patient and not to any other family members and certainly not to society because of the public health effects of the mutant gene. Nevertheless, the question of whether a mutant gene present in one member of a family constitutes clear-cut danger to others in the family, thereby justifying warning family members regardless of a patient’s preference, has not yet been answered satisfactorily.²³

20 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 34.

21 D Bell and B Bennett, ‘Genetic Secrets and the Family’ (2001) 9 *Medical Law Review* 130, 130.

22 See eg Ibid; L Skene, ‘Patients’ Rights or Family Responsibilities? Two Approaches to Genetic Testing’ (1998) 6 *Medical Law Review* 1; T Lemmens and L Austin, ‘The Challenges of Regulating the Use of Genetic Information’ (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 26; Pergament in M Rothstein, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven.

23 E Pergament in M Rothstein, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) Yale University Press, New Haven 92, 95.

18.24 Some submissions suggested that there should be more latitude for disclosure to genetic relatives given that the adverse health consequences of some genetic conditions may be both serious and preventable.²⁴ Other submissions expressed the view that the position with regard to disclosure in such circumstances should at least be clarified.²⁵

18.25 This chapter examines existing constraints on disclosure to genetic relatives and, in particular the content of, and exceptions to, the duty of medical confidentiality and the application of privacy legislation. Legal and ethical duties that patients and their health professionals may owe to family members are also discussed.

18.26 The Inquiry has concluded that privacy legislation inappropriately constrains health professionals' decisions about the disclosure of clinically relevant information to genetic relatives and proposes reforms to remedy this position, including amendments to the *Privacy Act* and the development of National Health and Medical Research Council (NHMRC) guidelines dealing with this issue.

Disclosure and prevention of harm

18.27 IP 26 noted that, in some circumstances, the disclosure of genetic testing information could allow the prevention of serious health consequences in genetic relatives.²⁶ The obvious practical benefits in disclosing this information to family members include the early detection and treatment of inherited genetic disorders.

18.28 Issues surrounding the disclosure of information to genetic relatives may become increasingly important as further preventative measures become available to mitigate genetic risk.²⁷ Associate Professor John MacMillan observed that, at present, maintaining individual privacy to genetic information is not likely to physically harm others in the family to a greater extent that they would be harmed without access to the information. However, he noted that

... this will change in the future as knowledge gained from genetic testing may enable effective prevention of some adverse outcomes. In such circumstances restricting the information to the single individual tested may fail to offer the opportunity for preventative action in other at risk family members.²⁸

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- 24 Centre for Law and Genetics, *Submission G048*, 14 January 2002; F Macrae, *Submission G069*, 14 January 2002; G Suthers, *Submission G026*, 30 November 2001; R Magnusson, *Submission G039*, 10 January 2002.
- 25 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G051CON*, 14 January 2002.
- 26 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.90.
- 27 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.
- 28 J MacMillan, *Submission G015*, 19 November 2001.

18.29 Developments in genetic medicine have implications for the extent to which the confidentiality of the doctor and patient relationship should be given primacy over other ethical considerations. That is, where genetic information only reveals an inherited susceptibility to a disease or cancer that is unpreventable it is easier to argue that the information should remain confidential as compared to situation where denying access may place family members at increased risk.²⁹

18.30 Clinical geneticists and others provided many examples of such situations in submissions to the Inquiry. Dr Graeme Suthers, the Head of the Familial Cancer Service in South Australia referred to the following situation, based on an actual case (names have been changed).

Deidre has had breast cancer and has been shown to have an inherited mutation in the BRCA1 gene. Her mother, Marjorie, also had breast cancer and presumably carries the same mutation. Marjorie has a large extended family with many young women at risk of having the mutant gene and of developing early-onset breast cancer. Deidre had given me the address of her mother and had agreed that she (and other relatives) could be informed of the outcome of genetic testing. This would pave the way for genetic testing of Marjorie's unaffected relatives. However, on receiving the test result Deidre changes her mind and revokes permission for this information to be released to her relatives. At this stage none of her relatives are aware that she has had a genetic test. Whose rights should prevail — Deidre's right to the confidentiality of her test result, or Marjorie's right to be informed of a result she doesn't know about but which maybe life-saving?³⁰

18.31 Dr Finlay Macrae, Head of Colorectal Medicine and Genetics at the Royal Melbourne Hospital expressed concerns about existing constraints on disclosure to genetic relatives. For example, where genetic testing confirms familial adenomatous polyposis (FAP)

Standard advice is that the affected and genotyped individual passes the information of the availability of predictive testing to at risk relatives. But some do not pass the information on to all relevant family members, for a variety of reasons. Avoidable deaths do occur because of this.³¹

18.32 The literature dealing with genetic information and confidentiality issues also contains examples where disclosure is clearly capable of averting significant health dangers.³² Professor Loane Skene has concluded that, at least presently, disclosure to genetic relatives is arguably most justified in the case of FAP.

29 Ibid.

30 G Suthers, *Submission G026*, 30 November 2001.

31 F Macrae, *Submission G069*, 14 January 2002.

32 L Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162, 169; W-C Leung, 'Results of Genetic Testing: When Confidentiality Conflicts with a Duty to Warn Relatives' (2000) 321 *British Medical Journal* 1464. Leung presents a hypothetical case study featuring a man recently diagnosed with Wilson's disease (hepatolenticular degeneration), an autosomal recessive disease, treatable in the presymptomatic stage, who refuses permission to disclose his diagnosis to his siblings: referred to in R Magnusson, *Submission G039*, 10 January 2002.

The risk is serious; it is a potentially lethal condition. The diagnosis is certain. And there is an effective intervention (monitoring and surgery is needed). Yet the risk could not be described as imminent. For these reasons I do not believe the common law exception is sufficient.³³

18.33 Other situations may be identified where the benefits for genetic relatives of knowing they are at increased risk are merely speculative and may not, therefore, be capable of justifying any breach of confidentiality.³⁴

18.34 In many situations where there are benefits in informing relatives, consent to do so may be obtained following discussion with the person tested. Existing ethical guidelines emphasise that when genetic information is to be shared with family members, the most appropriate person to make the initial contact is the individual who has undergone the genetic test.³⁵ Submissions confirmed that it is clinical practice to request the individual's permission to pass on relevant genetic information to relatives.³⁶

18.35 However, what is the legal position where the patient is unwilling to communicate with their relatives? In what circumstances does the law permit the doctor to take steps to inform genetic relatives about information relevant to their health? The law relating to this issue is discussed below, with reference to common law duties of confidentiality and the provisions of the *Privacy Act* and similar state and territory privacy legislation.³⁷

Duties of confidentiality

18.36 IP 26 asked whether the content of the duty of confidentiality should be revised to take account of the specific characteristics of the genetic information.³⁸

33 L. Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162, 169.

34 Eg M Burgess, C Laberge and B Knoppers, 'Bioethics for Clinicians: 14. Ethics and Genetics in Medicine' (1998) 158(10) *Canadian Medical Association Journal* 1309referring to a hypothetical involving breast cancer where there is no guaranteed prophylaxis for breast cancer (but early detection and treatment may lead to a better outcome) and there are social and psychological risks associated with informing and not informing a patient's sisters.

35 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 49.

36 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

37 This discussion proceeds on the basis that relevant disclosures to genetic relatives involve information about an individual patient whose identity is apparent, or can reasonably be ascertained, from the information. In some circumstances it may be possible to inform genetic relatives about their genetic risk without disclosing information about a particular individual.

38 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 8–6.

18.37 Doctors and other health professionals owe their patients a common law duty to maintain confidential information provided by that patient.³⁹ Where a doctor breaches this duty, the doctor may be liable for damages in tort, contract or for equitable breach of confidence. In addition, a breach of confidence may constitute unsatisfactory professional conduct and form grounds for proceedings before medical registration authorities.⁴⁰

18.38 In general terms, the common law duty of confidentiality may be breached where there is an unauthorised use of the information covered by it. That is, where the information is used for a purpose inconsistent with the purpose for which consent was expressly or impliedly given.⁴¹

18.39 In many circumstances, patients may be taken to have consented to certain disclosure of information, especially disclosure for purposes related to their own treatment, such as to other health service providers who assist their doctor to provide optimum care. However, disclosure by the doctor to facilitate diagnosis or treatment of family members cannot ordinarily be implied and will be likely to breach the duty of confidentiality, unless the disclosure is covered by some exception recognised by the law.

18.40 The exceptions to the common law duty of confidentiality were briefly summarised in IP 26.⁴² These exceptions permit disclosure of the information in ways that would otherwise infringe the duty. One exception is where a patient consents to the disclosure. It is the patient to whom the duty is owed and so he or she can choose to permit information to be released, including to facilitate and diagnosis or treatment of a genetic relative.

18.41 A second exception is where there is a statutory obligation to disclose information. This is regularly exercised in the compulsory disclosure of certain notifiable diseases or other conditions for which there is a statutory register. It also includes compulsion to disclose information in court proceedings as the duty of

39 Duties of confidentiality may also arise as a term of the contractual relationship between medical practitioner and patient: *Parry-Jones v Law Society* [1969] 1 Ch 1, or as an incident of the fiduciary character of that relationship: *Breen v Williams* (1996) 186 CLR 71, 81 (per Brennan CJ). Similar duties of confidentiality can be imposed directly by legislation governing the use of medical information in publicly funded health services: *Health Administration Act 1982* (NSW); *Public Health Act 1991* (NSW); *Private Hospitals and Day Procedure Centres Act 1988* (Qld); *Health Services Act 1991* (Qld); *Health Act 1937* (Qld); *South Australian Health Commission Act 1976* (SA); *Public and Environmental Health Act 1987* (SA); *State Service Act 1984* (Tas); *Health Services Act 1988* (Vic) or by the application of statutory disciplinary standards of unethical conduct: *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513. Duties of confidentiality are also expressed in codes of professional ethics.

40 Eg in proceedings before the NSW Medical Board or Medical Tribunal under *Medical Practice Act 1992* (NSW).

41 J Hamblin and D Bell, 'Confidentiality Sydney,' in J Golden and D Grozier (eds), *The Laws of Australia* (1994) The Law Book Company Limited, Sydney, 20.7, [6].

42 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 8.75–8.79.

confidentiality does not generally give a medical practitioner a justification for refusing to disclose such information.

18.42 The third exception permits the release of confidential information where to do so is in the public interest. The possible application of the public interest exception to disclosure of genetic information is of particular relevance, and is considered in more detail below.

The public interest exception

18.43 It has been stated that the public interest exception to the duty of medical confidentiality 'is notable for its extraordinary flexibility'.⁴³ It can potentially be invoked to justify the disclosure of confidential patient information in a wide range of circumstances. Whether these circumstances might encompass some disclosure of confidential information to genetic relatives is very much open to debate.

18.44 At least some legal commentators believe that the public interest exception might be used in this way and consider that the public interest exception could cover cases where

the patient's medical condition presents an infection risk to others, where a patient's ill health renders him or her unfit to continue certain activities because others would be placed at risk, or *where inherited genetic disorders should properly be disclosed to other family members*.⁴⁴ (Emphasis added.)

18.45 However, there has been no reported Australian case in which disclosure of genetic information has been found to be justified and other commentators have cast doubt on whether the public interest exception would extend to the disclosure of genetic information, given the limitations the relevant case law places on the circumstances in which disclosure may legally occur.

18.46 Dean Bell and Belinda Bennett state that the existing case law requires that disclosure must be confined to 'exceptional circumstances', where 'another's life is immediately endangered and urgent action is required'⁴⁵ or where there is a 'real risk and consequent danger to the public'.⁴⁶ Secondly, they cite cases in which

43 J Hamblin and D Bell, 'Confidentiality Sydney,' in J Golden and D Grozier (eds), *The Laws of Australia* (1994) The Law Book Company Limited, Sydney, 20.7, [31].

44 Ibid, [31].

45 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149, citing *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513.

46 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149, citing *W v Egdel* [1990] 1 All ER 835.

the courts have emphasised that disclosure should be to a responsible authority.⁴⁷ They conclude that

These limitations suggest that the public interest basis for disclosure to family members of a genetic condition has not, to date, been contemplated for a situation such as disclosure to a family member of genetic condition, both because such a condition will rarely, if ever, present an immediately life-threatening risk, and also because such disclosure would ultimately have to be disclosed to the family member rather than a responsible authority (although if the relative is not a patient of the doctors, it may be disclosed to that patient's treating doctor).⁴⁸

18.47 This is not to say that the point might not be argued sometime in the future in relation to a disclosure of genetic information. It has been suggested that the factors that a court might take into account in weighing up such a public interest claim might include the possible adverse effects of allowing disclosure of genetic medical information on the willingness of individuals to take advantage of genetic tests in the future, and the likely public health outcomes of such a policy.⁴⁹

18.48 However, as noted above, Professor Skene has concluded that the common law public interest exception may not always be sufficient to protect health professionals making disclosures of genetic risk to relatives.⁵⁰ Dr Roger Magnusson states that the scope of the discretion to disclosure under the public interest defence to a breach of confidentiality action is uncertain in Australia and probably requires High Court resolution.⁵¹

A duty to warn?

18.49 In some circumstances it might be argued that a health professional has a positive 'duty to warn' third parties — even if doing so would infringe the duty of confidentiality. Such a duty might be derived from common law principles relating to the tort of negligence, based on the concept of a duty of care. Some submissions questioned whether Australian law may impose such a duty on health professionals.

47 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149. *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513 involved a doctor who was alleged to have breached an obligation of confidentiality to a patient who worked as a bus driver by disclosing, to the Police and people in the community, that his patient had undergone a triple coronary artery bypass operation. The courts upheld a medical disciplinary committee decision finding that the doctor had unjustifiably breached confidentiality. In *W v Egdell* [1990] 1 All ER 835, the English Court of Appeal considered a case in which a consultant psychiatrist had disclosed information about a patient's mental state to the hospital in which the plaintiff was detained and to the Home Office. The Court found the disclosure justified in the public interest.

48 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149.

49 Ibid, 148–149.

50 L Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162, 168.

51 R Magnusson, *Submission G039*, 10 January 2002 contrasting the approaches taken by Gummow J in *Corrs Pavey Whiting & Byrne v Collector of Customs (Vic)* (1987) 14 FCR 434 and Kirby P in *Attorney-General (UK) v Heinemann Publishers Australia Pty Ltd* (1987) 10 NSWLR 86.

18.50 Cases in the United States, and in particular *Tarasoff v Regents of University of California*⁵² have established that, where there is a foreseeable risk of significant harm to an identified individual, doctors and other health professionals may have a duty to warn those individuals. In this regard, the legal position in the United States appears to differ from existing law in Australia.

18.51 Some of these United States cases involved genetic risks.⁵³ For example, in *Pate v Threlkel*⁵⁴ a daughter whose mother was diagnosed as having a genetic disease, medullary thyroid carcinoma, sued the mother's doctor for not warning her that she too might be at risk. The Supreme Court of Florida held that while a doctor may owe a duty of care to family members of a patient, in circumstances in which this includes a duty to warn of a genetic condition, the duty will be satisfied by warning the patient that family members should seek medical care.⁵⁵

18.52 A different approach was taken in *Safer v Pack*.⁵⁶ In this case the doctor had treated a patient for retroperitoneal cancer, ulcerative adenocarcinoma of the colon and adenomatous polyps. Twenty-six years after the patient died his daughter developed cancer of the colon and multiple polyposis. She sued, claiming that her father's doctor had breached a duty to warn of the hereditary risk to her health and had deprived her of the chance for monitoring, early detection and early treatment. Applying an infectious disease precedent, the Superior Court of New Jersey held that there can be a duty to warn genetic relatives directly.

18.53 This case has been criticised for not giving sufficient recognition to the differences between infectious disease and genetic conditions. For example, warning genetic relatives about genetic risks will not prevent them from having the gene and potential psychological harm resulting from disclosure should also be considered, especially where the genetic condition is not preventable.⁵⁷

... cases dealing with warning people about genetic risks are different than those dealing with violence or infectious disease since there are already established social policies embodied in laws that are aimed at preventing violence or contagion. Thus, breach of confidentiality furthers an established social policy that has been subject to

52 *Tarasoff v Regents of University of California* 551 P2d 334 (1976).

53 *Pate v Threlkel* 551 P2d 334 (1976); *Safer v Pack* 291 NJ Super 619 (1996), 677. These cases are discussed in D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149–152 and L Andrews, 'The Genetic Information Superhighway: Rules of the Road for Contacting Relatives and Recontacting Former Patients' in B Knoppers (ed), *Human DNA: Law and Policy* (1997) Kluwer Law International, The Hague, 133, 136–138.

54 *Pate v Threlkel* 551 P2d 334 (1976).

55 This appears inconsistent with the New Zealand and English authorities referred to above, which suggest that disclosure should be to a responsible authority: *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513; *W v Egdell* [1990] 1 All ER 835.

56 *Safer v Pack* 291 NJ Super 619 (1996), 677.

57 L Andrews, 'The Genetic Information Superhighway: Rules of the Road for Contacting Relatives and Recontacting Former Patients' in B Knoppers (ed), *Human DNA: Law and Policy* (1997) Kluwer Law International, The Hague, 133, 137–138.

legislative debate. In contrast, society's position on genetic disease is not so clear cut.⁵⁸

18.54 There is some limited recognition in Australian law that a doctor may owe duty of care to someone who is not a patient.⁵⁹ In *BT v Oei*,⁶⁰ the Supreme Court of New South Wales held that a duty of care was owed by a doctor to a patient's partner to exercise reasonable care in advising the patient to in relation to the need for an HIV test.⁶¹ It has been suggested that, therefore, a doctor or genetic counsellor may owe a duty of care to third parties to explain to the patient the implications of a genetic test for the future health of third parties, where disclosure by the patient could ameliorate future genetically-caused harm.⁶²

18.55 However, there is no direct legal authority for the imposition of a *Tarasoff*-style duty to warn in Australia. Professor Skene concluded, in 1998, that arguments that doctors have a duty to warn genetic relatives are unlikely to be successful in Australia.

The Australian law on duty to warn is less developed than that in the United States and there has been no case in which a doctor has been held to have a duty to warn in such a case. In any event, as in the United States, this is unlikely to be an issue in the genetic context because single gene disorders that cause immediate effects are rare.⁶³

Application of privacy legislation to disclosure

18.56 Another aspect of the familial nature of genetic information involves the constraints that the *Privacy Act* imposes on the disclosure of relevant genetic information by doctors and other health professionals to genetic relatives of their patients.

18.57 In particular, the *Privacy Act* appears to prohibit the disclosure of clinically relevant information to genetic relatives, in circumstances where it is possible to argue there is no breach of ethical or common law duties of confidentiality — in particular, because the public interest exception to the duty of confidentiality may apply (discussed above).⁶⁴

58 Ibid, 137.

59 *BT v Oei* (Unreported, Supreme Court of NSW, Bell J, 5 November 1999).

60 Ibid.

61 Ibid.

62 R Magnusson, *Submission G039*, 10 January 2002.

63 L. Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6 *Medical Law Review* 1, 29–30. See also D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 149–154.

64 This position may also apply under state and territory privacy legislation.

Disclosure to prevent 'serious and imminent' threat

18.58 Under the *Privacy Act*, disclosure of genetic information, other than for the primary purpose of treating the person tested, is generally only permitted with the consent of that person.⁶⁵ Where consent is not obtained, in most circumstances, a health services provider may only disclose personal information to a relative if this is necessary to lessen or prevent a 'serious and imminent threat' to an individual's life, health or safety.⁶⁶

18.59 This formula may have been derived from existing case law relating to the duty of confidentiality,⁶⁷ but appears to leave less room for flexibility than is provided by the possible range of public interest exceptions to the common law duty.

18.60 In most situations the consequences of someone not knowing about a genetically based predisposition to illness may not be a sufficiently imminent threat to their health to justify disclosure. The Privacy Commissioner has stated that

The threat is 'imminent' if it is about to occur. This test could also include a threat posed that may result in harm within a few days or weeks. It is much less likely to apply to situations where the risk may not eventuate for some months or longer.⁶⁸

18.61 Commentators confirm that the requirement that a threat be 'serious and imminent' is not likely to be met by many presently known genetic conditions.⁶⁹ The fact that, in the case of some genetic conditions, the threat is not to a living individual but to future children, may also prevent genetic risks from satisfying this requirement of the *Privacy Act*.

Disclosure 'required or authorised by or under law'

18.62 The *Privacy Act* also permits disclosure where 'required or authorised by or under law'.⁷⁰ Does this provision permit a doctor to disclose confidential information where the disclosure is covered by the 'public interest' exception to the duty of confidentiality? The answer is not entirely clear.

65 See *Privacy Act 1988* (Cth) NPP 2.1 (a)–(b).

66 Ibid NPP 2.1 (e)(i).

67 Eg *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513, *W v Egdell* [1990] 1 All ER 835.

68 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 19.

69 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130, 143 referring to *Privacy Act* IPP 10, which also contains the words 'serious and imminent'; R Magnusson, *Submission G039*, 10 January 2002.

70 *Privacy Act 1988* (Cth) NPP 2.1(d).

18.63 It appears to be accepted that 'law' may include the common law.⁷¹ In an Attorney-General's Department information paper, the Government acknowledged that the health profession already has a strong respect for the confidentiality of health information and maintains sound privacy practices in that respect and that the 'legislation is not intended to interfere with those professional values and standards'.⁷²

18.64 On the other hand, the explanatory memorandum to the Privacy Amendment (Private Sector) Bill 2000 stated that this provision of the *Privacy Act* was intended to cover situations where a law 'unambiguously' requires or authorises the use of disclosure of personal information.⁷³ The application of the *Privacy Act* to disclosure by doctors and other health professionals of health information, in circumstances that may not breach common law or ethical requirements of confidentiality, may require clarification.⁷⁴

18.65 Similar issues are raised under state and territory privacy legislation. The ACT and Victorian legislation include information privacy principles that incorporate reference to 'serious and imminent' threat or risk.⁷⁵ The ACT and Victorian legislation also refer to disclosure required or authorised by law.⁷⁶

Need for reform

18.66 Some commentators have argued that there is no need for a departure from the current approach to medical confidentiality.⁷⁷ For example, Bell and Bennett consider that given genetic information is more often predictive than

71 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 20.

72 Office of the Federal Privacy Commissioner, *Privacy Amendment (Private Sector) Act 2000: Information Paper* (19 February 2002), <<http://law.gov.au/privacy/royalinfo.html>>, 19 February 2002.

73 Privacy Amendment (Private Sector) Bill 2000 Explanatory Memorandum, stated that NPP 2.1(g) (enacted as NPP 2.1(d)) 'is intended to cover situations where a law unambiguously requires or authorises the use of disclosure of personal information. There could be some situations where the law requires some actions which, of necessity, involve particular uses or disclosures, but this sort of implied requirement would be conservatively interpreted'.

74 It seems clearer that a disclosure that is permitted by the *Privacy Act* may nonetheless breach common law duties of confidentiality. However, one submission to the Inquiry noted that 'A latent complexity is whether the common law of confidentiality and privacy exists alongside the Act or whether it is a complete and exhaustive regime of privacy obligations and rights': K Liddell, *Submission G141*, 23 March 2002. Section 91 of the *Privacy Act* states that, for the purposes of Part VIII (which creates rights to recover damages for breach of certain obligations of confidence), common law and equitable obligations of confidentiality continue to exist.

75 *Health Records (Privacy and Access) Act 1997* (ACT) Privacy Principle 10(1)(c); *Health Records Act 2001* (Vic) Health Privacy Principle 2.2(h); See also Exposure Draft Health Records and Information Privacy Bill 2001 (NSW) Health Privacy Principle 11(1)(d).

76 *Health Records (Privacy and Access) Act 1997* (ACT) s 10(1)(d); *Health Records Act 2001* (Vic) Health Privacy Principle 2.2(c). The Victorian exception appears broader than the ACT or Commonwealth provision and refers to disclosure 'required, authorised or permitted, whether expressly or impliedly, by or under law'.

77 D Bell and B Bennett, 'Genetic Secrets and the Family' (2001) 9 *Medical Law Review* 130.

determinative of the occurrence of a particular disease, the cases in which disclosure without consent to genetic relatives might be warranted are 'likely to be much less frequent than the proponents of treating genetic information as 'communal' information would allow'. The possible interest of relatives in not knowing genetic information also need to be considered and respected.⁷⁸

18.67 Privacy NSW submitted that 'a person who is the subject of genetic information is in the best position to assess their privacy interests and the interests of potentially affected relatives in deciding whether to disclose their genetic information to other family members'. On this view, providing adequate information and counselling to patients about the relevance of genetic information to relatives is a sufficient response.⁷⁹

Such an approach highlights the importance of meaningful consent and the role of consent in enabling privacy principles to be responsive to the interests of relatives who are potentially affected by another's genetic information.⁸⁰

18.68 Disclosure to genetic relatives by, or with the consent of, the patient is obviously preferable. However, during consultations the Inquiry was informed of circumstances in which a patient will neither disclose the information nor consent to the health professional doing so, such as where family relationships have broken down irretrievably.

18.69 Submissions and consultations have emphasised situations where there are strong ethical arguments that a genetic relative should be told by health professionals about the consequences for them of another person's genetic test results, especially where there is high risk of a genetically based cancer that is treatable.⁸¹

Where voluntary genetic testing reveals that a sibling, son or daughter may face a *substantial and quantifiable risk* of a serious disease or disability, in circumstances *where earlier interventions could alleviate or reduce the harm suffered*, then there may be strong moral reasons for breaching confidentiality. Similar considerations would apply, even where genetic testing reveals that a genetic relative is only a carrier of a harm-causing mutation.⁸²

18.70 Similarly, the Human Genetics Society of Australasia (HGSA) considered that, with regard to highly penetrant heritable genetic disorders

78 Ibid, 132.

79 Non-consensual disclosure should only occur where clear criteria have been satisfied and assessed by an appropriate judicial body: Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

80 Ibid.

81 R Magnusson, *Submission G039*, 10 January 2002; Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

82 R Magnusson, *Submission G039*, 10 January 2002.

doctors should consider the situation of the person's relatives and try to ensure that they are informed if they are at increased risk of having inherited the disorder in question (or susceptibility to it).⁸³

Serious and imminent threat

18.71 Such disclosures may not be sufficiently 'imminent' to allow disclosure without breaching privacy legislation — given most such conditions will take time to manifest themselves. Furthermore, it may not be clear whether the circumstances of any particular disclosure to genetic relatives of a patient will be a breach of medical confidentiality that should be subject to the public interest exception.

18.72 It has been suggested that the 'characteristics of genetic information and the way in which it is relevant to third parties call into question traditional justifications for disclosure or non-disclosure of health information and suggest there may be a need for unique guidelines for the disclosure of genetic information'.⁸⁴

18.73 These characteristics are said to include that where genetic relatives are found to have an increased risk, this risk is not created by the patient, unlike for example, where the patient has an infectious disease. It is a pre-existing risk that is identified because of the patient's genetic information. This may distinguish the impact of genetic information from the type of harm involved in recognised exceptions to the duty of confidentiality. Another important characteristic is that the harm disclosed by a pre-existing genetic condition is not necessarily preventable. If it is not preventable then disclosure may not help the third party and may even harm them by causing distress.⁸⁵

18.74 The application of the 'serious or imminent' harm test to genetic conditions is considered to be problematic by Australian and overseas commentators.

The first aspect of this question is the degree of likelihood of having a genetic condition. That is, is a 50 percent likelihood of carrying a mutation of the BRAC1 gene sufficiently serious? The second element is the degree of likelihood that the genetic predisposition will lead to the actual physical manifestation of the disease. In other words, if having a particular mutation is associated with a 60 percent risk of developing a particular condition then is this sufficiently serious? Does it matter that this represents the known lifetime risk, rather than some imminent health risk? Other questions include whether the notion of harm should refer only to an individual's health or also to situations of reproductive decision making?⁸⁶

83 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

84 T Lemmens and L Austin, 'The Challenges of Regulating the Use of Genetic Information' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 26, 32.

85 *Ibid.*, 32.

86 *Ibid.*, 32–33.

18.75 Dr Finlay Macrae reserved special criticism for the constraint on disclosure contained in existing privacy laws. He stated that those who operate the FAP Register

feel disappointed and frustrated when their work is truncated by these ethical barriers to disclosure of life saving information — albeit not a imminent threat. The lack of imminency precludes more direct contact [with genetic relatives] at that stage according to the Privacy Laws, but does not preclude the development of cancer at later stage which is not less lethal for its lack of imminency, and no less destructive within the family.⁸⁷

18.76 Another clinical geneticist argued that the right to individual genetic privacy ‘should not include the right not to disclose the information to another who would be harmed by such non-disclosure’ and that the obligation to disclose relevant information to genetic relatives should be more strongly emphasised.⁸⁸ The HGSA stated that, with regard to highly penetrant heritable genetic disorders, doctors should consider the situation of the person’s relatives and try to ensure that they are informed if they are at increased risk.⁸⁹

Need for clarity

18.77 Many submissions considered that the law and ethical guidelines in this area should be made clearer. Dr Roger Magnusson submitted that where there is a contest between a patient’s privacy and a risk of genetic harm to a third person, existing privacy laws are arguably deficient.⁹⁰ He concluded that the current law on confidentiality and disclosure of genetic information is ‘unreasonably opaque’⁹¹ and suggested that it is one area ‘where some “genetic-specific” privacy regulation would be welcome’.⁹²

18.78 A similar view was expressed by the Victorian Department of Human Services Genetics Advisory Committee which agreed that the responsibilities of health professionals in passing on information about a potential genetic risk to relatives on the basis of a genetic diagnosis should be made clearer.

Doctors have an obligation to pass on to relatives information about their familial risk. The case to disclose is strongest in relation to a condition such as FAP, where carriers of the gene mutation will almost certainly develop the cancer, and where successful treatment of the condition is available. Where the association between the gene mutation and the outcome is less clear, eg breast cancer, the case is less clear and will

87 F Macrae, *Submission G069*, 14 January 2002.

88 J MacMillan, *Submission G015*, 19 November 2001

89 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

90 R Magnusson, *Submission G039*, 10 January 2002.

91 *Ibid.*

92 *Ibid.*

depend on circumstances. These issues, and those which will become apparent in the future, are very hard to regulate effectively.⁹³

18.79 Several submissions expressed concern about the uncertainty of existing law dealing with doctors' duties to genetic relatives⁹⁴ and about its possible future development through case law or legislation.⁹⁵ Associate Professor John MacMillan considered that, whatever the current position, in future it may be held by courts that doctors' duties to genetic relatives are not discharged simply by informing their patient about the implications of genetic information for the patient's relatives.⁹⁶

18.80 The uncertainty surrounding this issue was highlighted in a confidential submission to the Inquiry from a woman whose mother was diagnosed with Huntington's disease.

It is quite probable that her GP told her that she should see a neurologist and that she may have the disease. She was completely irrational at the time and with her impaired ability to make sound judgments she decided to keep this information from me. I was having children at this stage and if I were aware of the possibility I would have investigated this further and would not have had any more children. ... The question is should my mother's doctor have tried to find me and warn me of my impending health issue. I still don't know what the answer is.⁹⁷

18.81 The HGSA noted that the current approach in medical practice is to encourage patients to disclose information about their genetic disorder to relatives. The HGSA stated that while this approach 'has much to commend it', it lacked certainty. As discussed below, imposing additional obligations on doctors to contact genetic relatives, rather than permitting them to do so when ethically justified, raises difficult practical issues.⁹⁸

The need for ethical guidelines

18.82 Many submissions suggested that the exceptions to medical confidentiality should be governed primarily by ethical codes, rather than be prescribed by legislation.⁹⁹ For example, Sister Regis Mary Dunne commented that 'the ethics of the profession are sufficiently active to continue to safeguard medical

93 Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

94 G Suthers, *Submission G026*, 30 November 2001; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

95 J MacMillan, *Submission G015*, 19 November 2001; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

96 J MacMillan, *Submission G015*, 19 November 2001.

97 *Confidential Submission G051CON*, 14 January 2002.

98 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

99 Centre for Law and Genetics, *Submission G048*, 14 January 2002; M Dunne, *Submission G041*, 17 December 2001; Sydney IVF Limited, *Submission G062*, 14 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

genetic information'.¹⁰⁰ Sydney IVF stated that medical practitioners can be assumed to be able to deal with conflicting interests between family members in matters concerning genetic information, as they have to date.¹⁰¹ The Centre for Law and Genetics stated that:

The general medical duty of confidentiality is not absolute. There are exceptional circumstances in which the duty of confidentiality may be broken where there are significant threats to third party interests. ... In this respect the interests of family members in the results of genetic tests are not entirely novel. ... It is not appropriate for these matters to be covered by legislation. Applications of the exceptions to the rules of patient confidentiality must remain in codes of ethics practice.¹⁰²

18.83 Existing Australian codes of ethics do not deal with disclosure of genetic information to genetic relatives with any specificity, although the NHMRC information paper on human genetic testing recognised that

there may be rare circumstances in which a health professional considers that the risk to the health of relatives is sufficiently large, serious, imminent and potentially preventable that consideration should be given to breaching the individual's confidentiality.¹⁰³

18.84 The Australian Medical Association's Code of Ethics recognises that exceptions to the duty of confidentiality 'may arise where the health of others is at risk'.¹⁰⁴ This statement seems capable of supporting some disclosure that would not be supported by the current law. The code contains no guidance on the application of this exception and none has been issued by the AMA.

18.85 In 1996, the federal Privacy Commissioner argued that the AMA Code of Ethics should be supplemented with a clearer set of guidelines on what threshold of risk must be satisfied for a disclosure without the patient's permission to occur; the steps that should be followed before making such a disclosure and a set of safeguards applying to any such disclosures.¹⁰⁵ While the AMA Code of Ethics has remained unchanged, as discussed above, a threshold of risk permitting disclosure has been imposed for the purposes of the *Privacy Act* — that is, the 'serious and imminent threat' test.¹⁰⁶

18.86 The Centre for Law and Genetics submitted that the Inquiry should ensure that exceptions to medical confidentiality recognised by codes of ethics properly reflect the family context of genetic information. In particular, they

100 M Dunne, *Submission G041*, 17 December 2001.

101 Sydney IVF Limited, *Submission G062*, 14 January 2002.

102 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

103 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 51.

104 Australian Medical Association (NSW), *Code of Ethics* (1996) AMA, para 1.3.4.

105 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), OFPC, Sydney, 18.

106 *Privacy Act 1988* (Cth) NPP 2.1 (e)(i).

suggested that the content of doctors' ethical duties should be revised by the AMA to take account of genetic information.¹⁰⁷

18.87 Other submissions focussed on the need for such ethical guidelines. The New South Wales Genetics Service Advisory Committee supported the development of national guidelines on the duties of care and confidentiality, in consultation with expert groups such as the HGSA.¹⁰⁸ The HGSA itself stated that it would welcome the development of ethical guidelines dealing with the application of privacy law to genetic information, including with AHEC involvement.¹⁰⁹ The Androgen Insensitivity Syndrome Support Group Australia submitted:

As a general rule, GPs have a good reputation amongst consumer groups for protection of patient information. Such a reputation could easily be destroyed without appropriate guidelines for recording and storing genetic information on patient records along with knowledge of appropriate disclosure upon referral to specialists. GPs should not be placed in a position where appropriate handling of genetic information is a matter of guesswork. Medical associations should work with consumer groups to provide guidelines for the handling of genetic information by GPs.¹¹⁰

18.88 Ethical guidelines dealing specifically with disclosure to genetic relatives have been developed elsewhere. An important example of such guidelines are those issued in 1983 in the United States by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. The President's Commission proposed that health care professional disclosure to genetic relatives should take place only when:

- reasonable efforts to elicit voluntary consent to disclosure have failed;
- there is a high probability both that harm will occur if the information is withheld, and that the disclosure of information will actually be used to avert harm;
- the harm that identifiable individuals would suffer would be serious; and
- appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease is disclosed.¹¹¹

107 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

108 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

109 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

110 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

111 President's Committee for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research, *Screening and Counseling for Genetic Conditions: The Ethical, Social and Legal Implications of Genetic Screening, Counseling, and Education Programs* (1983), Government Printing Office, Washington DC, 44 cited in T Lemmens and L Austin, 'The Challenges of Regulating the Use of Genetic Information' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 26, 32.

18.89 These guidelines were adopted in 1991 by the Science Council of Canada in its recommended guidelines for physician disclosure to third parties.¹¹² In 1998, a sub-committee of the American Society of Human Genetics (ASHG), including prominent Canadian academic Professor Bartha Knoppers, reported on this issue. The sub-committee concluded that disclosure of genetic information by physicians to genetic relatives should be permitted in exceptional circumstances:

1. Disclosure should be permitted where: attempts to encourage disclosure on the part of the patient have failed; the harm is highly likely to occur and is serious, imminent, and foreseeable; the at-risk relative(s) is identifiable; and the disease is preventable, treatable, or medically accepted standards indicate that early monitoring will reduce the genetic risk.

2. The harm from failing to disclose should outweigh the harm from disclosure.¹¹³

18.90 Interesting, the ASHG statement includes an 'imminent' harm test. However, it is also clear that the authors consider that disclosure may be justified in cases where the condition has not yet manifested but may be prevented.

18.91 Most recently, in November 2001, a report of the Ontario Provincial Advisory Committee on the New Predictive Genetic Technologies recommended that further research should be undertaken to determine whether disclosing genetic information to high-risk relatives against an individual's wishes should be permitted. It was suggested that criteria to permit this disclosure should include the following conditions:

- the interest in informing relatives strongly outweighs the interest in maintaining confidentiality;
- reasonable attempts to elicit voluntary disclosure are unsuccessful;
- there is a high probability of serious and irreparable harm to an identifiable person;
- the disclosure of the information will enable that person to prevent the harm and there is a high probability that the harm will occur if the information is withheld; and

112 Science Council of Canada, *Genetics in Canadian Health Care* (1991), Minister for Science (Canada), Ottawa, 72–73, cited in T Lemmens and L Austin, 'The Challenges of Regulating the Use of Genetic Information' (2001) 2(3) *Isuma: Canadian Journal of Policy Research* 26, 32.

113 American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure, 'Professional Disclosure of Familial Genetic Information' (1998) 62 *American Journal of Human Genetics* 474, 474–483. See American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure, 'Professional Disclosure of Familial Genetic Information' (1998) 62 *American Journal of Human Genetics* 474. This paper also contains a summary of relevant international ethical standards and statements.

- the disclosure is limited to the information necessary for the diagnosis and treatment of the third party.¹¹⁴

Policy positions

18.92 There are three basic policy positions relating to the disclosure of otherwise confidential information to genetic relatives. These may be summarised as follows:

- The legal and ethical duty of confidentiality owed to the patient should be absolute. While the doctor may inform the patient of the implications of genetic information for genetic relatives, the duty of confidentiality prevents the doctor from disclosing this information to relatives.
- Exceptions to the duty of confidentiality should be recognised where disclosure of genetic information to genetic relatives is legally and ethically justified. Where such circumstances exist the doctor should be able to disclose genetic information without incurring liability, but would have no duty to do so.
- Doctors should be considered to have a legal or ethical duty to warn genetic relatives about genetic information relevant to them. That is, in some circumstances there should be a positive legal or ethical obligation to disclose genetic information, rather than simply a discretion to do so.

An exception to the duty of confidentiality

18.93 The Inquiry has concluded that reform of existing legal and ethical regulation in this area should focus on the implementation of the second policy position set out above.

18.94 The Inquiry recognises the importance of the duty of confidentiality to medical practice. Medical confidentiality is important not just to individual patients. It rests on the premise that there is a public interest in patients being candid with their doctors. Confidentiality is vital to secure public as well as private health and should not be breached other than for compelling reasons. However, it is also clear that an absolute approach to medical confidentiality is not defensible. There are many circumstances in which it is already recognised that the confidentiality may be breached in order to serve other interests.

114 The Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (2001), Ministry of Health Ontario, Toronto, 37.

18.95 In addition, a strict view of medical confidentiality may not be consistent with the way in which health professionals approach these issues in practice. As discussed in Chapter 7, Professor Loane Skene has proposed that a 'medical model' of regulation should apply to genetic information, based primarily on what health professionals consider best practice in providing medical care for patients and their families.¹¹⁵

18.96 In relation to confidentiality, Loane Skene has observed that it is the experience of clinicians and genetic counsellors that, in the vast majority of cases, patients are happy to involve their genetic relatives in the consultation or follow-up process to a genetic diagnosis.¹¹⁶ Even if the law were to be reformed to be more permissive of non-consensual disclosure of information to genetic relatives, breaches of confidentiality would not be the norm.

Ordinary medical practice would continue with the inquirer encouraged from the start to involve and inform blood relatives (and also the wider family where appropriate). In cases where that openness is rejected by the inquirer, the clinician or counsellor might refuse to do the test; say that they could not guarantee confidentiality in every case; or to decide to do the test and not inform relatives.¹¹⁷

A duty to warn

18.97 The Inquiry does not favour reforms that would impose a duty of care on doctors or other health professionals obliging them to warn genetic relatives about genetic information relevant to them. Where certain circumstances exist the doctor should be able to disclose genetic information without incurring liability, but should have no duty to do so.

18.98 There are considerable practical difficulties in extending reform to impose a duty to warn them. As the HGSA observed, imposing a duty of care to warn genetic relatives

... is likely to be hard to define precisely, will require doctors to be given 'powers' in order to identify and make contact with relatives, and will require substantial resources to carry out'.¹¹⁸

18.99 The policy reasons not to require disclosure of genetic information to relatives have been summarised as including:

115 L. Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6 *Medical Law Review* 1, 24.

116 L. Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162, 166.

117 Ibid, 166.

118 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

The negative impact that such a breach of confidentiality will have on patients' willingness to seek genetic testing in the first place; the potential negative social, psychological, and financial impact that such information will have on the relative who receives the information; and the eugenic message that is conveyed by mandating such disclosures.¹¹⁹

18.100 Practical difficulties in recognising a duty to warn include the following:

- A legal test of the circumstances in which it would be appropriate to impose a duty to warn would be likely to be quite complex. It would, for example, be likely to require the doctor or other health professional to assess such matters as how serious or imminent is the genetic risk, their prevention and treatment options and so on.
- Defining the relatives to whom the duty is owed may be difficult. For example, should the duty extend to first degree relatives only or any genetic relative potentially at risk?
- How far would health professionals be required to go in seeking to contact genetic relatives? If the patient will not provide contact details, to what extent would health professionals be obliged to take steps to find genetic relatives and what information sources can they use in order to do?
- What level of advice should be provided to the genetic relatives in order to discharge the duty? Is it enough to contact them and advise them to see their own medical advisers or should detailed information about the likely level of risk, possible prevention or treatment options be provided?
- Significant additional resources may be required in order for health professionals to discharge a duty of care to genetic relatives.¹²⁰

18.101 Similar practical difficulties will arise even where disclosure is permitted (as an exception to the duty of confidentiality) rather than obligatory. However, permitting, rather than requiring, disclosure in exceptional circumstances better recognises that in many situations it may not be practicable to contact relatives.

119 L. Andrews, 'The Genetic Information Superhighway: Rules of the Road for Contacting Relatives and Recontacting Former Patients' in B Knoppers (ed), *Human DNA: Law and Policy* (1997) Kluwer Law International, The Hague, 133, 1138–139. Andrews also notes that 'Similar cautions are appropriate with respect to recontacting patients when new genetic information is available about them': L. Andrews, 'The Genetic Information Superhighway: Rules of the Road for Contacting Relatives and Recontacting Former Patients' in B Knoppers (ed), *Human DNA: Law and Policy* (1997) Kluwer Law International, The Hague, 133, 139.

120 See Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

The right not to know

18.102 Policy positions on disclosure of genetic information must take into account the fact that some people may not wish to know about their genetic risk and have a 'right not to know'. IP 26 noted that protecting the 'right not to know' may be more difficult when the genetic information is derived from the testing of another person who is a genetic relative and that this is a reason to approach disclosure of information to other people affected by test results with caution.¹²¹

18.103 Privacy NSW considered the wishes of genetic relatives not to know their genetic information are better protected if the 'subject of the information' (that is, the patient) has control over disclosure and is appropriately supported in making a decision as to whether or not to disclose the information to others. In contrast, the OFPC observed that

in some families the person best qualified to make a particular decision regarding disclosure to a relative is another member of the family or even a friend of the family. Alternatively, it may be impossible for family members to communicate at all, let alone about the implications of genetic test results affecting one of the family.¹²²

18.104 The Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria has observed that:

With a condition like FAP, in which virtually all who carry a gene mutation develop cancer, and in which the cancer may be prevented, the strong presumption should be that the relatives will be grateful for being warned. The same presumption should not be made in a cancer such as breast cancer, where the risk of developing cancer ... is less than 100% and there is no assurance of a successful medical intervention.¹²³

18.105 If the circumstances in which disclosure is permitted are limited to situations where it is necessary to lessen or prevent the serious illness or death of an individual (as proposed by the Inquiry), it is reasonable to assume that only rare individuals would not wish to know about such a risk. Therefore, recognition of a 'right not to know' is not a barrier to sensible reform in this area.

Reform options

18.106 The Inquiry has concluded that there may be exceptional circumstances in which disclosure by health professionals of genetic information to genetic relatives without the consent of their patient should be permissible.

121 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.101.

122 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

123 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne, Guideline 16.

Amending privacy legislation

18.107 Privacy legislation may inappropriately constrain health professionals' decisions about such disclosures. As discussed above, there are strong arguments that the 'serious and imminent threat' test contained in NPP 2.1(e)(i) of the *Privacy Act* may be too restrictive.

18.108 Therefore, one set of reform options being considered by the Inquiry relates to the application of the *Privacy Act* to disclosure to genetic relatives. The options include, but may not be limited to, the following:

- Amending NPP 2.1(e)(i) to change the 'serious and imminent threat' test to a more permissive formulation. For example, the circumstances in which disclosure is permitted could be extended to situations where disclosure is necessary to lessen or prevent 'the serious illness or death' of an individual. The intention of such an amendment would be to permit disclosure where the genetic risk is not necessarily imminent but failure to disclose could place the health or life of a genetic relative at serious risk.
- Enacting a new NPP 2.1(e)(iii) to permit disclosure 'in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality'.¹²⁴
- Enacting a new NPP 2.1(e)(iii) to permit organisations to exercise a discretion, subject to guidelines issued by the NHMRC and approved by the federal Privacy Commissioner, to disclose an individual's genetic information to a genetic relative, where such disclosure could reasonably be expected to lessen or prevent serious harm to the relative.¹²⁵
- Recommending that a relevant organisation seek a public interest determination under the *Privacy Act* to permit the disclosure of genetic information to genetic relatives in circumstances to be defined in the determination.¹²⁶

18.109 Depending on the option taken, consistent amendment of the equivalent Information Privacy Principle (IPP 11), applying to doctors or other health professionals working for Commonwealth government agencies, may be needed. It may also be appropriate for the Inquiry to recommend that state and territory governments consider parallel amendments to state and territory privacy

¹²⁴ This form of words appears in NPP 10.2(b)(ii), which relates to the collection of sensitive information.

¹²⁵ Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

¹²⁶ The *Privacy Act* authorises the NHMRC to make an application for a public interest determination on behalf of other agencies concerned with medical research or the provision of health services: *Privacy Act 1988* (Cth) s 73.

legislation. Proposals along these lines may be subsumed under new federal or national health privacy legislation (see Chapter 7).

Amendment of the Privacy Act

18.110 The simplest solution may be to amend NPP 2.1(e)(i), to refer to ‘serious illness or death’ or some similar formulation. Such an amendment would have implications beyond genetic medicine, by permitting disclosure of any personal information where disclosure is necessary to prevent or lessen serious illness or death, even where it is not clear whether the threat is ‘imminent’. The Inquiry would be interested in comments on the possible wider consequences of such a reform on disclosure of non-genetic health information.

New ethical guidelines

18.111 Health professional bodies may need to clarify ethical guidelines applying to disclosure by doctors and other health professionals to genetic relatives. Submissions to the Inquiry strongly favoured the further development of such guidelines.¹²⁷

18.112 The circumstances in which it may be justifiable to disclose genetic information in breach of privacy principles or legal or ethical duties of confidentiality are not easily defined and may require detailed consideration of specific genetic conditions (such as their probable penetrance and expression), the prevention and treatment options and the extent to which the patient has been counselled to disclose relevant information directly. The OFPC observed that an attempt to legislate exhaustively on such disclosures ‘would be defeated by the multiplicity of situations which could arise and by future scientific advances’.¹²⁸

18.113 Arguably, such detailed guidance is more appropriately located in guidelines than in legislation. Therefore, the Inquiry proposes to encourage the development of guidelines on disclosure of genetic information by health professionals to genetic relatives by an appropriate body.

18.114 Ideally, there should also be some mechanism for recognising such guidelines within the fabric of the *Privacy Act* to minimise the possibility that a disclosure complying with ethical guidelines may nevertheless breach the *Privacy Act*. Incorporating reference to ‘disclosure in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality’ in NPP 2.1(e) might provide a solution. Given that the obvious

127 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

128 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

bodies to issue such rules are state and territory health professional registration authorities, this mechanism may be cumbersome.¹²⁹

18.115 However, while desirable, complete consistency between the *Privacy Act* and professional ethical guidelines relating to confidentiality is not essential. Health professional ethical guidelines and legislative privacy principles perform different functions. In the context of medical practice, the former focus on promotion of appropriate professional standards of practice and the latter on the rights of individual patients to exercise control over information about them.

18.116 It is possible for a professional disciplinary body to find that a disclosure of health information constituted unsatisfactory professional conduct on the part of a medical practitioner (and take disciplinary action against the practitioner) in circumstances where the *Privacy Act* would permit disclosure. Similarly, a breach of the *Privacy Act* may not necessarily constitute unsatisfactory professional conduct.

18.117 The Inquiry considers that the NHMRC would be the most appropriate body to issue guidelines on disclosure to genetic relatives. Such guidelines would be issued in accordance with s 7 of the *National Health and Medical Research Council Act 1992* (Cth), following the prescribed consultation.¹³⁰ The NHMRC has issued guidelines in related areas, notably the guidelines for genetic registers which include extensive guidance for genetic register staff on contacting the family members of registrants.¹³¹

Disclosure by an independent agency

18.118 Another reform option, favoured by the OFPC also envisages a role for the NHMRC. The OFPC submitted that the *Privacy Act* should be amended to permit organisations to exercise a discretion to disclose an individual's genetic information to a genetic relative, where such disclosure could reasonably be expected to lessen or prevent serious harm to the relative.¹³²

129 The federal Privacy Commissioner's *Guidelines on Privacy in the Private Health Sector* state that to qualify as professional rules within the meaning of NPP 10.2, rules must be binding on the health service provider, and must be established by a competent health or medical body. The Commissioner suggests that competent bodies might include medical boards and other rule-making bodies recognised in Commonwealth, State or Territory legislation and that binding rules are rules that must be followed, and generally, will give rise to some sort of adverse consequence if breached: Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 3.

130 *National Health and Medical Research Council Act 1992* (Cth) s 13.

131 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, Ch 6. See also National Health and Medical Research Council, *General Guidelines for Medical Practitioners on Providing Information to Patients* (1993) National Health and Medical Research Council.

132 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

18.119 The OFPC submitted that the exercise of this discretion should be made subject to guidelines as to the circumstances in which such a discretion may be exercised and the factors to be taken into account, including the genetic relative's right not to know.¹³³ Appropriate amendments to the Act could be effected, placing the responsibility for the formulation and issuing of comprehensive guidelines, after extensive consultation, within the province of a suitable authority, such as the NHMRC, possibly subject to approval by the OFPC.

Disclosure by government health authorities

18.120 An alternative option for reform has been suggested by Dr Roger Magnusson. This option draws by analogy from approaches taken in the context of HIV/AIDS. Dr Magnusson suggests that, as in the context of HIV/AIDS,¹³⁴ there should be a protocol that would provide doctors and other health professionals with legal authority to disclose genetic information to a government health authority. It would then be up to that health authority to take steps to inform the genetic relatives about their genetic risks.

18.121 Dr Magnusson suggested that, under such a protocol, disclosure to genetic relatives should be permitted in circumstances where:

- the test results carry clear implications for next of kin;
- early intervention could reduce the burden of disease in genetic kin (or prevent transmission to the next generation);
- the burden of the disease is a substantial one; and
- a process of counselling to encourage voluntary disclosure has failed.¹³⁵

18.122 This option would not require any amendment to the federal *Privacy Act*, or to state and territory privacy legislation, which permit disclosure where authorised by law.¹³⁶

133 Ibid.

134 Eg health legislation in New South Wales permits the disclosure of the identity of a patient (who poses an HIV transmission risk to third parties) to the Health Department, activating the Department's public health powers, exercised in accordance with a Departmental protocol: *Public Health Act 1991* (NSW) s 17(3); *Public Health Regulation 1991* (NSW) s 7(2).

135 R Magnusson, *Submission G039*, 10 January 2002. The Queensland University of Technology also submitted that the model for HIV/AIDS testing should be considered a useful and appropriate starting point: Queensland University of Technology, *Submission G109*, 14 March 2002.

136 See *Privacy Act 1988* (Cth) NPP 2.1(d); *Health Records (Privacy and Access) Act 1997* (ACT) s 10(1)(d); *Health Records Act 2001* (Vic) Health Privacy Principle 2.2(c).

18.123 The Inquiry does not favour this option. Such a reform would be more cumbersome and resource intensive to implement, requiring the involvement of state government health authorities in order to permit sensible disclosure.¹³⁷ While this mechanism may be appropriate in view of the public health implications of non-consensual disclosure of an infectious disease like HIV/AIDS, it is not clear that such a restrictive approach is justified in the case of disclosure of genetic information.

Future development of the common law

18.124 An important reform consideration relates to the implications of reform for the future development of the common law. At least two possible effects of the proposed reforms may be identified.

18.125 Legislative reform, or the development of ethical guidelines, to permit disclosure of genetic information to genetic relatives in a wider range of circumstances may make it more likely that, in future, courts may accept that disclosure of genetic information falls within the public interest exception to the duty of confidentiality. Secondly, it may make it more likely that courts might impose positive duties on doctors and other health professionals to inform genetic relatives.

18.126 The Inquiry tends to the view that, while the first of these possible effects may be desirable, the second (involving the development of a ‘duty to warn’) would not be desirable. However, it is difficult to predict developments in the common law. These conjectures should not be considered as a barrier to sensible reform.

18.127 The Inquiry leaves open, for the present, the question of whether health professionals may in future require some form of statutory protection from legal proceedings for breach of confidentiality or negligence in failing to warn genetic relatives of their patients about relevant genetic risks.

Proposal 18–1. NPP 2.1(e)(i) of the *Privacy Act* should be amended so that disclosure of genetic information by a health professional to the genetic relatives of a patient is permitted where failure to disclose would place the health or life of a genetic relative at serious risk.

Proposal 18–2. State and territory governments should consider amending their privacy legislation in accordance with Proposal 18–1.

¹³⁷ However, health professionals involved with genetic registers might, in some circumstances, be appropriate sources of advice, or even decision making, in relation to disclosure of information to genetic relatives.

Proposal 18–3. The NHMRC should develop guidelines for health professionals pursuant to s 7 of the NHMRC Act dealing with disclosure of genetic information to the genetic relatives of their patients. These guidelines should address the circumstances in which disclosure to genetic relatives is ethically justified or required, and the need for patients to be counselled about the disclosure of information in these circumstances.

Access rights and genetic information

18.128 As discussed above, the *Privacy Act* and other privacy legislation impose constraints on the disclosure of genetic information by doctors and other health professionals to the genetic relatives of their patients. However, privacy legislation also provides individuals with rights to access information about them.

18.129 NPP 6 of the *Privacy Act* states that, subject to some exceptions, if an organisation holds personal information about an individual, it must provide the individual with access to the information on request.¹³⁸ The Act provides a legally enforceable right for patients to obtain access to their medical records held by private medical practitioners.¹³⁹ Such records may also contain information about genetic relatives, including, for example, information about non-paternity as well as the probable genetic status of other individuals.

18.130 IP 26 observed that where information relates to a genetic relative who is not a patient, the obligation to provide access to the genetic relative under the *Privacy Act* may conflict with a health professional's legal and ethical duties of confidentiality with respect to his or her patient.¹⁴⁰ On the other hand it may be argued that, for example, information about a particular allele in a family should be available not just to one individual but also to his or her blood relatives.¹⁴¹

18.131 NPP 6 provides that access may be refused to the extent that 'providing access would have an unreasonable impact upon the privacy of other individuals'.¹⁴² Therefore, in some circumstances, a health professional may be

¹³⁸ See also *Health Records Act 2001* (Vic) Health Privacy Principle 6.

¹³⁹ Notwithstanding the decision of the High Court in *Breen v Williams* holding that there was no basis at common law or in equity to find a general right of patient access to medical records: *Breen v Williams* (1996) 186 CLR 71. State and territory health privacy legislation includes similar provisions: *Health Records Act 2001* (Vic) Health Privacy Principle 6; *Health Records (Privacy and Access) Act 1997* (ACT) s 10.

¹⁴⁰ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 4.96.

¹⁴¹ Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

¹⁴² *Privacy Act 1988* (Cth) NPP 6.1(c). Under the Victorian health privacy legislation, access may be refused if providing access would have an unreasonable impact on the privacy of other individuals and refusing access is accordance with guidelines issued or approved by the Health Services Commissioner: *Health Records Act 2001* (Vic) Health Privacy Principle 6.1(b).

entitled to refuse access to part of the records. A health professional may provide access in ways that do not have an impact on the privacy of another person, for example, by removing the other person's identifying details or getting his or her consent to the release of his or her information.¹⁴³

18.132 The HGSA suggested that health professionals may need more guidance on dealing with access by family members to genetic information held by them.

Medical practitioners would appreciate guidance on access by family members to genetic health information they hold. Having a separate file for each family member is appropriate and laboratories should not record the results of tests on multiple family members on the one report form. It would be very helpful to have advice on how to handle information in a file that has not been disclosed to the person tested eg. the result of a genetic test that the doctor knows reveals non-paternity because he/she also holds information on other family members or where a laboratory has tested multiple members of a family and records inconsistent results in its report. Also, while a senior next of kin should be entitled to access specific information about a deceased person that could be of use in the health care of other family members, it should not be possible to access the whole medical record, which may contain information that the next of kin does not know about relatives, or paternity and other highly sensitive information.¹⁴⁴

18.133 In order for genetic relatives to exercise their access rights under privacy legislation they first have to know that information about has been collected and is held, for example, by a particular health professional. In this context, the Privacy Charter Council has suggested that

[p]erhaps a new principle should require each individual to be notified that some genetic information exists that relates to them, giving them the choice of whether to seek access or not. But this may be impracticable on logistic grounds if there are too many individuals involved — how far would organizations be expected to trace the family tree? And there will also no doubt be situations where the knowledge that a genetic test had been carried out would be unreasonably intrusive into the privacy of the tested individual — even to the point of potential harm.¹⁴⁵

18.134 This discussion highlights the practical difficulties for health professionals and others of dealing with shared or familial information in a way that both respects the privacy rights of patients and the rights of other people to whom health information also relates. Nevertheless, the Inquiry is not convinced that any change to existing privacy legislation is necessary to address these difficulties.

18.135 The *Privacy Act* already contains a mechanism by which the competing interests of a patient and genetic relatives may be balanced — that is, access may be refused if it would have an unreasonable impact upon the privacy of other

143 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 35.

144 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

145 Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

individuals. In this context, health professionals may have latitude, in dealing with requests for access, to recognise a distinction between familial and individual genetic information. Skene has referred to this distinction in the following terms.¹⁴⁶

There is the fact that a mutation is in the family; and the fact that a particular person has tested positive for the mutation. The information that is familial is the first kind. A person's own genetic status is personal information and should generally be kept confidential in the same way as information concerning the patient's clinical or surgical history. Whether the person chooses to disclose his or her own genetic status to family members — or even chooses not to know it at all — is a matter for that person alone.¹⁴⁷

18.136 There also may be a range of practical ways in which a health professional may be able to release familial genetic information without disclosing information about any specific person's own genetic status.

18.137 Further, while it may be appropriate for familial genetic information to be released to a genetic relative, access to the sample itself relates to a specific person's own genetic status and might be resisted on this ground (assuming that genetic samples are covered by the *Privacy Act*, as proposed in Chapter 7).

18.138 It seems clear that health professionals would benefit from further guidance on how to deal with requests for access to genetic information held by them. The Inquiry considers that these issues might usefully be considered in conjunction with the proposed development by the NHMRC of guidelines dealing with disclosure of genetic information by health professionals to the genetic relatives of their patients.

Proposal 18–4. The guidelines referred to in Proposal 18–3 also should assist health professionals in dealing with requests for access to genetic information by the genetic relatives of their patients.

146 Ie the distinction referred to by Professor Loane Skene (see Ch 7): L. Skene, 'Genetic Secrets and the Family: A Response to Bell and Bennett' (2001) 9 *Medical Law Review* 162.

147 Ibid, 166.

19. Genetic Registers and Family Genetic Information

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Introduction

Families have black sheep, missing sheep and dead sheep.¹

19.1 This chapter deals firstly with general questions about the operation of genetic registers and, in particular, whether the existing regulatory framework to protect the privacy of genetic information collected and held on genetic registers is adequate.

19.2 The collection and disclosure of family genetic information is central to the operation of genetic registers and the conduct of genetic counselling. The familial or collective nature of genetic information raises particular issues for genetic registers and genetic counselling, notably in relation to the application of privacy laws. These issues are also discussed below.

¹ L Skene, 'The Genetics Debate: Why Doctors Must be Heard' (Paper presented at 2001 UMMS Lecture, 15 November 2001), quoting Professor Graham Giles, Director of the Cancer Epidemiology Centre, Anti-Cancer Council of Victoria, explaining the need for genetic registers: Lecture to Graduate Students in Law and Human Genetics, University of Melbourne, October 2001.

What are genetic registers?

19.3 Health professionals may need to collect information about an individual's family medical history in order to provide effective health care (see Chapter 18). In some ways, genetic registers may be seen as an extension of this established part of medical practice. Family pedigrees are documented in greater detail than would be usual in routine medical practice and linked to medical information, including genetic test results and tissue samples. The bringing together of pedigrees and medical information about multiple families constitutes a genetic register.

19.4 The primary purpose of genetic registers is to operate as an effective way of identifying and contacting members of families who are at significantly increased risk of developing an inherited disorder or of having affected children.² Information on a genetic register will generally comprise genetic information about many genetically related people and may also contain tissue samples.

19.5 Each genetic register usually addresses one disorder or a closely related group of disorders. Genetic registers in Australia include those for Huntington's disease, familial adenomatous polyposis (FAP), Duchenne muscular dystrophy and fragile X mental retardation.³

19.6 Genetic registers are said to contribute to the provision of health care to family members by: undertaking the systematic collection of accurate and up-to-date information over a long period; ensuring that family members have an opportunity to become aware of their risk and testing, prevention, treatment and reproductive options; and bringing together pedigree and medical information relating to individuals, nuclear families and branches of the family in order to construct a single large pedigree.⁴

19.7 Genetic registers may improve risk assessment, provide information about disorder expression in the family, prevent duplication of genetic testing, help validate genetic test results and facilitate research.⁵ The information on genetic registers may be used, along with information in other medical records,⁶ to assist in genetic counselling. Some registers assist health professionals to provide surveillance for inherited disorders such as familial cancer.

2 See National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 7.

3 Ibid, 7.

4 Ibid, 17–19.

5 Ibid, 17–19.

6 The NHRMC Guidelines for Genetic Registers note that the following are not considered to be genetic registers: medical records kept by health professionals, hospitals and clinical genetics units; records of research studies, research databases; public health surveillance data sets (such as statutory cancer registers); the results of genetic tests or collections of tissues held by laboratories and blood banks. See Ibid, 8–9.

19.8 The NHMRC's *Guidelines for Genetic Registers and Associated Use of Genetic Material* (the NHMRC Guidelines for Genetic Registers)⁷ distinguish genetic registers from statute-based health data collections, including cancer registers. Each State and Territory maintains a statutory cancer register.⁸ The core function of these registers is to measure the incidence or prevalence of cancers in a defined population.⁹ This chapter does not deal with statute-based health data collections, the regulation of which is governed by the state and territory laws that establish them.

Existing regulation of genetic registers

19.9 Existing regulation of genetic registers is based on the NHMRC Guidelines for Genetic Registers.¹⁰ These guidelines may be supplemented by other, more specific, guidelines developed by clinical genetics services and other organisations that operate genetic registers.¹¹

19.10 The collection, use and disclosure of genetic information on genetic registers may be subject to information and privacy legislation, depending on where it is held.

NHMRC Guidelines for Genetic Registers

19.11 The content of the NHMRC Guidelines for Genetic Registers was summarised in IP 26.¹² Briefly, the Guidelines deal with the establishment of registers, the recruitment of registrants, consent issues, confidentiality guidelines, contacting other family members and the security, amalgamation and winding up of registers.

7 Ibid.

8 Eg in Victoria the Anti-Cancer Council of Victoria operates cancer registers established pursuant to the *Cancer Act 1958* (Vic) and in NSW the NSW Central Cancer Registry operates cancer registers established pursuant to *Public Health Act 1991* (NSW).

9 Some registers have additional functions, such as providing population based cases for case-control or cohort epidemiology studies, or collection of information which can be used to monitor the effectiveness of the treatment and clinical management of cancers.

10 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra.

11 Eg SA Clinical Genetics Service, *Confidentiality and Consent Guidelines* (2001) SA Clinical Genetics Service: attached to G Suthers, *Submission G026*, 30 November 2001.

12 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 8.36–8.37.

19.12 In particular, the Guidelines deal in detail with consent to inclusion of genetic information on a register and list information to be provided to a person before they choose to participate.¹³ There are detailed provisions relating to obtaining consent from people other than the initial registrant, such as children and other nominated relatives and in relation to deceased persons.¹⁴ The Guidelines contain detailed confidentiality provisions¹⁵ and guidelines on contacting other family members.¹⁶

19.13 The Guidelines have no direct legal effect and do not provide any formal sanction for non-compliance. However, non-compliance may influence NHMRC advice and recommendations to government on research funding related to the operation of a genetic register.

19.14 In addition, as the Guidelines will be used if complaints about the conduct of health professionals responsible for genetic registers are assessed by health complaints commissioners, registration authorities or professional associations, they are likely to positively influence professional behaviour. Furthermore, as is the case with clinical practice guidelines, courts may approach the guidelines as a form of expert evidence of accepted standards of practice.¹⁷

Application of privacy legislation to genetic registers

19.15 The collection, use and disclosure of genetic information on genetic registers may be subject to information and health privacy legislation. The extent to which such registers are covered by existing legislation depends on whether they are maintained by federal or state public sector entities or community or private sector organisations.

19.16 Genetic registers are most commonly hospital based or community based. Where registers are established and maintained as part of the services provided by a public hospital they may be covered by state privacy legislation such as the

13 This information includes: the fact that participation is voluntary; the aims of the register and how it may help the individual and relatives; how the register operates; relationships between registrants and register staff; policy about communicating new research information; registrant's role in introducing other family members to the register; what is on the register; how long it will be held; the sources from which register information is derived; procedures to ensure confidentiality; rights of access; and uses of register data and any stored genetic material: National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 17–19.

14 Ibid, 20–22.

15 Ibid, 23–27.

16 Ibid, 29–32.

17 See J Pelly and others, 'Clinical Practice Guidelines Before the Law: Sword or Shield?' (1998) 169 *Medical Journal of Australia* 330; B Bennett, 'Setting the Standard? Clinical Practice Guidelines and Medical Negligence Litigation' (1997) 20(3) *University of New South Wales Law Journal* 707.

*Health Records (Privacy and Access) Act 1997 (ACT), Privacy and Personal Information Protection Act 1998 (NSW)*¹⁸ or *Health Records Act 2001 (Vic)*.

19.17 Genetic registers maintained by community based organisations, such as disease support groups, would be covered by the private sector amendments to the federal *Privacy Act*, along with any registers maintained by clinical genetics services or other private sector organisations.

19.18 Some genetic registers are maintained by state and territory cancer councils. For example, the NSW Cancer Council maintains Hereditary Bowel Cancer Registers. Where such bodies are established for a public purpose under a law of a State they will not be covered by the federal *Privacy Act*¹⁹ but may be covered by state legislation.

19.19 In their submission Professor Nick Saunders and Associate Professor Paul Komesaroff observed that a genetic register may take the form of a network of data sources that links information stored in a number of locations, such as hospital records, pathology laboratories and research institutes. They noted that

in such settings it is important that an individual is identified who assumes responsibility for ensuring security of the data and for discharging the other responsibilities normally associated with the conduct of a register.²⁰

19.20 The Inquiry observes that this may also be important in order to establish which laws apply to the collection, use and disclosure of the information on the particular genetic register.

19.21 Privacy and related issues are raised by the application of the *Privacy Act* and similar state or territory privacy legislation to the collection, use and disclosure of genetic information on genetic registers. These issues are discussed below.

Is there any need for further regulation?

19.22 IP 26 asked whether, in the specific context of genetic registers, federal, state and territory privacy laws provide an adequate framework for protecting the privacy of genetic samples and information.²¹

18 Or the proposed NSW health privacy legislation: Exposure Draft Health Records and Information Privacy Bill 2001 (NSW).

19 *Privacy Act 1988* (Cth) s 6C(1), 6C(3)(c).

20 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

21 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 9–2.

19.23 One submission raised concerns about the privacy of information contained on a Huntington's disease genetic register.²² The submission stated that identifying information had been transferred in the 1980s from the Queensland Institute of Medical Research to the Mater Hospital, Brisbane, without the knowledge or consent of the individuals to whom the information related.

As a result of this experience neither I or any of my family will participate in future genetic research.²³

19.24 The *Privacy Act* would generally require consent to be obtained prior to such a transfer of health information.²⁴ However, if the organisations involved are state authorities,²⁵ the *Privacy Act* may not apply to the collection or disclosure of the information being transferred²⁶ — emphasising the need for harmonisation of federal, state and territory privacy laws.

19.25 To date, the Inquiry has not been made aware of any other specific concerns about the privacy of genetic samples and information held on genetic registers. The Human Genetics Society of Australasia (HGSA) observed that, in fact, there are very few genetic registers in Australia at the present time and that 'participation in such registers is with consent'. The HGSA considered that

professional ethics/codes of conduct and mechanisms for censure of health professionals, the Privacy Acts and associated penalties for breach, State privacy laws/regulations, guidelines from the NHMRC and other bodies, the risk management practices of hospitals and the common law appear to provide adequate protection for genetic information collected in the context of genetic registers.²⁷

19.26 A similar view was expressed by the Centre for Law and Genetics, which stated that it was not aware of any specific breaches of privacy in dealings with established genetic registers governed by the NHMRC Guidelines for Genetic Registers and considered that genetic registers and their operation should remain under the regulation of codes of ethical practice.²⁸

19.27 However, submissions have focussed on certain practical problems concerning the way in which the federal *Privacy Act* and other privacy legislation may overly constrain the operation of genetic registers and the conduct of genetic counselling. These concerns are discussed below.

22 Confidential Submission G126CON, 12 March 2002.

23 Ibid.

24 Or, at least, prior to the collection of the information by the new organisation: see Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 47–48.

25 In terms of *Privacy Act 1988* (Cth) s 6C(3).

26 Depending on where registers are established and maintained, state or territory privacy legislation may apply.

27 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

28 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

Collection of information on genetic registers

19.28 Issues concerning the collection of information for inclusion on genetic registers were raised in several submissions.²⁹ For example, the HGSA referred to the collection of information needed to construct pedigrees and stated that

it is essential there be clarification on the use of family data by medical practitioners and other involved health professionals. The gathering of family information to construct a family tree, without the consent of the other family members, is essential to the diagnosis and risk assessment in families. The use of these data by registers is of great value in the management of other family members. The HGSA believes it should be made clear that obtaining family information in this context is considered an exception to the Privacy Act.³⁰

19.29 The Peter MacCallum Cancer Institute (PMCI) also expressed concerns that the *Privacy Act* could make the collection of pedigree information difficult

It seems that a pedigree constructed from information provided by an individual will become part of his/her medical records, but cannot be verified or used during consultation with another family member. Does this mean a fresh pedigree must be drawn for every family member who attends a genetic clinic? Will the genetic risk of an individual be assessed only on the basis of the information provided by that individual rather than, as now, on a fully verified family history drawn from many sources? How are fully verified pedigrees to be obtained under the Act? Will there be a need to tag the sources of the information used to construct the pedigree so as to minimise the chances that information volunteered by one family member would be transmitted to another? This seems unworkable. At the very least there is a need for a clearer definition in the Paper of the genetic information that blood relatives and other family members should be able to supply and the character of the access to that information by clinicians and genetic clinics that is appropriate.³¹

Collection of information and the NHMRC Guidelines

19.30 The NHMRC Guidelines for Genetic Registers note that potential registrants may be identified in different ways. They may themselves contact the register on the advice of health professionals or community based support groups. However, they also may be identified by register staff from the information provided by another registrant who identifies other family members.³²

19.31 The Guidelines recognise that the collection and recording of family genetic information in a genetic register may involve a breach of the privacy of those family members who have not consented to be registrants. They state that registers should distinguish information that identifies people who are not

29 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002;

30 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

31 Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

32 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 13–14.

registrants and not disclose it in identifiable form without the consent of the identified person. In general, the persons identified should be approached, in due course, so that their consent can be sought for inclusion of their information in the register.³³

19.32 However, in some circumstances it appears that collection of information for genetic registers, in ways that would comply with the NHMRC Guidelines for Genetic Registers, may nevertheless breach the *Privacy Act* or similar state and territory privacy legislation.

Application of privacy legislation to collection

19.33 As discussed in more detail in Chapter 18, NPP 1 of the *Privacy Act* provides that, in general, an organisation must collect personal information about an individual only from that individual, rather than from any third party, unless it is not 'reasonable and practicable' to do so.³⁴ Further, under NPP 10, an organisation generally must not collect sensitive information (including genetic and other health information) unless the individual has consented.

19.34 The federal Privacy Commissioner's *Guidelines on Privacy in the Private Health Sector* imply that in some circumstances consent may be obtained on an 'opt out' basis:

Where consent is required from individuals for the collection and use of data in relation to the establishment and maintenance of a disease register, it may sometimes be appropriate to give individuals the opportunity to opt out of being included on the register. The use of this approach by a health service provider would only be appropriate where individuals are clearly informed about the option to opt out and this is prominently presented and easy to adopt.³⁵

Collection from registrants

19.35 In some circumstances it may be possible to argue that it is not reasonable and practicable to collect family medical history information directly from the genetic relatives (for example because they are not contactable or are dead).

19.36 However it would appear that, in many circumstances, the collection of family medical history information for the purposes of a genetic register, without the consent of those family members, might breach the *Privacy Act*. The fact that consent may later be sought from these family members, whether by the registrant or staff of the genetic register, does not appear to alter this position.

³³ Ibid, 21–22.

³⁴ *Privacy Act 1988* (Cth) NPP 1.4.

³⁵ Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, xiii.

19.37 As discussed in Chapter 18, a Temporary Public Interest Determination (the Temporary PID) has been issued by the federal Privacy Commissioner to ensure that organisations can continue to collect family medical history information without breaching the NPPs where the collection of health information from an individual about another individual (a third party) is:

- necessary for the organisation to provide a health service directly to the individual and to diagnose, treat or care for the individual; and
- the third party is a member of the individual's family or household, or the third party's information is otherwise relevant to the individual's family medical history or social medical history.³⁶

19.38 The Temporary PID, therefore, only applies to situations where a health service is being provided directly to the individual (the patient) from whom family history information is sought. This criterion is likely to be satisfied where, for example, the information is being collected, for example, by the patient's treating doctor for the patient's own medical records.

19.39 However, where information is collected in order to facilitate the diagnosis or treatment of other people, to ensure that genetic relatives have opportunity to become aware of their genetic risk, access genetic counselling and medical advice, the Temporary PID may not apply. The Temporary PID may not, therefore, apply to the collection of third party information for inclusion on genetic registers.

Collection from other health professionals

19.40 Another issue concerning the collection of genetic information for genetic registers relates to the verification of information provided by registrants. The PMCI stated that the rules relating to the collection of pedigree information may create problems for registries where there is a need to verify diagnoses without the consent of the genetic relative of a registrant.³⁷ In this context, the NHMRC Guidelines for Genetic Registers state that

At the time of constructing the pedigree there will be relatives of the registrant in whom register staff have no interest other than to confirm that the diagnosis provided by the registrant is correct. If the relative is deceased or if there are circumstances in which it would be intrusive or potentially upsetting to approach a living relative for consent, confirmation of diagnosis may be obtained without consent provided that identifiers are removed once the confirmed diagnosis has been recorded in the register.³⁸

³⁶ Privacy Commissioner Temporary Public Interest Determination No. 2001-1 2001 (Cth).

³⁷ Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

³⁸ National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 22.

19.41 Again, the collection of information in this way may breach the *Privacy Act* and other privacy legislation and may not be authorised by the Temporary PID.³⁹ Verification of diagnosis is vital to the operation of a genetic register.

Reform options

19.42 The collection of family medical history information from registrants is essential to the operation of genetic registers. The Inquiry has concluded that privacy legislation may inappropriately constrain established practices for the collection of family medical history from registrants and that this should be remedied.

19.43 A more difficult question is whether verification of such information should occur only with the consent of the genetic relative or next of kin (where the genetic relative is deceased). For example, as noted above, the NHMRC Guidelines for Genetic Registers state that confirmation of diagnosis may be obtained without consent where approaching the individual would be 'intrusive or potentially upsetting'. This guidance is not consistent with the requirements of the *Privacy Act*.⁴⁰ The Inquiry is interested in further comments on this issue.

19.44 The most obvious reform option would be the application of a Public Interest Determination (PID) to permit the operators of genetic registers to collect certain family medical information in ways that might otherwise breach the NPPs of the *Privacy Act*. As noted above, a Temporary PID has already been issued in respect of the collection of family medical history by health service providers from their patients.

19.45 In this regard, the federal Privacy Commissioner could either issue a PID dealing solely with the operation of genetic registers or deal with the operation genetic registers when the Temporary PID is finalised.

19.46 The former option appears more desirable, as the contexts of collection to be covered are quite distinct and, as discussed below, a PID dealing with the operation of genetic registers may need to deal not only with the collection of genetic information, but also aspects of its use, disclosure or de-identification.⁴¹

19.47 In practice, the federal *Privacy Act* has limited coverage of genetic registers in Australia. The Inquiry understands that, with few exceptions, all genetic registers are public hospital based. These registers will be governed by state or territory privacy legislation, where it exists.

39 The *Privacy Act* does not apply to the collection of personal information about a deceased individual. See *Privacy Act 1988* (Cth) s 6: an individual means a natural person.

40 *Privacy Act* NPP 1, NPP 10.

41 An issue of timing also arises. The federal Privacy Commissioner is required to issue the final PID in respect of the collection of family medical history by health service providers from their patients by 21 December 2002.

Proposal 19–1. An organisation operating a genetic register for public health purposes should seek a Public Interest Determination (PID) under the *Privacy Act* to ensure that it can continue to collect family medical history information without breaching the NPPs.

Proposal 19–2. State and territory governments should consider amending their privacy regulation in accordance with Proposal 19–1.

Question 19–1. Should the proposed PID referred to in Proposal 19–1 also apply to the collection of health information from other health professionals for the purpose of verifying information provided by the registrant?

De-identification of family information on genetic registers

19.48 The NSW and ACT Hereditary Bowel Cancer Register, expressed a related concern about the application of the NHMRC Guidelines for Genetic Registers.⁴² This concern relates to requirements to de-identify information where register staff have not been able to obtain consent to retain identified information provided by a registrant about a relative.

19.49 The NHMRC Guidelines for Genetic Registers provide that where consent is not obtained register staff should remove identifiers from the information. The information which remains in the register, usually represented by a symbol in the pedigree, will be the position of the individual in the pedigree, the individual's gender, whether or not the individual was considered to have the genetic disorder and whether the individual is alive or dead.⁴³ The Guidelines also state that

At the time of constructing the pedigree there will be relatives of the registrant in whom register staff have no professional interest other than to confirm that the diagnosis provided by the registrant is correct. If the relative is deceased or if there are circumstances in which it would be intrusive or potentially upsetting to approach a living relative for consent, confirmation of diagnosis may be obtained without consent provided that identifiers are removed once the confirmed diagnosis has been recorded in the register.⁴⁴

19.50 The Hereditary Bowel Cancer Register submitted that retention of identified information may be important in order to link affected families.

42 NSW and ACT Hereditary Bowel Cancer Registers, *Submission G079*, 16 January 2002.

43 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra 22.

44 *Ibid.*, 22.

One of the unique functions of a central repository of genetic information is that information from families thought to be separate units may be linked so they are shown to be part of a single extended family ...⁴⁵ The aggregation of families is an important role of the Hereditary Bowel Cancer Register because it:

- assists with identifying those at risk;
- provides information about disorder severity and manifestations in that family;
- prevents unnecessary genetic testing if another family member has already been tested;
- helps validate genetic test results;
- facilitates research.⁴⁶

19.51 The Hereditary Bowel Cancer Register stated that because of the large number of families on genetic registers, linking is now done initially by computer searches of names and submitted that de-identification of information about individuals who have not consented to be on a register ‘would make it extremely difficult to link families’.⁴⁷

19.52 At least for the purposes of the *Privacy Act*, information on a genetic register may not be truly de-identified even where identifiers, such as name and date of birth have been removed. The information remains ‘personal information’⁴⁸ because it is about an individual whose identity can reasonably be ascertained from the surrounding information — the fact that the person is, for example, the father, mother, or sibling of another individual whose full details are on the register.⁴⁹

19.53 The Inquiry is interested in further comments on the de-identification requirements contained in the NHMRC Guidelines for Genetic Registers and whether any modification should be examined.

Question 19–2. Do the requirements for the de-identification of information on genetic registers contained in the NHMRC Guidelines for Genetic Registers cause problems for the effective operation of genetic registers? If so, how should these Guidelines be modified?

Use and disclosure of information on genetic registers

19.54 A related concern, raised by the PMCI and Dr Graeme Suthers,⁵⁰ involves the use of family genetic information provided by one individual in the diagnosis or treatment of another genetically related family member who is attending the

⁴⁵ NSW and ACT Hereditary Bowel Cancer Registers, *Submission G079*, 16 January 2002.

⁴⁶ *Ibid.*

⁴⁷ *Ibid.*

⁴⁸ In terms of the definition in *Privacy Act 1988* (Cth) s 6(1).

⁴⁹ From the definition of personal information in the *Privacy Act* s 6(1).

⁵⁰ Peter MacCallum Cancer Institute, *Submission G104*, 20 February 2002.

same clinical genetics service. Dr Suthers, the Head of the Familial Cancer Unit at the SA Clinical Genetics Service provided the following example of such a situation:

Both Brendon and Bradley have been tested by me. As far as they know, they have no living relatives who would be at risk of having inherited this mutation. However, a long lost cousin, Claude, is seen by a doctor in another department of my hospital. Claude says that he had a relative called Bradley whose brother had early-onset bowel cancer, but he cannot remember Brendon's name. The further medical care of Claude would be greatly enhanced if the doctor seeing him could find out details of Brendon, Bradley, and the genetic testing that is now available. Should he ask me? Should the doctor have access to my database?⁵¹

19.55 Graeme Suthers notes that this issue often arises within the SA Clinical Genetics Service which has a number of discrete, yet related, units (a Familial Cancer Unit, Clinical Genetics Unit, Familial Cancer Registry, and research staff) sharing a common database for reasons of cost and to assist in managing familial disorders:

It is very common for one unit to have data about one end of a family, and another unit to have relevant information about another branch of the family. Should this information be shared?⁵²

19.56 Graeme Suthers also noted constraints on the disclosure of such information to the treating doctors of other family members. Using the facts described in paragraph 19.54 above, Dr Suthers noted that:

If Claude's doctor was not part of our genetics service, he would not have access to our database, and I would not be able to release any information to him about Bradley and Brendon. He would not necessarily know that I had this information. In practice, we are the main repository of familial cancer information in the State, and Claude's doctor would probably call me. I could tell him non-identified information about the family and recommend that Claude be referred to our Service for genetic counselling and testing. But — as noted above — when a family has a limited number of affected people, it is impossible to avoid identifying the person with a familial mutation.⁵³

19.57 Under the *Privacy Act*, use or disclosure of health information for a secondary purpose by an organisation is permitted if the secondary purpose is directly related to the primary purpose of collection⁵⁴ and the individual would reasonably expect the organisation to use or disclose the information for the

51 G Suthers, *Submission G026*, 30 November 2001.

52 Ibid.

53 Ibid.

54 In the *Guidelines on Privacy in the Private Health Sector*, the Office of the Federal Privacy Commissioner has indicated that the Commissioner would consider a reasonable interpretation of 'primary purpose' in the health context to be the 'main and dominant reason' a health service provider collects information: Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), OFPC, Sydney, 12.

secondary purpose⁵⁵ or where the individual has consented to the use or disclosure.⁵⁶

19.58 The requirement that a secondary purpose be directly related and within the reasonable expectations of the individual appears to restrict the use or disclosure of genetic information collected from one patient in the diagnosis and treatment of another.

19.59 However, there seems no reason this cannot be addressed by routinely seeking consent from patients to the use or disclosure of their family genetic information for the diagnosis and treatment of other patients of the same clinic or hospital. Even broader consent could also be sought to the use or disclosure of family genetic information in the treatment or diagnosis of other family members, including to their treating doctors. Alternatively, in the situation described by Dr Suthers in the quote directly above, the clinic has the option of later seeking consent to a particular disclosure.

19.60 Dr Finlay Macrae, Head of Colorectal Medicine and Genetics at the Royal Melbourne Hospital raised related issues concerning the application of privacy legislation to the disclosure of family genetic information in the course of genetic counselling. He stated that genetic counselling is impeded by the need to ensure information on an accumulating pedigree is not shared with the family member being interviewed in case the already collected information includes information 'provided confidentially by others in the family'.⁵⁷

19.61 He noted that while, in theory, consent might be obtained for the disclosure of family genetic information to other family members

... there may still be information about other family live members provided indirectly for the pedigree, and the status of consent for this disclosure is never clear, and potentially could lead to privacy difficulties.⁵⁸

19.62 Dr Macrae observed that:

Working pedigrees rarely include, on the pedigree, the source of the information (except if death certified or cancer register retrieved), so the usual practice is not to disclose anything other than the immediate family to the person being interviewed. The full impact of the pedigree pattern of inheritance is not then pictorially available to the family member being interviewed, and this deprives the counsellor of one of his/her most cogent educational tools to promote surveillance in the family. Displaying an anonymous pedigree is possible, but leads to confusion for both the

55 *Privacy Act 1988* (Cth) NPP 2.1(a).

56 *Ibid* NPP 2.1(b).

57 F Macrae, *Submission G069*, 14 January 2002.

58 *Ibid*.

counsellor and the family member (potentially) as names act as anchors to understanding the pedigree to the naive witness.⁵⁹

19.63 He suggested that this constraint on the disclosure of genetic information hampers effective counselling and causes more ‘overall harm than good’.⁶⁰

19.64 For a variety of reasons, pedigrees contain information which may include personal information about relatives who have not consented to having their information recorded. These relatives may have died, not been approached for consent, or have denied consent to have the information collected or disclosed.

19.65 Some genetic services have developed detailed guidelines on how such information should be dealt with. The South Australian Clinical Genetics Service, Familial Cancer Registry has developed *Confidentiality and Consent Guidelines* that, among other things, provide guidelines on the recording and release of pedigree information. These distinguish between situations where the relative (to whom the information relates) has died, is alive and consent has yet to be sought, where consent has been sought but no response has yet been received and where consent has been denied.⁶¹ For example, the guidelines state that:

- Pending consent of a relative, identifying data may be recorded but not released to another party outside the Familial Cancer Registry and the Familial Cancer Unit; identifying data is not released to other services (eg laboratory services) of the SA Familial Cancer Service. Pending consent, confirmation of diagnoses may not be sought from other sources.
- Where consent has been denied, the following non-identifying data may be recorded on the database: gender, cancer diagnosis, and age at diagnosis. These data are not released to another party outside the Familial Cancer Registry and the Familial Cancer Unit.⁶²

Reform options

19.66 The proposals put forward in this Discussion Paper would ensure that organisations can continue to collect and retain family medical history information from the registrants on genetic registers without the consent of the genetic relatives. However, there may also be aspects of the use or disclosure of this information that require similar attention.

⁵⁹ Ibid.

⁶⁰ Ibid. Dr Macrae also noted that while the pedigree can be discussed with the patient (and verified against their own understanding) without the patient directly viewing the document, this ‘leads to an awkward interview where the counsellor is seen to be a controller of family information which “does not belong to him”’.

⁶¹ G Suthers, *Submission G026*, 30 November 2001.

⁶² Ibid. The SA guidelines note that where consent is denied identifying details (ie name, date of birth, and address) must be deleted from the person’s record in that family. However, ‘a record of these people must be kept so that we know not to bother them again’.

19.67 For example, one issue that may need to be dealt with is disclosure of pedigrees by medical practitioners to genetic registers, in order to assist in identifying individuals at risk. Another is that disclosing information about genetic relatives on a genetic register, even in ‘de-identified’ form, could breach NPP 2 of the *Privacy Act*. As noted above, information on a genetic register may not be truly de-identified even where identifiers, such as name and date of birth have been removed.

19.68 The Inquiry is interested in comments on what other or additional matters might usefully be dealt with as part of a PID on genetic registers.

Question 19–3. Should the proposed PID referred to in Proposal 19–1 also apply to the use or disclosure of health information recorded on genetic registers?

20. Genetic Counselling and Medical Education

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Introduction

Somebody told her she's not going to live forever and she's been preparing to die ever since.¹

20.1 When individuals receive genetic test information it may have profound medical and psychological implications for them. These implications will depend on the nature and context of genetic testing — the genetic condition being tested for and the reasons for testing. The results and implications of genetic testing will often be complex and difficult to understand. Some of the factors that create this complexity and uncertainty include the interaction between genes, the interplay between genetic and environmental causes of disease, different patterns of inheritance of genes, the degree of penetrance associated with particular genetic mutations, and the varying accuracy of genetic test results.²

20.2 For these reasons it is important that individuals are provided with appropriate information about a genetic test and, in some cases, assisted in decision making through genetic counselling.

¹ From the screenplay of A Niccol, *GATTACA* (1997), Columbia Pictures.

² For further information about these aspects of genetics and genetic testing, see Ch 4–6; Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Ch 2.

20.3 The provision of information about a genetic test and genetic counselling are not synonymous. Information-giving is primarily an educational process utilising printed and audiovisual resources or explanation by a health professional, or both. This can be contrasted with genetic counselling, which encompasses both information-giving and the discussion of the implications for the individual in a contextual framework that is unique for each person.³

20.4 This chapter discusses genetic counselling, the need for genetic counselling services, and issues related to its further development as a professional discipline. The chapter then examines the education and training of medical practitioners in clinical genetics, genetic counselling and related ethical issues.

Relevance to the Inquiry

20.5 The provision of appropriate information about genetic testing by medical practitioners to their patients and the provision of genetic counselling may have an important, albeit indirect, role to play in protecting genetic information from inappropriate discriminatory use and in promoting privacy protection and the ethical treatment of genetic information.

20.6 For example, inappropriate discriminatory use of genetic information may arise where an employer seeks to rely on genetic information in making its employment decisions without fully comprehending the health implications of the information. Such misconceptions may be corrected by the provision of more complete or nuanced information by a medical practitioner or genetic counsellor. Similarly, inappropriate disclosure (or non-disclosure) of genetic information to an individual's relatives may be minimised where patients are properly advised about the implications for others of their test results.

20.7 More generally, submissions and consultations have highlighted concerns about access to genetic counselling and that medical practitioners are not sufficiently knowledgeable about genetics and related ethical issues.

What is genetic counselling?

20.8 The Human Genetic Society of Australasia (HGSA) defines genetic counselling as a communication process that deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family.

3 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 30.

The process involves an attempt by one or more appropriately trained persons to help the individual or family (1) comprehend the medical facts including the diagnosis, the probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; (3) understand the options for dealing with the risk of recurrence; (4) choose the course of action which seems appropriate to them in view of their risk and family goals and act in accordance with that decision; and (5) make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.⁴

20.9 At present such counselling is generally performed within a clinical genetics centre or a specialist service such as a familial cancer service. To ensure the effectiveness of genetic counselling, a multi-disciplinary team of professionals work together, including a clinical geneticist and or appropriate medical specialist, genetic counsellor, social worker or other health worker, as appropriate.

Genetic counsellors

20.10 In Australia, genetic counsellors are tertiary trained health professionals with specialist training in genetics and counselling, certified by the HGSA to provide genetic counselling in conjunction with a clinical geneticist (a medical practitioner who has undertaken specialist training in clinical genetics). Genetic counselling itself is a relatively new discipline in Australia — the first genetic counsellor received certification from the HGSA in 1991.

20.11 To commence training as a genetic counsellor requires tertiary qualifications, generally in a related discipline such as nursing, science, social work or education. To become an HGSA certified genetic counsellor requires accredited qualifications in both genetics and counselling (Part I) and two years full time equivalent supervised practice (Part II). The HGSA has recommended that persons with Part I of the training, and who are working towards attaining Part II, should use the title Associate Genetic Counsellor. They also recommend that the title Genetic Counsellor should be used only after attainment of Part II of the Certification. The HGSA Board of Censors for Genetic Counselling has established a program for the maintenance of professional standards for certified genetic counsellors.⁵

20.12 There are an increasing number of persons who have attained Part I of the HGSA training but who are working in areas such as research and education. The Australasian Society of Genetic Counsellors (ASGC), a Special Interest Group of the HGSA, is discussing the use of the title of Genetic Associate for such persons.

4 Human Genetics Society of Australasia, *Guidelines for Human Genetics Society of Australasia (HGSA) Training and Certification in Genetic Counselling*, <<http://www.hgsa.com.au/policy/GTrainGenCoun.html>>, 28 June 2002.

5 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

Anticipating future need for genetic counselling

20.13 In a submission to the Inquiry, Dr Jennifer Kromberg of the Queensland Clinical Genetics Service remarked:

Genetic tests include prenatal tests, neonatal tests (eg. newborn screening), predictive and diagnostic tests. A large proportion of the population will require one or more of these tests sometime during their life. Physicians cannot meet the demand. Therefore if consent to testing is to be adequately informed properly trained Genetic Counsellors who are registered in a regulated profession must be available.⁶

20.14 As genetic medicine and testing technology develop, there will be an increasing need for genetic counselling and related services. This demand has been recognised by similar inquiries overseas. In Canada, the November 2001 report of the Ontario Provincial Advisory Committee on New Predictive Genetic Technologies noted that:

Since genetic testing often produces complex results, testing must be part of broader integrated multidisciplinary genetic services that incorporate genetic assessment and counselling, quality testing, psychosocial support and follow-up services, including surveillance, prevention and treatment. Every effort should be made to integrate genetic services into current health care.⁷

20.15 The Committee referred to the potential growth in the number and volume of genetic tests and their accompanying costs. The Committee made recommendations to increase recruitment and training capacity for genetic service health care providers.⁸

20.16 Resourcing of all aspects of genetic services in the United Kingdom is currently being looked at by the Department of Health, as it is expected that the increasing demand for genetic counselling will not be met by the current or projected resources.⁹

20.17 In Australia, submissions and consultations to the Inquiry have highlighted similar concerns about increasing demand for genetic counselling.¹⁰ Steps need to be taken now to plan for this increased need.

6 J Kromberg, *Submission G060*, 11 January 2002.

7 The Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (2001), Ministry of Health Ontario, Toronto, 7.

8 Ibid, 7, 56–60.

9 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 52.

10 *Confidential Submission G051CON*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Thyroid Australia Ltd, *Submission G020*, 28 November 2001; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002; *Confidential Submission G030CON*, 17 December 2001. See also S Metcalfe and others, 'Needs Assessment Study of Genetics Education for General Practitioners in Australia' (2002) 4 *Genetic Medicine* 71, 71–77.

20.18 The Commonwealth Department of Health and Ageing is currently working with States and Territories through the Australian Health Ministers' Advisory Council (AHMAC) on a number of issues relating to the provision of presymptomatic and diagnostic genetic testing.¹¹

20.19 In February 2002, the National Public Health Partnership established a Public Health Genetics Working Group.¹² Its terms of reference include identifying the opportunity for national approaches that promote and facilitate consistent policies for screening and genetic testing, the provision of accurate and timely information to health professionals and the general public, workforce and community education and understanding of human genetics and genetic testing. AHMAC or National Public Health Partnership working groups may be appropriate forums within which national approaches to the provision of genetic counselling services could be pursued.

20.20 The funding of genetic counselling services is a closely related issue that may also require close consideration. At present, genetic counselling is mainly provided within the state and territory public health system, for example, by genetic counsellors working in public hospital-based clinical genetics services. The Medicare Benefits Schedule does not cover genetic counselling by HGSA certified genetic counsellors. Some genetic counselling provided by medical practitioners may be covered by consultation fees.

Proposal 20–1. As a matter of priority, Commonwealth, state and territory governments should develop strategies to assess and respond to the need for more genetic counselling services throughout Australia.

Registration of genetic counsellors

20.21 Unlike medical practice, nursing or psychology, genetic counselling is not a registered health profession. There is, therefore, no equivalent of provisions in medical practice acts that make it an offence for persons who are not registered medical practitioners to claim or hold themselves out as medical practitioners.¹³ There is no prohibition on any person, however qualified, holding themselves out

11 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

12 The Working Group is chaired by the Commonwealth and has representation from all States, the Australian Institute of Health and Welfare, the HGSA, the Consumers' Health Forum and the Medical Services Advisory Committee. See National Public Health Partnership, *Public Health Genetics Working Group*, Department of Human Services (Victoria), <<http://www.dhs.vic.gov.au/nphp/genetics/index.htm>> 2 July 2002.

13 See eg *Medical Practice Act 1992* (NSW) s 105; *Medical Practice Act 1994* (Vic) s 62.

as a genetic counsellor or offering genetic counselling services.¹⁴ There are no formal sanctions for breach of ethical or professional standards in genetic counselling.¹⁵

20.22 Some submissions have suggested that genetic counselling should be a registered health profession.¹⁶ Associate Professor John MacMillan of the Queensland Clinical Genetics Service submitted that:

Regulation of genetic testing to the public hospital and public health care systems offers the opportunity to ensure it is appropriately available to all who need it and that full informed consent is obtained by an appropriately trained health professional. I believe that such individuals should be part of a profession whose practice is governed by a licensing process or registration board. This would require that Genetic Counsellors (who are not medically trained) become registered with the Professional Registration Boards in each state under an appropriate system. These professionals would also be required to have professional indemnity insurance. Failure to regulate this 'new profession' could have serious adverse consequences for patients and families through the provision of misleading or incorrect information concerning the results and interpretation of genetic tests.¹⁷

20.23 Dr Kromberg stated that the public needs to have access to expert genetic counsellors, but it also needs to be protected against untrained people who may set themselves up as genetic counsellors.

Genetic Counsellors are being trained at post-graduate level to provide Genetic Counselling services in Australia. However they are not yet recognised as a health profession and professional recognition and regulation are essential. Such regulation would contribute to the progression and much needed expansion of the profession, protect the public, and lead to the development of a standardised, high quality and ethical service.¹⁸

20.24 As noted above the HGSA has recommended that only those who have attained certification should use the title of Genetic Counsellor. Kromberg noted that, in the United Kingdom, the Association of Genetic Nurses and Counsellors is pursuing statutory registration of genetic counsellors through the Health Professions Council.¹⁹ The Health Professions Council is a new independent regulatory body responsible for setting and maintaining standards of professional training, performance and conduct of the 12 health care professions that it

14 Subject, for example, to the provisions of trade practice legislation, which prohibits misleading or deceptive conduct in trade or commerce: *Trade Practices Act 1974* (Cth) s 52; *Fair Trading Act 1987* (NSW) s 42; *Fair Trading Act 1999* (Vic) s 9 and cognate legislation in other States and Territories.

15 However, as some genetic counsellors are registered health professionals, such as nurses or psychologists, unethical conduct as a genetic counsellor may have consequences under the regulatory frameworks applying to those registered health professions.

16 J Kromberg, *Submission G060*, 11 January 2002; J MacMillan, *Submission G015*, 19 November 2001.

17 J MacMillan, *Submission G015*, 19 November 2001.

18 J Kromberg, *Submission G060*, 11 January 2002.

19 Ibid. See also Association of Genetic Nurses and Counsellors, *Registration*, <www.agnc.co.uk/registration.htm>, 23 July 2002.

regulates. The Council also ensures that registration of professionals is linked to continual professional development.²⁰

20.25 The primary purpose of the registration of health professionals is said to be to protect the public.²¹ The public interest is protected through the powers granted to health registration boards to recognise qualifications and assess the character of persons seeking registration, to discipline health professionals found guilty of unprofessional conduct, and to suspend or place conditions upon those whose capacity to practice is impaired.²²

20.26 As at May 2001, all Australian jurisdictions regulated doctors, nurses, dentists, optometrists, physiotherapists, pharmacists, chiropractors and psychologists. However, only some jurisdictions register other health professions such as dental technicians, osteopaths, occupational therapists, radiographers and aboriginal health workers.²³

20.27 Regulation of health professions has important competition policy implications. The National Competition Council has noted that overly restrictive or anti-competitive regulation can impose major and unnecessary costs on consumers and may contribute to the severe shortages of many health professionals, particularly in rural and regional Australia.²⁴

20.28 At present the Inquiry has no concluded view on whether a new registration Act for genetic counsellors is desirable. However, Commonwealth, state and territory governments should closely examine all options for the further development of genetic counselling as a health profession.

Proposal 20–2. Commonwealth, state and territory governments should examine options for the further development of genetic counselling as a recognised health profession, including the possibility of a registration system for certified genetic counsellors.

20 Health Professions Council, *About Us*, <http://www.hpcuk.org/docs/about_us.htm>, 2 July 2002. The HPC is the successor body to the Council for Professions Supplementary to Medicine, established under the *Professions Supplementary to Medicine Act 1960* (UK).

21 See K Breen, V Plueckhahn and S Cordner, *Ethics, Law and Medical Practice* (1997) Allen & Unwin, Sydney, 77.

22 Ibid, 77.

23 R Deighton-Smith, B Harris and K Pearson, *Reforming the Regulation of the Professions National Competition Council Staff Discussion Paper*, (2001) National Competition Council, 4.

24 National Competition Council, *Reform of the Health Care Professions*, Community Information Brochure, 2000.

The delivery of genetic counselling

20.29 The Inquiry received a range of comments relevant to the delivery of genetic counselling services. These comments highlighted the importance of recognising that the need for genetic counselling will vary depending on the particular genetic test involved and the context of testing.

20.30 Genetic counselling may be required both before and after predictive or presymptomatic tests,²⁵ following a positive genetic carrier test, and following an abnormal result on a prenatal diagnostic or screening test.²⁶ However, where the testing is purely diagnostic, the provision of appropriate information prior to testing may be sufficient.²⁷ If the result is positive, discussion of implications for relatives is essential. Some predictive tests may need skilled multi-disciplinary teams to deal with different aspects of the patient's medical and social care.²⁸ For example, internationally accepted protocols for presymptomatic testing for Huntington's disease (HD) include provision of psychosocial support.

20.31 Madelyn Peterson and Dr Jennifer Kromberg noted that, while Queensland Health currently funds the provision of psychosocial support in Huntington's disease testing, funding is not available to support individuals referred for predictive tests for other adult-onset neurodegenerative diseases or familial cancers, which raise similar psychosocial issues. They noted, for example, that genetic testing for familial cancer genes 'generates potentially life-altering information about self, whether the result is positive or negative'. Such genetic tests will potentially necessitate decisions about prophylactic surgery, chemoprevention trials, dietary and other health modifications, additional medical surveillance and insurance or privacy issues.²⁹

25 As discussed in Ch 4, predictive testing is also called presymptomatic testing where an individual's family medical history suggests that he or she may have the genetic disorder but symptoms of it are not yet manifest.

26 HGSA guidelines state that the reasons a person may seek genetic counselling include: concerns regarding a disorder which runs in a family or a partner's family; having had a previous child with a disorder; concerns regarding individuals in the family who have unusual features or multiple malformations; a woman in her mid-30's or older who is either planning a pregnancy or is already pregnant; intending parents are close relatives; potential teratogen exposure; history of stillbirth or recurrent abortion; detection of carrier status for a mutation (eg cystic fibrosis, Duchenne muscular dystrophy, fragile X); prenatal diagnosis for a known problem; unexpected detection of a foetal abnormality during pregnancy: Human Genetics Society of Australasia, *Guidelines for Human Genetics Society of Australasia (HGSA) Training and Certification in Genetic Counselling*, <<http://www.hgsa.com.au/policy/GTrainGenCoun.html>>, 28 June 2002, 1.

27 See National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 30.

28 A multidisciplinary team is the ideal for a comprehensive Human Genetics Service: J Kromberg, *Submission G060*, 11 January 2002.

29 M Peterson and J Kromberg, *Submission G108*, 19 February 2002.

20.32 Other genetic testing has fewer or less complex implications for the individuals tested and their families. Even some predictive testing, where the penetrance of the gene is low, may be considered analogous to other tests used in clinical practice, such as the measurement of blood pressure or serum cholesterol,³⁰ and may not necessitate counselling.

Access to medical genetic testing and counselling

20.33 While genetic testing for medical purposes usually requires a referral from a medical practitioner,³¹ there are currently no uniform protocols regarding such referral.³² At least where there is no centralised clinical genetics service, protocols for dealing with referrals may vary between laboratories. Some laboratories may place more emphasis than others on ensuring that testing is linked with access to genetic counselling, or provide more interpretative information about genetic test results than others.

20.34 Where there is no established protocol to ensure that best practice has been followed, and where the request for a predictive test has not been received from a clinical genetics service, the laboratory may have to act as a 'gatekeeper'. In this role the laboratory may have to assess whether the requesting medical practitioner has understood the need for the provision of information or counselling prior to testing. If not, the laboratory may have to discuss the matter with the practitioner or even decline to provide testing.

20.35 The absence of clear protocols on access to genetic testing services through health professionals may leave open the possibility for genetic testing in inappropriate circumstances. For example, the Australian Huntington's Disease Association (NSW) Inc expressed concern that some people at risk for Huntington's disease

undergo presymptomatic testing without accessing a recognised genetics service and therefore can have the predictive test for HD without the comprehensive support and expertise of a genetic counsellor and geneticist.³³

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- 30 R Zimmern and C Cook, *The Nuffield Trust Genetics Scenario Project: Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), The Stationery Office, London, 53.
 - 31 National Pathology Accreditation Advisory Council, *Standards for Pathology Laboratories* (1998), Commonwealth of Australia, Canberra, Standard 5 – Specimens: see <<http://www.health.gov.au/npaac/docs/stanplab.htm>> (12 July 2002).
 - 32 However, the Inquiry understands that, in general, laboratories do not accept requests from general practitioners for sensitive types of genetic tests without referral to a genetic counsellor and clinical geneticist. Further, the HGSA has produced a range of policies and guidance notes relevant to requests for genetic testing: Human Genetics Society of Australasia, *HGSA Policies*, <<http://www.hgsa.com.au>>, 23 July 2002.
 - 33 Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002.

20.36 A related concern is that medical practitioners may not make appropriate referrals for genetic counselling.³⁴ One genetic counsellor suggested that systems for referral to genetic counselling may need to be developed so that requests for certain types of genetic test automatically generate a referral to appropriate genetic counselling.³⁵

20.37 It would be inappropriate to apply the same protocols to all types of genetic testing for medical purposes. The importance of recognising the different implications of various types of genetic tests was often noted in consultations. For example, it was stated that, while ‘testing for cystic fibrosis to confirm a diagnosis is just another test, testing someone at 18 for Huntington’s disease has enormous significance’.³⁶

20.38 Although some submissions suggested that the ability to order genetic tests for medical purposes should be limited to certain categories of medical practitioner,³⁷ this approach was generally rejected. For example, the Department of Health and Ageing stated:

Beyond the general need to ensure privacy and competency in the use of genetic tests, the Department cautions against the imposition of a blanket ‘one-size fits all approach to attempting to specify in detail the competency requirements for ordering, interpreting or otherwise using genetic tests. Genetic tests are used for a variety of purposes, e.g., diagnosis of a high-penetrance disorder versus general screening for a disease indicator, and their results are accepted to varying degrees in clinical practice. In addition, some tests are used rarely while others are performed routinely, further confounding the need for competency requirements and the nature of tests they should apply to. The Department’s view is that advice and policy development on this is required and would appropriately be a matter for the AHMAC advisory group on genetic testing.

20.39 The HGSA was critical of the current level of genetics understanding in the medical profession, but stopped short of recommending restrictions on the ability of medical practitioners to order genetic tests.

At present, most health professionals do not have the expertise to interpret the results of many genetic tests, whether done for diagnosis, carrier detection or predictive testing. This situation is not unique to genetic tests and applies in other specialised areas of medicine. It would be inappropriate to restrict the ability of health professionals to order diagnostic, carrier or prenatal genetic tests.³⁸

34 Association of Genetic Support Australasia Inc, *Consultation*, Sydney, 11 February 2002; Genetic Support Network of Victoria, *Consultation*, Melbourne, 18 March 2002.

35 Genetic Counsellor, *Consultation*, Townsville, 3 April 2002.

36 Advisory Committee members, *Advisory Committee meeting*, 29 November 2001.

37 Eg the Neurofibromatosis Association of Australia submitted that ‘In our opinion medical practitioners should be required to undergo specific training before being able to order genetic testing or interpret the results for patients. In the ideal situation, only medically trained clinical geneticists should be authorised to order such tests and interpret their results’: Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

38 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

Classification of genetic tests

20.40 One option would be to develop a scheme for classifying genetic tests, or categories of genetic tests, in order to provide an enhanced level of oversight for ordering sensitive tests and to ensure prior access to genetic counselling. For example, it might be considered appropriate to develop protocols so that predictive testing of late onset neurological disorders (such as Huntington's disease) can only be ordered by, or in collaboration with, a clinical genetics service.

20.41 The development of such a classification scheme has been examined in the United States by the Secretary's Advisory Committee on Genetic Testing (SACGT).³⁹ The SACGT developed a classification proposal that was subjected to pilot testing and public consultation. After considerable internal and public review the SACGT concluded that 'fundamental, irresolvable questions had been raised about the feasibility of categorising tests for oversight purposes based on a limited set of elements in a simple, linear fashion'.⁴⁰

20.42 Despite the possible practical difficulties, the Inquiry proposes further development of genetic testing and counselling practice guidelines by the proposed Human Genetics Commission of Australia (HGCA), in consultation with the HGSA, state clinical genetics services, and other interested organisations. Such guidelines could provide, for example, that certain types of genetic test may be ordered only where genetic counselling has been provided, or by medical practitioners with specific qualifications, or both. Guidelines could also emphasise the importance of using skilled multidisciplinary teams in the management of some genetic conditions.

Proposal 20–3. The proposed HGCA should develop genetic testing and counselling practice guidelines, in consultation with the Human Genetics Society of Australasia, state clinical genetics services, and other interested organisations. These guidelines should identify genetic tests, or categories of genetic tests, that require special treatment in relation to procedures for ordering testing and ensuring access to genetic counselling. (See Proposal 3–3).

39 See Secretary's Advisory Committee on Genetic Testing, *Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT* (2000), National Institutes of Health, Baltimore; Secretary's Advisory Committee on Genetic Testing, *Development of a Classification Methodology for Genetic Tests: Conclusions and Recommendations of the Secretary's Advisory Committee on Genetic Testing* (2001), National Institutes of Health, Bethesda.

40 Secretary's Advisory Committee on Genetic Testing, *Development of a Classification Methodology for Genetic Tests: Conclusions and Recommendations of the Secretary's Advisory Committee on Genetic Testing* (2001), National Institutes of Health, Bethesda.

Genetics education and training

20.43 The appropriateness of decisions to order genetic testing or counselling ultimately depends on the level of training and degree of understanding that the referring practitioner has about genetics. Submissions and consultations have highlighted concerns that medical practitioners, including some specialists, are not sufficiently knowledgeable about ordering genetic tests, interpreting the results of genetic tests, and providing or facilitating the provision of appropriate genetic counselling for patients.⁴¹

20.44 The Commonwealth Department of Health and Ageing stated that there is a need to better educate health professionals about both the ethical and scientific principles involved in genetic testing and information.⁴² In relation to general practitioners, the Department noted that a needs assessment among Victorian general practitioners had found that

current knowledge of genetics among general practitioners is poor and that education and training is needed in technical, clinical and counselling aspects of genetic testing as well as ethical and privacy of information issues.⁴³

20.45 The Medical Practitioners Board of Victoria submitted that there is clearly a need to educate health professionals better about the ethical principles involved in genetic testing and information, given the rapid developments in this area. The Board noted that many doctors, especially older practitioners, are likely to be insufficiently informed in this area.⁴⁴

20.46 The New South Wales Genetics Service Advisory Committee noted that, without additional training, some medical practitioners may have difficulties in interpreting the results of some complex predictive genetic tests and in providing appropriate counselling and support.⁴⁵ Similarly, the HGSA submitted that there is insufficient understanding in the medical profession, outside specialised genetics services, of the wider implications of genetic testing.⁴⁶

41 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; *Confidential Submission G051CON*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Thyroid Australia Ltd, *Submission G020*, 28 November 2001; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002; *Confidential Submission G030CON*, 17 December 2001; F Richards, *Submission G044*, 14 January 2002; Medical Practitioners Board of Victoria, *Submission G155*, 10 April 2002; N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

42 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

43 Ibid; S Metcalfe and others, 'Needs Assessment Study of Genetics Education for General Practitioners in Australia' (2002) 4 *Genetic Medicine* 71 71–77. The needs assessment was undertaken as part of a project to develop a pilot resource for genetics education: See Royal Australian College of General Practitioners, *The Genetics File*, <www.racgp.org.au>, 2 July 2002.

44 Medical Practitioners Board of Victoria, *Submission G155*, 10 April 2002.

45 New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002.

46 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

There is a need to improve health professionals' understanding of the ethical principles involved in predictive testing of currently healthy individuals for later onset disorders, and of the practical consequences that flow from those principles in terms of information giving, counselling and support.⁴⁷

20.47 Submissions from genetic support groups also raised questions about the genetics knowledge of medical practitioners in specific contexts.⁴⁸ Thyroid Australia Ltd submitted that:

After dealing with close to 2,000 thyroid patients nationwide, we find that many doctors (particularly general practitioners) quite commonly do not test thyroid patients (especially those suffering from hypothyroidism) for antibodies, and these patients are therefore blissfully unaware of the genetic implications of their conditions and believe that they can be 'cured'. They are also unaware of the risks other members of their families face in developing autoimmune thyroid conditions or other autoimmune conditions. This, I believe, is a sad state of affairs. We frequently are faced with the dilemma of telling people that their thyroid problems are probably genetic in nature, suggesting to them that they contact their doctors for the necessary antibody tests to verify this. I believe it is not the role of a support group to perform this function, but that it falls to doctors to do so.⁴⁹

20.48 The Association of Genetic Support of Australasia (AGSA) had similar concerns and submitted that medical practitioners need to increase their genetic knowledge base.⁵⁰ The results of a member survey conducted by the Neurofibromatosis Association of Australia led it to conclude that

there is a need for the better education of health professionals into the full implications of genetic testing and the information generated by it. This needs to extend to education on the impact on the whole family (including extended family), not just the person being tested.⁵¹

20.49 Submissions also noted that medical practitioners may be insufficiently aware of relevant resources available to patients affected by genetic conditions, including genetic counselling, clinical genetics services and genetic support groups.⁵² One submission from a patient noted that following diagnosis by her general practitioner

there was no time for counselling about the implications [of the genetic condition] or how to discuss this with family members, implications re life insurance etc. There was no mention of the State's Clinical Genetics Service. The GP is very thorough in general and there has been no other cause for complaint at all.⁵³

47 Ibid.

48 Thyroid Australia Ltd, *Submission G020*, 28 November 2001; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

49 Thyroid Australia Ltd, *Submission G020*, 28 November 2001.

50 Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

51 Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002.

52 *Confidential Submission G030CON*, 17 December 2001; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

53 *Confidential Submission G030CON*, 17 December 2001.

20.50 The submission from AGSA highlighted the important role of genetic support groups and that more medical practitioners need to be aware of this role.

After diagnosis of a genetic condition, we believe it is important that the family is referred to AGSA or a similar genetic support group. We believe we are the 'third arm' of genetic services – which is just as vital. AGSA provides the essential information to families on what to expect – day-to-day, from families coping with the same condition. ... AGSA has received feedback from many people who have never been referred to us, and have found out about our services through their own research. AGSA is often asked "where have you been?" and "why has nobody ever told us about you?"⁵⁴

20.51 Submissions were consistent in suggesting that the main focus of additional genetics education and training for medical practitioners should be on developing the ability to recognise the complex implications of genetic testing and the consequent need for specialised advice and counselling, rather than on skilling up medical practitioners to provide genetic counselling services themselves. For example, Fiona Richards stated:

I believe that, with regard to presymptomatic testing for HD and similar disorders, it is not appropriate or necessary for medical practitioners to gain '...increasing...skill in providing counselling related to genetic tests' as highly trained and experienced genetics professionals already exist for this purpose. Medical practitioners do, however, need to become better informed about the ethical principles involved in genetic testing and information and the consequent importance of referring to specialised genetics services.⁵⁵

20.52 Similarly, AGSA stated that:

The emphasis should be on training medical practitioners to be able to refer patients to the appropriate existing services and support groups for genetic counselling and testing. It is impossible to educate all medical practitioners because of the speed with which genetic knowledge is changing. It is more appropriate for them to be trained in the correct referral procedure to the appropriate health professional and support group.⁵⁶

20.53 The Medical Practitioners Board of Victoria stated that medical practitioners need to be 'aware of the limits of their knowledge in interpreting test results' and noted that the Board may be able to assist by informing them about genetic counselling resources through its publications.⁵⁷

54 Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

55 F Richards, *Submission G044*, 14 January 2002.

56 Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

57 Medical Practitioners Board of Victoria, *Submission G155*, 10 April 2002.

Implementing new education and training programs

20.54 In the course of the Inquiry, a broad consensus has emerged suggesting that the answer to many of the concerns raised by new and future uses of genetic information lies in education. In relation to medical practitioners specifically, the Inquiry received many comments about the need for additional education and training programs relating to clinical genetics and ethics.

20.55 The Department of Health and Ageing submitted that, to address general practitioner education and training needs nationally

it would be necessary to further develop education and training resources for general practitioners to access voluntarily as part of their quality assurance and continuing professional development requirements. An increased emphasis on genetics education in both the undergraduate medical curriculum and in postgraduate training programs would also be required.⁵⁸

20.56 Professor Nick Saunders and Associate Professor Paul Komesaroff submitted that training of health professionals in ethics, the implications and uses of genetic testing and genetic counselling should be an integral part of all undergraduate courses and vocational education programs, and should be an important focus for continuing education programs.⁵⁹

20.57 The HGSA agreed that 'the problem of an inadequately skilled workforce' needs to be addressed by undergraduate and postgraduate education. The HGSA also referred to the need for laboratories to provide interpretation of test results in their reports, as well as the need for consultation between those who order a test and health professionals who can interpret the results properly.⁶⁰

20.58 The need to address genetics education has been recognised in inquiries overseas. For example, the Ontario Provincial Advisory Committee on New Predictive Genetic Technologies noted that:

Until recently, much of the practice of genetics involved diagnosing rare inherited disorders, estimating risk for family members, and providing prenatal diagnosis. There was little need for most health care providers to have any more than a rudimentary knowledge of genetics. Now, there is an urgent need for the Ministries of Education and of Colleges and Universities to review the curricula of secondary and post-secondary schools and incorporate core genetic issues.⁶¹

58 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

59 N Saunders and P Komesaroff, *Submission G084*, 9 January 2002.

60 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

61 The Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (2001), Ministry of Health Ontario, Toronto, 7.

20.59 In Australia, the bodies responsible for undergraduate medical education include the Australian Medical Council (AMC) and the Committee of Deans of Australian Medical Schools (CDAM). The functions of the AMC include review and accreditation of courses conducted by medical schools in Australia and New Zealand leading to basic medical degrees.⁶² Sufficient coverage of genetics could be included as a standard for accreditation.

20.60 From 2002, the AMC will be responsible, with the support of the specialist medical colleges, for the accreditation of programs of postgraduate (specialist) medical education and training and continuing professional development programs.⁶³ In relation to continuing medical education, the Australian Medical Association (AMA) submitted that:

responsibility for improving the knowledge of medical practitioners in this rapidly expanding area lies with the Colleges. They should be encouraged to give this area high priority in their educational activities.⁶⁴

20.61 The Committee of Presidents of Medical Colleges (CPMC) provides a forum for interaction between the Colleges and the AMC, CDAM and the AMA, including on issues concerning educational standards and professional training. The CPMC provides advice to government departments and health ministers on request.

20.62 The Inquiry is of the view that attention to the further development of genetics education is required across all phases of professional medical education. The proposed HGCA should also play a role in working with the relevant groups to design or enhance education and training programs aimed at improving the provision of genetic health services by medical practitioners and other health professionals.

20.63 The issues involved in developing appropriate genetics education and training programs are complex. For example, while some submissions focused on the need for specialised advice and counselling, some genetic conditions can and should be handled by general practitioners. The reasons for this include that genetic conditions, or clinical disorders with some form of genetic component, will become more common and it would therefore be counterproductive to duplicate the present medical establishment by expecting genetic counsellors to deal with all these conditions. Genetic counsellors cannot be expected to have detailed knowledge of the clinical implications of many genetic conditions. Most clinical

62 The AMC is a national standards body for medical education established by Commonwealth and State Health Ministers. Its other functions include: examination of overseas trained doctors for general (non-specialist) registration; advice to State and Territory Medical Boards on uniform approaches to the registration of medical practitioners; advice to Commonwealth and State Health Ministers on matters relating to the registration of doctors: Australian Medical Council, *Submission G065*, 15 January 2002.

63 Ibid.

64 Australian Medical Association, *Submission G091*, 29 January 2002.

geneticists and genetic counsellors deal with a full range of clinical disorders and there may be a risk of inappropriate counselling because of a lack of knowledge about the clinical condition.⁶⁵

20.64 Among the approaches to education and training that should be examined are programs to assist medical practitioners in identifying the genetic conditions that should be referred to specialist genetics clinics and programs by which medical practitioners may enhance their knowledge and skills in genetics and genetic counselling.⁶⁶

Proposal 20–4. The Australian Medical Council and the Committee of Deans of Australian Medical Schools should pursue measures to enhance medical school programs in clinical genetics, genetic counselling and related ethical issues.

Proposal 20–5. The Australian Medical Council and the Committee of Presidents of Medical Colleges should pursue measures to enhance postgraduate training and continuing professional development programs for medical practitioners, whether general practitioners or specialists.

Proposal 20–6. The proposed HGCA should play a role in working with the relevant groups to design and enhance education and training programs aimed at improving genetic health services provided by medical practitioners and other health professionals. (See Proposal 3–2).

65 R Trent, *Correspondence*, 20 July 2002.

66 *Ibid.*

21. Population Genetic Screening

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What is population genetic screening?

21.1 Population genetic screening involves testing large numbers of people for their genetic status in relation to a particular gene or condition. As discussed in Chapter 4, screening tests are performed on individuals not necessarily known to have an increased risk of a particular genetic condition.¹

21.2 Population genetic screening programs take a number of forms, which differ in both scope and objectives. They include:

- Selective screening programs (also known as ‘cascade screening’) — targeting individuals within the community who may be at increased risk for a genetic disorder. The screening identifies whether the individual has the genetic trait for the disorder.
- Epidemiological surveys — involving mass screening approaches to determine the prevalence and incidence of a particular disorder in the community.

¹ See Ch 4.

- Mass screening programs — involving the testing of entire population groups, in order to identify a condition or conditions suitable for treatment or prevention.²

21.3 A variety of screening programs are currently being conducted in Australia, including newborn screening programs in all States and Territories, and screening programs being carried out in schools and workplaces.

Examples of population screening programs

21.4 A number of screening programs currently being undertaken in Australia were outlined in detail in the Issues Paper.³ These are only briefly summarised here:

- Genetic screening of newborns — newborns are screened for a number of genetic conditions including Phenylketonuria (PKU) and cystic fibrosis. Tests are carried out by taking a small sample of blood via a heel-prick, and the blood is stored on blotting paper cards.⁴ Screening is administered by state or territory health service providers and cards are stored for varying periods of time.⁵ Cards are retained for a number of reasons, including public health research, screening program audit, modification of existing tests and assistance in coronial and forensic investigations.⁶
- Genetic screening programs in schools — students at a number of private Jewish schools in Sydney are taking part in a voluntary, privately funded program screening for carrier status of Tay-Sachs disease. Students are educated about the implications of carrier status and about the disease in general. The program employs a gene trustee who will hold results until the student requests them.⁷
- HaemScreen — HaemScreen is a program conducted by the Murdoch Childrens Research Institute in a number of Melbourne workplaces. Participants voluntarily agree to be tested for predisposition to

2 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 193.

3 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 9.12–9.34.

4 See Ch 16.

5 Two years in Western Australia and indefinitely in most other states and territories. Human Genetics Society of Australasia, *Draft Policy Statement on the Retention, Storage and Use of Sample Cards for Newborn Screening Programs*, <<http://www.hgsa.com.au/policy>>, 7 June 2001.

6 Ibid.

7 This system has been discussed in Ch 15.

haemochromatosis, a treatable condition. Individuals are contacted by telephone where they have tested positive for the predisposition.⁸

Benefits of population genetic screening

21.5 Some genetic conditions can be treated more effectively if they are diagnosed early. An example is Duchenne Muscular Dystrophy (DMD), a genetic disorder that causes muscle wasting in boys. Symptoms first appear at age two or three and become progressively worse, eventually affecting the child's movement, breathing and cardiac function. The disorder is generally not detected until symptoms are noticed unless there is a history of the condition in the affected child's family. The disorder can, however, be detected immediately after birth by screening dried blood spots for high levels of a specific muscle enzyme known as creatine kinase.⁹

21.6 Pre-emptive measures can be taken to slow the development of the disorder and its symptoms, including range-of-motion exercises to postpone contractures and catabolic steroids and calcium supplements to slow deterioration of muscles and bones. The earlier these measures are taken the more effective they are likely to be. DMD is not screened for in Australia at present, however other countries such as Germany do carry out newborn screening to detect the condition.¹⁰

21.7 Other disorders have the potential to cause irreversible damage, but if diagnosed early this can be completely avoided. PKU is currently one of the conditions for which almost all Australian newborns are screened. Newborns affected by PKU are unable to break down the amino acid phenylalanine. Untreated, the disorder causes significant brain damage within months, as levels of phenylalanine increase and cause damage to neural tissues. Detection allows newborns to be placed on a special diet that will prevent brain damage and ensure normal development.

21.8 Screening programs can detect conditions like DMD and PKU before symptoms appear and in some cases before permanent damage has occurred, allowing for treatment to begin as soon as possible. Screening can also give parents an accurate explanation for their child's condition early on, as it may take some time for the correct diagnosis to be made without the test. As one parent of a child with DMD noted in her submission to the Inquiry, had she known the reason for his symptoms:

8 Dr Martin Delatycki, Murdoch Children's Research Institute, *Communication*, 27 August 2001. See also Murdoch Children's Research Institute and Genetic Health Services Victoria, 'Gene Test to Prevent Common Disease', *Press Release*, 10 September 2001.

9 D Robins, *Submission G154*, 10 April 2002.

10 Ibid.

I could have done more for him, had I known. We would never have labelled him lazy or a dreamer. We could have started steroid treatment and other therapies earlier and to the best advantage. More importantly, he could have had a name for his difference and understood the weakness he felt.¹¹

21.9 Where symptoms of an inheritable disorder are usually not detected until some time after birth, screening programs can also help prevent families from bearing more children who will have the disorder. DMD is an example of such a disorder, as the symptoms may not be correctly diagnosed for some years, and hence no genetic test will be performed until that point.

21.10 Screening can provide parents with information that may then inform their future reproductive decisions. As this may influence parents to refrain from bearing more children who will have a genetic disorder, screening programs can work to decrease the incidences of those disorders in the population.

21.11 Part of the rationale behind HaemScreen is to target a section of the population (18–35 year olds) that is less likely to visit their doctor and take a genetic test for predisposition to the condition. Screening programs for adults may inform a larger proportion of the community that they have a condition, and this in turn may enable them to make health decisions that may slow or cure the condition.

Issues arising from population screening programs

Privacy

21.12 Like other types of genetic testing, screening for genetic conditions generates information about an individual's genetic status. People may wish to keep their genetic status private, and may be concerned that screening programs will lead to others being informed that they have a genetic condition. This may include other family members, employers, and insurance companies. In contrast, one submission argued that privacy concerns 'should not be used as a pretext not to screen the population for [a] disorder' where there are effective treatments available.¹²

21.13 In the course of screening, genetic samples will be obtained from participants. These must also be maintained in a secure environment to ensure privacy of individuals is protected. In general, genetic samples are not covered by information and health privacy legislation, except in New South Wales.¹³

11 Ibid.

12 C Maurer, *Submission G113*, 18 March 2002.

13 *Privacy and Personal Information Protection Act 1998* (NSW) s 4.

Consent to testing

21.14 Individuals should not be subjected to genetic testing without their consent, once they are of an age where they are able to give that consent. Consent should be obtained after full information has been provided. The Office of the Federal Privacy Commissioner (OFPC) submitted that the need for participation in population screening programs to be voluntary and informed was critical, despite the benefits such programs produce.¹⁴

21.15 In the specific context of population genetic screening, the particular consent issue may be whether consent was fully voluntary and informed. Consent for newborn screening is often obtained during labour or shortly afterwards, as testing is performed soon after birth. While mothers are provided with information leaflets by hospital authorities, there is no check to test that they have read and understood them. Their consent is obtained during a period of great stress when they are likely distracted by pain and the fact of the birth itself. It has been doubted whether this constitutes proper consent.¹⁵

21.16 Elizabeth Thompson, a registered nurse speaking at the 1st International Conference on DNA Sampling and Banking said that this form of consent has been referred to as 'uninformed dissent'. She reported that many women often do not understand what they are consenting to when they agree to their newborn being given a heel-prick test. She asserted that 'most of them don't get it ... [t]hey don't even remember it when they give consent during childbirth'.¹⁶ Similarly, Professor Loane Skene has asserted that the process of obtaining consent to newborn testing in Australia is more akin to 'informed refusal' than 'informed consent'.¹⁷

21.17 One suggestion is that consent to the heel-prick itself should continue to be obtained during or just after childbirth. However, consent to testing of the sample and to the storage of the sample and results should be sought a few days after birth. Full information should be provided at this point and the mother should be given the opportunity to withhold consent to testing and storage.

21.18 With other screening programs, participants should be made fully aware of the implications of their involvement. This would include being informed that they will be required to reveal the results of the screening test to insurers, and being made cognisant of the emotional effects of the possible test results. In general, the OFPC submitted that there was

14 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

15 L. Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 138.

16 Quoted in J Lyttle, 'Is Informed Consent Possible in the Rapidly Evolving World of DNA Sampling?' (1997) 156(2) *Canadian Medical Association Journal* 257, 258.

17 L. Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 138.

a need for greater education and counselling to enable those individuals involved in screening programs to understand the implications of their participation.¹⁸

21.19 The OFPC asserted that funding of such education and counselling should be considered by the government.¹⁹

Provision of counselling

21.20 Genetic testing can yield information that is distressing to the recipient, whether they are the parent of an affected child or are themselves the subject of the test. Given this, adequate counselling should be made available both before screening and after the receipt of test results.

Costs to health care system

21.21 While population screening programs can produce the long-term benefit of reducing disease, they may over-burden health care systems in the short-term. This may occur where individuals are identified as suffering from a condition that the health care system is not fully prepared to cope with at that time. For example, the cost of treating the condition that has been identified may not have been budgeted for or there may not be the counselling services in place to deal with the needs of recently diagnosed sufferers.

Reliability of results

21.22 Genetic tests performed as part of a screening program must produce reliable and accurate results. Where this is not the case, screening may cause unnecessary trauma and inconvenience if individuals are supplied with incorrect information about their genetic status. Lack of reliability will also render any population health information generated by the program scientifically unsound.²⁰ It is possible, then, that participants in a screening program may receive inaccurate information about their health status.

21.23 The need for reliability of tests was highlighted in the submission from the Human Genetics Society of Australasia (HGSA), which stated that new tests for use in the public health arena 'should be assessed for utility, sensitivity, specificity and likelihood of facilitating the desired outcome'. The HGSA states that assessment should continue throughout the early stages of the implementation of a screening program as well to ensure these desired outcomes are being met.²¹

18 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

19 Ibid.

20 For example, the reliability of current tests use to detect haemochromatosis has been queried: E Beutler and others, 'Penetrance of 845G-A (C282Y) HFE Hereditary Haemochromatosis Mutation in the USA' (2002) 359 *Lancet* 211.

21 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

Question 21–1. Should tests used in population genetic screening programs be required to meet an agreed standard for reliability, sensitivity and utility? If so, should the proposed HGCA play a role in such regulation?

Implications for insurance

21.24 An individual has a duty to disclose the results of any genetic test they are or should be aware of where the result is relevant to the insurance risk, including results discovered in the course of population screening.²² This duty is discussed in more detail in Chapter 23 in relation to the obligations of disclosure under the *Insurance Contracts Act 1984* (Cth).

The ‘right not to know’

21.25 It may be that some people would rather remain ignorant of their genetic status or the genetic status of their child. For late-onset degenerative diseases with no cure, like Huntington’s disease, people may not wish to live their lives in the knowledge that they will eventually develop such a condition. If a condition is treatable, they may be more inclined to want to know whether they are or will be affected.

21.26 Due to the familial nature of genetic information, participation in a screening program may also reveal information about an individual’s relatives, who may not wish to know their genetic status.

21.27 In the context of newborn screening, the administrators of a German DMD screening program had determined that they would cease screening if there were a significant number of distressed parents. It was found, however, that most parents were relieved to be provided with a diagnosis so early.²³

21.28 Deborah Robins, in her submission, felt that early diagnosis had more benefits than protecting parents from worry. As she put it, ‘[f]or a little anxiety for new parents followed by a lovely gift — the affirmation of good health, our affected children would benefit from early diagnosis’.²⁴

21.29 Protection of a ‘right not to know’ is particularly important where individuals are screened for conditions that have no cure. If screened at birth, parents will be better able to understand their child’s condition early. They will

22 *Insurance Contracts Act 1984* (Cth) s 21.

23 D Bradley, E Parsons and A Clarke, ‘Experience with Screening Newborns for Duchenne Muscular Dystrophy in Wales’ (1993) 306 *British Medical Journal* 357.

24 D Robins, *Submission G154*, 10 April 2002.

also be able to make informed reproductive decisions. However, the knowledge will place a significant burden on both parent and child, especially where the condition develops late in life.

21.30 While some people may wish to be screened for all kinds of conditions, others may wish to know only where the knowledge will enable them to take action to prevent or treat it.

21.31 Protection of the right not to know should be considered where screening for incurable conditions is proposed. It may be that screening for such conditions is inappropriate as the risks of harm may be greater than the value of screening.

Research use of genetic samples and information

21.32 Screening programs involve the collection of genetic samples and personal identifying information. Due to the scale and focus of these collections, they may have great value for research. They provide a large collection of samples and information already tested for a condition and may include information about age and origin of tested individuals. Research might involve use of genetic material or studies using the results of screening tests.

21.33 One submission pointed out that screening for diagnosis and treatment, and screening for research are not mutually exclusive.²⁵ Test results can be used to diagnose genetic status and as part of research into genetic causes of disease such as the interaction between environmental and genetic factors.

21.34 This is what occurs when Guthrie cards are used in later research projects. Such research use should only occur where consent has been obtained to use samples and information for those purposes.

Regulation of population screening

21.35 Most population screening programs will be conducted through state and territory government health authorities, and the collection, storage, use and disclosure of information will be subject to state and territory information and health privacy law, where it exists.²⁶ The federal *Privacy Act 1988* (Cth) will also apply to some screening programs, for example those conducted by ACT public health authorities.

25 Ibid.

26 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Privacy Act 1988* (Cth).

21.36 The HGSA felt that the current regulatory system appeared to provide adequate protection for genetic information collected in the context of population screening programs.²⁷ This view was supported by the OFPC, which asserted that the *Privacy Act* provided a 'robust and flexible framework for genetic privacy' for the purposes of population genetic screening.²⁸

21.37 The Australian Society of Medical Research noted that population screening and genetic registers 'have been important components of the effective delivery of health care in this country' and stated that they 'would be concerned if new actions were taken that would make this genetic information regulated in a differential way to other sensitive medical information'.²⁹

Reform proposal

21.38 As developments in genetic medicine continue, it is likely that more disorders will become either treatable, or able to be slowed by prophylactic measures.³⁰ Regulatory controls on population screening should be flexible enough to take account of this and allow for screening programs to change in response to new medical technologies.

21.39 Population screening programs are another example of instances in which genetic samples and information are collected, but where only the information will be subject to legislative protection. If samples are not disposed of following testing, screening programs effectively create genetic databases, and hence raise the same privacy problems as discussed in Chapters 15 and 16.

21.40 The OFPC suggested that a form of 'third party gene broker', similar to the 'gene trustee' system described in Chapter 15, could be an innovative solution to the problems posed by population screening programs.³¹ This system could be appropriate for some screening programs, particularly those that are relatively small and discrete in scope, by ensuring the privacy and anonymity of participants.

21.41 There may be a need for nationally consistent policies and practices in relation to population genetic screening programs. These policies should cover matters such as consent to testing, including the provision of information about the implications of testing and the provision of genetic counselling.

27 The Department of Human Services Victoria Genetics Advisory Committee agreed. Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002.

28 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

29 Australian Society for Medical Research, *Submission G124*, 18 March 2002.

30 J MacMillan, *Submission G015*, 19 November 2001.

31 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

21.42 Informed consent should include information about the purpose of the screening, the voluntary nature of participation, the meaning of test results and the factors to consider in deciding whether or not to participate.³²

21.43 Testing standards could also be set, requiring that screening programs only be conducted using tests that reach an acceptable level of reliability, sensitivity and utility.

Proposal 21–1. The Australian Health Ministers’ Advisory Council, in collaboration with the proposed HGCA and key professional bodies, should develop nationally consistent policies and practices in relation to the implementation and conduct of population genetic screening programs, covering such matters as informed consent, counselling and testing standards.

32 See for example American College of Obstetricians and Gynecologists and American College of Medical Genetics, *Preconception and Prenatal Carrier Screening for Cystic Fibrosis: Clinical and Laboratory Guidelines* (2001), American College of Obstetricians and Gynecologists, Washington.

Part G. Insurance

22. Personal Insurance in Australia

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Introduction

22.1 The purpose of insurance is risk distribution — to spread risk across a large pool of individuals.¹ For the payment of a regular premium, an insurer undertakes to pay the insured an agreed sum in the event that a particular event occurs. The contract between the parties is embodied in an insurance policy. In law, this contract is said to be one of ‘utmost good faith’: the applicant has a special duty at common law² and under legislation³ to disclose to the insurer all information that is known, or which reasonably ought to be known, to be relevant to the insurer. In practice, disclosure occurs when applicants for insurance answer questions posed by insurers in the application form or proposal. This information is used for the process of underwriting (or rating), in which the insurer assesses whether to accept the insurance application and, if so, on what terms.

¹ J Outreville, *Theory and Practice of Insurance* (1998) Kluwer Academic Publishers, Massachusetts, 147.
² *Carter v Boehm* (1766) 3 Burr 1905, 1909 (Mansfield LJ).
³ *Insurance Contracts Act 1984* (Cth) s 21. See also Australian Law Reform Commission, *Review of the Marine Insurance Act 1909*, Report 91 (2001), ALRC, Sydney, Ch 10.

22.2 Insurance in Australia is commonly divided into three categories: life, health and general insurance. Life insurance encompasses a variety of products, including policies that provide payment upon death, continuous disability or trauma.⁴ Health insurance provides payment for the provision of hospital and ancillary medical and health services. General insurance covers matters not attached to either life or health insurance, such as product liability, travel, professional indemnity, and sickness and accident.

22.3 The Australian insurance industry is one of substantial economic importance. Across the full range of products, general insurers managed 37.6 million policies during 2000, with \$14.6 billion collected in premiums and \$12.2 billion paid in claims.⁵ During the 1999–2000 financial year, life insurers operating in Australia received \$41.9 billion in premiums and paid \$33.4 billion in claims.⁶ During the 2000–2001 financial year private health insurers collected \$7.1 billion in contribution income and paid over \$5.6 billion in benefits.⁷

Personal insurance

22.4 For the purposes of this Inquiry, the collection and use of genetic information is likely to have the greatest impact on insurance policies that collect and use health information and are mutually rated, that is, they require an assessment of an applicant's risk of mortality or morbidity and use this information in underwriting. The most important examples of this kind of insurance product are life insurance products, but there are several general insurance products, such as sickness and accident insurance, that are also of relevance to the Inquiry. Some of the main life products and general insurance products relevant to this Inquiry are as follows:

- **Term life insurance:** provides for the payment of an agreed lump sum in the event of death of the insured. According to the Investment and Financial Services Association (IFSA), the approximate average level of cover for term life insurance in Australia is \$235,000.⁸

4 Other life products include annuities, which provide a periodic payment for a fixed period or (in the case of a life annuity) over the insured's lifetime.

5 Australian Prudential Regulation Authority, *General Insurance Trends December Quarter 2000* (2001), APRA, Sydney.

6 These statistics include life insurance that is incidental to superannuation, which comprises 87% of total insurance premiums collected by life insurers. See Australian Prudential Regulation Authority, *Half Yearly Life Insurance Financial Bulletin Year Ending June 2000* (2001), APRA, Sydney.

7 Private Health Insurance Administration Council, *Industry Performance*, <http://www.phiac.gov.au/circularspublications/publications/AR_registered_health/part_a1/index.htm>, 25 July 2002.

8 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

- **Income protection (or disability income) insurance:** provides for regular sums to be paid while an insured is unable to work in his or her occupation. According to IFSA, the approximate average level of cover for disability income insurance in Australia is \$3,700 per month.⁹
- **Trauma insurance (critical illness):** provides for the payment of an agreed lump sum on the happening of defined medical events, such as a heart attack, cancer or stroke within a specified period. The average level of cover for trauma insurance in Australia is \$165,000.¹⁰
- **Superannuation:** provides employees with protection for death, total and permanent disability, as well as income protection, where the insurance is purchased through an employee's superannuation fund.
- **Sickness and accident insurance:** a general insurance product that provides for payment of a lump sum or periodic payments to cover losses or expenses incurred as result of accidental injury or sickness.
- **Travel insurance:** a general insurance product that provides for the payment of agreed sums to cover losses or expenses occurred in the course of travel, including medical expenses.

22.5 The largest part of personal insurance business in Australia is operated by the life insurance industry either as a component of superannuation or as voluntary mutually rated life insurance. There are currently 42 registered life insurers in Australia, of which six are reinsurance companies.¹¹ Not all registered life insurers are currently active and several do not operate in the mutually rated market.

Mutually rated and community rated insurance

22.6 Mutually rated underwriting operates on the principle that insureds with similar risks should be treated in a similar way. The price that insureds pay for insurance is thus proportional to the risk they bring to the insurance pool. In mutually rated insurance, the amount of insurance sought and the particular characteristics of applicants are taken into account when rating. An applicant's age and sex will nearly always be considered as relevant characteristics. However, depending on the type of insurance, other factors such as occupation, family medical history, current health condition and lifestyle may also be considered.¹²

9 Ibid.

10 Ibid. Critical illness insurance does not provide cover for accidental events.

11 Ibid, 5.

12 R Brackenridge and W Elder, *Medical Selection of Life Risks* (1998) Macmillan Reference, London, 181.

22.7 Under the mutual principle, insurers classify applicants into three risk categories — ‘standard’, ‘extra risk’ or ‘declined’. The lowest premium charges attach to the standard rating. Increased premiums, referred to as loadings, apply to applicants who are rated as extra risk. In lieu of a loading, insurers may offer the applicant alternative insurance products. Applicants who are declined insurance present a risk that the insurer considers too great to insure at a realistically affordable premium.

22.8 An alternative approach to mutuality in underwriting is community rating, in which individuals pay either a flat rate or a sliding means-based premium, regardless of their particular personal risk factors. Although this risk is shared collectively across the entire pool of insureds, actuaries and underwriters still collect health information to determine the overall premium that insurers must charge to sustain the pool.

22.9 Community rating is the basis of Australia’s public and private health insurance system. For underwriting purposes, private health insurance contracts are community rated under the *National Health Act 1953* (Cth), such that insurers are prevented from using genetic information or other health information to assess individual risk.¹³ This restriction is significant in assessing the overall impact of the use of genetic information in the Australian insurance context, particularly when compared with the position in the United States, which does not have a comprehensive national health insurance system.

22.10 The major advantages of community rated insurance are access and equity. No applicant is denied insurance because he or she brings too high a risk to the insurance pool, as may happen with mutually rated products. As a result, access to insurance for those with higher risks is offered at more affordable premiums.

22.11 A disadvantage of community rating is that insureds with lower risk — such as young, healthy individuals — may pay more for an insurance product than they would under a mutually rated product. As a result, where participation is voluntary, they may abstain from taking insurance or drop out of the insurance pool, skewing the pool towards people with higher risk, which in turn leads to higher premiums. This process of ‘adverse selection’ is discussed later in this chapter and in Chapter 24.

Superannuation and personal insurance

22.12 Superannuation schemes in Australia can be divided into three basic categories: award or legislation-based schemes (where contribution by employers is mandatory); personal schemes; and company schemes (contributed to by the

13 *National Health Act 1953* (Cth) ss 67(1), 73(2A), 73(2B).

employer and/or the employee with the aim of providing a benefit when the employee leaves the company).

22.13 Personal insurance is sometimes included as a component of superannuation in award-based, personal or company schemes. In company-based superannuation schemes with a reasonable number of employees and tight rules, employers are granted an automatic acceptance limit (AAL), which allows automatic cover to be granted to employees up to the specified limit.

22.14 Group insurance is the term that describes the various types of insurance cover that can be provided by industry superannuation funds and most large company-based superannuation. Where the insurance cover required is above the AAL, the extra cover is mutually rated. This means that the individual is underwritten by a life insurer for the additional cover required. The AAL for industry funds usually depends on the number of members in the group and the level of compulsion, and may reach large sums (for example, \$1 million for groups of 1000 lives or more).

22.15 As a result, the circumstances in which issues are raised by the use of genetic information in superannuation are generally limited to:

- employees who are self-employed or are employed by small businesses that do not satisfy the AAL; or
- employees who require a greater amount of insurance than that provided by the AAL.

The policy cycle

22.16 This section briefly summaries the insurance policy cycle, that is, the steps that a person wishing to obtain personal insurance must take in order to obtain personal insurance. Applicants often have little or no contact with an insurance company because insurance is usually purchased through an agent of the insurer, an insurance broker or a financial planner.

Application

22.17 The application form allows applicants to indicate the type and level of insurance for which they wish to apply, as well as the method and timing of future premium payments. There is provision for personal details such as health, family medical history, occupation, sports and pastimes. An information brochure describing the key features of the insurance product is usually included as part of the information package accompanying the application form. Depending on the product and the insurer, this package may also include the terms and conditions of the policy.

22.18 When completing the application, the applicant is required to disclose relevant information about themselves, to allow the insurer to classify the potential risk that it is being asked to cover. For example, if the applicant has had a heart complaint or history of high blood pressure, this information is relevant and must be disclosed. Failure to provide material information at the time the contract is made can have significant consequences when a claim is lodged after the insurance event has occurred. This issue is considered further in Chapter 23.

22.19 The questions asked by an insurer depend on the type of insurance and the level of cover sought. Insurers generally request more information the higher the amount to be insured. The extent of information sought may therefore vary from a few questions about medical history to extensive information — including full medical examinations, blood and urine tests, an electrocardiogram and so on — on policies involving large sums.¹⁴

Assessment

22.20 Once the application is complete, the authorised representative relays the application to the insurer for assessment. In most cases, the information received through the application form is sufficient for the insurer to make an assessment. Further information may be required, however, if the level of cover sought exceeds a certain limit, or if the information provided indicates that there may be a risk that requires further information for the purpose of assessing the application fully.

Terms and conditions

22.21 The process of underwriting enables the insurer to determine whether it will accept the applicant's risk, and if so on what terms. The underwriting cycle is described further below. It is at this stage of the process that the authorised representative informs an applicant of the reasons why an application has been underwritten in a particular way, if it has not been accepted at standard rates. If the underwriting decision is unfavourable, the applicant may wish to test the reasons for the decision with the insurer or, failing satisfactory resolution, pursue more formal channels of review.

Premium

22.22 The continuance of any insurance policy depends on the timely payment of the premium by the insured. The premium may be payable monthly, quarterly or annually, depending on the terms of the policy and the policyholder's preference.

14 R Brackenridge and W Elder, *Medical Selection of Life Risks* (1998) Macmillan Reference, London, 214.

Policy renewal and the duty of disclosure

22.23 Some categories of insurance products, such as those offered by life insurers, are guaranteed 'yearly renewable'. These policies are assessed only once and applicants are obliged to disclose risks of which they are aware on only one occasion — at the time they enter into the contract. By contrast, some general insurance products are not guaranteed yearly renewable and depend on a reassessment at the end of the term of the policy, or some other periodic basis. For example, sickness and accident insurance (a general insurance product) is generally renewed annually on the assumption that there has been no change in risk. However, if there has been a change in risk (such as health status), the insured must disclose this and the underwriting decision will then be reassessed.

Insurance event

22.24 The insurance event is the occurrence that may trigger the payment of a claim under the insurance policy. The insurance event will depend on the type of insurance policy and the terms and conditions in the policy.

22.25 At this stage of the policy cycle, the insurer scrutinizes the claim in order to determine whether the insured has fulfilled his or her duties under the contract. In addition to checking that the insurance event falls within the terms of the policy, the insurer also assesses whether the insured fulfilled the disclosure obligations under the contract. Failure to disclose all relevant facts at time of application (in the case of life insurance products) or at the time of application or subsequent renewal (in the case of general insurance products) may negate the insured's right to make a claim.

The underwriting process

22.26 Insurance applications provide insurers with a key tool for determining whether they will insure a person and, if so, upon what terms. The process of obtaining and evaluating information about an applicant to determine on what terms risk will be insured is called underwriting. Underwriting is based on actuarial data and is either mutually rated or community rated, as discussed above.

Agents and brokers

22.27 In completing an insurance application, applicants often receive advice from an insurance agent, broker or financial planner. An insurance agent acts exclusively on behalf of an insurer — marketing and selling insurance policies to

their customers.¹⁵ A insurance broker acts on behalf of applicants and insureds, providing advice on which products, from a range of insurers, best suit their clients' needs.¹⁶ The *Financial Services Reform Act 2001* (Cth) regulates the conduct of agents, brokers and financial planners (now referred to as authorised representatives) in the sale of insurance products.

22.28 Authorised representatives provide applicants with guidance on matters relating to the type of products needed to cover the identified risk, including the choice of insurance policy and the interpretation of questions in the application. Authorised representatives may also assist insurers by providing a report about the applicant. When advising applicants about underwriting matters, authorised representatives usually rely on guidelines, provided by the insurer, about the effect of risk factors on underwriting.

Role of actuaries

22.29 In assessing different risk characteristics, insurers rely on actuarial data and informed judgment from actuaries and chief medical officers. Actuaries specialise in tabulating statistics that assist underwriters in applying risk ratings to insurance policies. They frequently use a method of converting risk factors into numerical values (numerical rating system)¹⁷ which, when applied to certain variables, provides an overall summary of the risk to be insured. This is referred to as the standard baseline risk or standard rating for an insurance product. The standard baseline risk varies between insurers, according to their experience, strategy and objectives.

22.30 Unfavourable health risk factors that are expected to produce additional risk are usually added to the standard baseline risk as a percentage of the standard risk. Each risk factor has a rating that is expected to cover the additional risk that the factor causes relative to the norm. Some countries have a 'preferred risk' class, which offers a discount on the standard rate for those applicants with favourable characteristics (for example, non-smokers with an active lifestyle and favourable blood chemistry readings). Australian life and disability insurers commonly separate their standard risk class into smoker and non-smoker groups but do not otherwise separate the standard lives pool based on more detailed characteristics that may be used to give premium discounts to preferred lives in some overseas countries.¹⁸

15 Agency is not limited to natural persons. Banks or building societies may act as tied agents, finding customers through the ordinary course of business and recommending a particular insurer: Ibid, 183–184.

16 Ibid.

17 For an account of the methodology applied in the numerical rating system see Ibid, 61–88.

18 Investment and Financial Services Association and Institute of Actuaries of Australia, *Consultation*, Sydney, 19 June 2001.

22.31 Actuaries rely on various sources of data to determine risk, including assessment of the historical experience gained from reviewing domestic and global insurance portfolios and surveying the literature on advances in medical research and treatment.¹⁹

22.32 In practice, the underwriting manuals used by Australian actuaries, underwriters and insurers are developed mainly from those compiled by one of the six large international reinsurance companies operating in Australia — the ‘insurers for insurers’.²⁰ Most Australian insurance companies do not reinsure policies that fall below a certain monetary limit.²¹

22.33 Life companies will select different levels of reinsurance depending on factors such as their own size and their level of expertise with a particular insurance product. A small, inexperienced insurer may make a treaty arrangement to reinsure almost all of the cover it underwrites, whereas a large insurer wishing to retain a high level of risk on its own account may reinsure only sums insured in excess of, say, \$1 million.²²

22.34 Reinsurers play a critical role in formulating basic underwriting manuals because of the large amount of data they obtain through their dealings with many insurance companies globally, and thus their exposure to a wide range of clients and circumstances. Reinsurance manuals are generally used as a guideline both for policies that fall within reinsurance treaties and those that do not, in order to maintain consistency in underwriting practice.²³

Role of underwriters

22.35 Underwriters are employed by insurers to assess the risk factors that applicants disclose in the application or reveal to the insurer in other ways, for example, through a medical report supplied by the applicant’s medical practitioner. Assessment of personal insurance proposals requires underwriters to (a) apply statistical data (usually based on reinsurance manuals) to the risk factors disclosed in each particular case; (b) apply these to the particular company guidelines; and (c) judge whether to accept, reject or alter the terms of each application.

19 Some sources of data relied upon by insurance underwriters include: R Brackenridge and W Elder, *Medical Selection of Life Risks* (1998) Macmillan Reference, London; *Journal of Insurance Medicine*; *American Academy of Insurance Medicine*; *International Journal of Epidemiology*.

20 Risk sharing between the insurer and reinsurer is said to be essential to guard against large fluctuations in profits when insurers are faced with multiple claims in one area (eg, those caused by a natural disaster). See J Outreville, *Theory and Practice of Insurance* (1998) Kluwer Academic Publishers, Massachusetts.

21 Investment and Financial Services Association and Institute of Actuaries of Australia, *Consultation*, Sydney, 19 June 2001.

22 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

23 Ibid.

22.36 A relevant issue for this Inquiry is how insurers assess genetic information for underwriting purposes. Genetic information must be used sensitively and accurately, especially where underwriting seeks to rely on the predictive value of genetic information. The issue of actuarial relevance of genetic information is considered in Chapter 24.

Insurance decision

22.37 According to an IFSA survey, approximately 93% of all applicants for life insurance are issued policies on standard terms.²⁴ However, there are other potential outcomes from the underwriting process, including that insurance is offered on non-standard terms, deferred or declined. These terms are described below. On occasions, an insurer may offer an alternative insurance product rather than decline an application or offer a policy on non-standard terms.

Accepted on standard terms

22.38 ‘Standard’ is the insurance risk benchmark for a policy. Applicants who fall into the standard risk grouping have no particular adverse risk factors that warrant a premium loading.

Accepted on non-standard terms.

22.39 This refers to the situation where the application is accepted, but subject to one or more of the following conditions.

- *Premium loading*: the application is accepted but with a higher than standard premium. Premium loadings are imposed as a percentage of the standard premium or as a dollar loading, on a temporary or permanent basis.
- *Exclusion*: the policy includes a term that lists events for which the insurer will not pay. An exclusion may be imposed on a temporary or permanent basis.
- *Restricted period of coverage*: the policy limits the duration of insurance cover, for example where a person may be at risk for a late-onset disorder, which would otherwise be uninsurable.
- *Reduced sum*: the policy reduces the amount that will be paid in the event of a claim.

24 Ibid.

Deferred

22.40 A deferred decision means that the insurer has declined the insurance proposal at the time of underwriting, but offers the applicant the opportunity to have the application re-rated at a future date. A deferred decision is given where a risk factor is expected to reduce over time, for example, where an applicant is receiving medical treatment for a condition that may stabilise over time.

Declined

22.41 Insurance is declined when the insurer determines that the risk that the applicant would bring to the pool is too high to accept, at least for a realistically affordable premium. Life insurance is rarely declined but, where it is, it is usually in respect of applicants with serious health impairments or extremely hazardous occupations.

Adverse selection

22.42 Under-rating or over-rating the risk that insureds bring to the pool of insurance can have adverse impacts. Over-rating risks, and thus charging excessive premiums, may reduce the demand for insurance and make the insurer uncompetitive in the market place. Under-rating risks, and thus charging premiums below the level appropriate for the risk that insureds bring to the pool, may result in a situation referred to as adverse selection.

22.43 In consultations with the Inquiry, IFSA stated that adverse selection may result if genetic information or other health information were excluded from underwriting.²⁵ The concern is that if applicants are not required to disclose relevant genetic information, insurers may be faced with a disproportionate number of people at higher risk applying for extended cover. In an adverse selection environment, the value of recoverable claims exceeds the premiums charged because the calculated risk underestimates the true risk.²⁶ If insurers are unable to rate risk accurately, premiums will rise for the entire insurance pool as insurers seek to cover unexpected claims. The higher premiums in turn provide a disincentive for those with low risk to obtain insurance. A spiral of price increases results, in which low risk individuals drop out of the insurance pool and the proportion of high-risk insureds systematically increases, eventually challenging the long term viability of the insurer.

25 Investment and Financial Services Association and Institute of Actuaries of Australia, *Consultation*, Sydney, 19 June 2001.

26 R Brackenridge and W Elder, *Medical Selection of Life Risks* (1998) Macmillan Reference, London, 30; J Outreville, *Theory and Practice of Insurance* (1998) Kluwer Academic Publishers, Massachusetts, 152.

22.44 Adverse selection can arise in three situations. The first is where the applicant does not disclose, or misrepresents, his or her risk and the insurer is unable to underwrite the full extent of the true risk. Adverse selection arises in this case because the applicant knows more about the risk than the insurer. For example, if an applicant knows that he or she shows signs of heart disease and does not disclose the condition to an insurer, the applicant may obtain insurance at a rating that does not reflect the risk that he or she brings to the insurance pool.²⁷

22.45 The second situation is where the insurer is aware of the applicant's true risk but chooses not to underwrite the full extent of the risk. Insurers do not always underwrite to the full extent of the insured's risk. In the risk classification process, each insurance company determines the classes of risk to be declined, to be issued at a loaded premium, or to be issued at standard rates.²⁸ These risk classes differ among insurers according to their experience, corporate strategy and objectives. One insurer might be prepared to accept some applicants with significant additional risks on standard rates as part of its broad market strategy of expanding risk pools and capturing market share.²⁹ Another may be more selective. Insurers may choose not to underwrite to the full extent of the risk in order to remain competitive with other insurers. Yet, as Australia has witnessed in recent times, poor assessment of these risks by insurers can result in significant losses or, in the case of some general insurers, insolvency.

22.46 The third situation is where the law limits the information that insurers are permitted to use in underwriting, despite the actuarial relevance of the information. For example, insurers cannot discriminate between individuals on the basis of race even though the life expectancy of indigenous Australians is known to be markedly lower than for the population at large.³⁰

22.47 The possibility that adverse selection may result from excluding genetic information from the underwriting of personal insurance in Australia is discussed further in Chapter 24.

27 Material non-disclosure can result in the insurer lawfully refusing to pay the claim. See Ch 23 for further discussion.

28 See House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000-1), The Stationery Office Limited, London, 63 (Memorandum submitted by Genetics Group, Faculty and Institute of Actuaries).

29 Ibid, 62.

30 In contrast to other federal anti-discrimination legislation, the *Racial Discrimination Act 1975* (Cth) does not include exemptions in the area of insurance. See Ch 24.

23. The Use of Genetic Information in Insurance

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Introduction

23.1 Statistical information collected by the Investment and Financial Services Association (IFSA) indicates that Australian life insurers have received very few insurance applications to date involving genetic test results. However, the number of applications in which genetic information is collected in the form of family medical history is unknown.

23.2 The Inquiry has received a number of submissions that are critical of the use of genetic information in underwriting. This chapter discusses the use of genetic information in insurance, particularly in relation to the current legal obligations of disclosure and the development of industry policy with respect to the use of genetic test information in underwriting. The following chapter provides further detail about the potential for discriminatory use of genetic information in underwriting and makes a number of proposals to address related concerns.

The applicant's duty of disclosure

23.3 An applicant for insurance has a legal obligation to disclose all information that is relevant to the insurer in assessing an application for insurance. The duty of disclosure is based on the principle that contracts of insurance require that the 'utmost good faith' be shown by each party. The duty of disclosure was

developed at common law¹ but is now embodied in the *Insurance Contracts Act 1984* (Cth) (ICA).²

23.4 Section 22 of the ICA requires the insurer to inform the applicant clearly and in writing (usually in the insurance brochure and application) about the general nature and effect of the duty of disclosure. Under s 21(1), the applicant has a duty to disclose every matter that is known before the contract of insurance is entered into, being a matter that:

- the applicant knows to be a matter relevant to the decision of the insurer whether to accept the risk and, if so, on what terms; or
- a reasonable person in the circumstances could be expected to know to be relevant.

23.5 The first test of relevance under s 21(1) has a subjective element. It imposes a duty on the applicant to disclose every matter that the applicant actually knows to be relevant to the insurer's decision. An applicant is said to know what might be relevant by reference to the questions contained in the application. If an applicant does not answer a question in the application, or gives an obviously incomplete or irrelevant answer, the ICA puts the onus on the insurer to prove that the non-disclosure is relevant.³

23.6 The duration of the obligation of disclosure depends on the insurance product in question. In the case of life products, there is no obligation on an applicant to disclose a risk of which he or she becomes aware after the contract of insurance is concluded, unless the contract itself imposes such an obligation. In relation to certain general insurance products, such as sickness and accident insurance, knowledge of a new risk will be relevant to any new contract or to a renewal of an existing contract, and must be disclosed.

What need not be disclosed

23.7 Under the ICA, an applicant is not required to disclose a matter that diminishes the risk; is of common knowledge; the insurer already knows; or an insurer ought to know in the ordinary course of its business.⁴

1 Historically derived from the statement by Lord Mansfield in *Carter v Boehm* (1766) 3 Burr 1905, 1909.

2 The ICA, which substantially reformed the common law position governing insurance contracts, arose from recommendations of the ALRC: Australian Law Reform Commission, *Insurance Contracts*, Report 20 (1982), AGPS, Canberra, para 151, 328.

3 *Insurance Contracts Act 1984* (Cth) s 21A(8).

4 *Ibid*, s 21(2).

23.8 The ICA also provides that in some cases the insurer can be held to have waived its right to disclosure from the applicant, such as where the insurer has not taken steps to investigate obviously incomplete or inaccurate answers provided by the applicant.⁵

Consequences of material non-disclosure

23.9 The insurer may raise non-disclosure as a defence when an insured makes a claim under an insurance policy. In a contract of life insurance, if the insurer can show that the insured failed to disclose relevant information, the insurer may:

- avoid the contract from its inception if the non-disclosure or misrepresentation was made fraudulently;
- avoid the contract within three years if the insurer would not have entered into the contract but for the non-disclosure; or
- vary the contract within three years by substituting the sum insured (including any bonuses) according to a statutory formula.⁶

23.10 For all other personal insurance contracts, if an insurer can establish that the insured failed to disclose relevant information, the insurer may:

- avoid the contract from its inception if the non-disclosure or misrepresentation was made fraudulently; or
- reduce the amount paid to the insured to the amount that would place the insurer in the position it would have been in if there had been no failure to disclose or no misrepresentation.⁷ This permits the insurer to reduce its liability to zero in appropriate cases.

Insurer's duty to provide reasons

23.11 The ICA also regulates the information, notices and reasons that insurers must provide to the applicant in certain circumstances. Upon a request, an insurer is required to provide reasons where it:

- does not accept an offer to enter into a contract of insurance;
- cancels a contract of insurance;

5 Ibid, s 21(2).

6 Ibid, s 29(4).

7 Ibid, s 28.

- indicates to the insured that it does not propose to renew the insurance cover provided under a contract of insurance; or
- offers insurance cover to the applicant on terms that are less advantageous to the applicant than the terms that the insurer would otherwise offer by reason of some special risk relating to the applicant or to the subject matter of the contract.⁸

23.12 The redress available to applicants in the event of disagreement about the underwriting decision is limited. An applicant may, in the first instance, make an internal complaint to the insurer concerned. If the matter is not resolved, the applicant may lodge a complaint with a relevant agency, such as the Human Rights and Equal Opportunity Commission. There is currently no independent industry-specific complaints mechanism in Australia with respect to underwriting. The Financial Industry Complaints Service (FICS) is specifically excluded by its rules from receiving complaints regarding premium or underwriting.⁹ This issue is discussed further in Chapter 24.

Collection of general health information

23.13 The legal duty of disclosure has an important practical consequence for the underwriting of personal insurance: insurers can and do collect a great deal of information from applicants to determine whether, and on what terms, they will accept the risk. Health information is gathered because research shows that particular characteristics of individuals impact on their likelihood of making a claim now or in the future.¹⁰

23.14 Insurers collect health information about the applicant from questions posed in the insurance application. Health related questions asked by insurers vary according to the type of policy, but typically include questions about state of health, physical features, lifestyle, results of medical tests and individual medical history.¹¹

23.15 Additional health information is not required in many cases. Underwriting would be an expensive process if all potentially available medical reports and examinations were used. As a result, insurers make a pragmatic trade-off between cost and risk. The expense of admitting a few higher risk individuals to the pool may be outweighed by the lower costs of underwriting and administration.

⁸ Ibid, s 75.

⁹ Financial Industry Complaints Service, *Rules* (2002), Melbourne, Rule 15. FICS is a company that has been established to provide free advice and assistance to consumers to help them in resolving complaints relating to members of the financial services industry, including life insurance, superannuation, funds management, financial advice, stock broking, investment advice and sales of financial or investment products.

¹⁰ Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002, 16.

¹¹ Ibid.

23.16 However, further health information may be required in two cases. The first is if the amount of cover sought exceeds the underwriting limit. Insurers generally operate within certain medical underwriting limits, such as those published by the RGA Reinsurance Company of Australia.¹² The underwriting limits take into account a number of variables, including the amount insured, the type of insurance, age, and the additional health information sought (such as an examination by a general practitioner or specialist).

23.17 Second, the applicant may disclose current or past medical conditions that require further investigation through a questionnaire, a report from a current doctor, or a medical examination. Application forms usually include a standard medical authority, which gives the insurer written consent to obtain full particulars of the applicant's medical history, including details of any clinical notes.

Collection of genetic information

23.18 Insurers may also have an interest in using genetic information to underwrite an application for personal insurance. This is because certain kinds of genetic information about an individual, or his or her family, may reveal information about present or future health, which may in turn affect the likelihood of the insured making a claim under the policy. Insurers may ask applicants to disclose genetic information derived from a genetic test or from family medical history.

23.19 Life insurers have collected family medical history information for many decades because there is well-developed epidemiological evidence about familial patterns of inheritance in regard to particular disorders. Typically, questions about family medical history ask whether parents, brothers, sisters, aunts, uncles or grandparents — living or dead — suffered from heart disease, stroke, high blood pressure, diabetes, kidney disease, cancer, or familial disorders. Family medical history information is used as a means of assessing longevity and the likelihood that an individual will develop a familial or inherited condition in the future.

23.20 The insurance industry has not developed a policy on the use of genetic information derived from family medical history.

23.21 In recent times, the life insurance industry has also sought to use genetic test information for underwriting. The basis for using genetic test information in underwriting was expressed by IFSA in the following terms:

The industry views the use of genetic test results in underwriting as an integral part of the medical information currently used, with the important exception that an insurer will not ask an applicant to undergo a genetic test.

12 RGA Reinsurance Company of Australia, *Medical Underwriting Limits (Life/Crisis/TPD)* (2000).

Medical information, including results of medical tests, individual and family medical history, and medical examinations is used by underwriters to understand an individual's current and likely future health, and thereby to assess their risk of claiming.¹³

23.22 In 2001, IFSA initiated a research project to monitor both the volume of genetic tests disclosed in Australian life insurance applications and the progress of these applications through the underwriting process. IFSA commissioned the Institute of Actuaries of Australia (IAAust) to survey all life insurance companies that sell term life insurance, total and permanent disability insurance, disability income insurance, and business expenses insurance in Australia on a six-monthly basis ending on 31 May and 30 November each year.¹⁴

23.23 The number of applications received by Australian life insurers involving genetic test information is currently small. Figure 23–1 shows the genetic disorders for which genetic test results were disclosed during the survey period. During the first two reporting periods (ending 31 May 2001 and 30 November 2001) insurers received a total of 115 applications with a genetic test result, of which 105 had had their underwriting completed. Of the 105 applications that had been assessed, 46 were underwritten on standard terms, 32 were underwritten on non-standard terms, 12 were deferred and 15 were declined. Moreover, of the 59 applications that were underwritten adversely (ie deferred, declined or non-standard terms), the major reason given for the adverse decision was said to be the genetic test result in 16 cases (27% of adverse cases) and some other medical reason in 31 cases (53% of adverse cases).

13 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

14 The first survey was an exception: the start of the collection period was open-ended to capture as much historical data as possible.

Figure 23–1 Categories of genetic tests in insurance applications for year ended 30 November 2001.

Disease or Disorder Tested For	Number of applications
Hereditary Haemochromatosis	76
Huntington's Disease	16
Factor V Leiden	4
Breast Cancer	3
Hereditary Non Polyposis Colorectal Cancer	2
Myotonic dystrophy	3
Cystic Fibrosis	2
Familial Adenomatous Polyposis	2
Colorectal Cancer	2
Polycystic Kidney Disease	2
Charcot-Marie-Tooth Disease	1
Prothrombin gene mutation	1
Tuberous Sclerosis Complex	1
Total number of applications	115

Source: Data prepared by the Institute of Actuaries of Australia and provided to the Inquiry by IFSA.

23.24 To place these figures in perspective, according to statistics collected by the Australian Securities and Investments Commission (ASIC) and made available to the Inquiry by IFSA, during the calendar year ended 31 December 2001 approximately 1.23 million new policies were issued by life insurers in Australia (excluding group life products).

23.25 The initiative to collect and publish statistics about the use of genetic test information in insurance is to be commended. However, further data would be useful, within the constraints imposed by the *Privacy Act 1988* (Cth) on the collection of information. It is important to note that the IAAust Genetic Test Survey was restricted to DNA test information and did not include family medical history information or other medical tests that may reveal genetic information. It would be useful to know, for example, how many applicants without genetic test results were adversely underwritten on the basis of genetic information revealed from their family medical history. It would also be useful to know how many applicants with genetic test results would have been adversely underwritten solely on the basis of their family medical history.

Industry policy on the use of genetic information

23.26 Prior to 1995 the life and general insurance industries in Australia did not have a developed policy with respect to the use of genetic information for underwriting. In the mid 1990s, IFSA's predecessor, the Life Investment and Superannuation Association (LISA), developed a draft policy on genetic testing, which was released to its members for consideration in June 1997.

23.27 In February 1999, IFSA released an agreed draft industry policy, which was lodged with the Australian Consumer and Competition Commission (ACCC). IFSA applied to the ACCC for an 'authorisation' because some clauses in the policy could be construed as being anti-competitive.¹⁵ This was because the draft policy impeded insurers from competing on the basis of price in so far as it prohibited 'preferred risk underwriting', that is, the practice of discounting premiums to persons who present less than standard risk. The draft policy had been framed in this way to prevent indirect coercion to undergo a genetic test, and thus to respect an applicant's 'right not to know' about a genetic disorder or predisposition.

23.28 The *Trade Practices Act 1974* (Cth) provides that the ACCC may grant an authorisation if satisfied that any anti-competitive aspect of the arrangements or conduct is outweighed by the public benefits arising from the arrangements or conduct.¹⁶ In support of its application, IFSA submitted that the primary purpose of the draft policy was to provide a framework in which insurers do not initiate genetic tests. According to IFSA, the key issue in the authorisation application was whether there was public benefit in insurers not initiating genetic tests.

23.29 Although the ACCC was initially disinclined to authorise the policy, in November 2000 it granted IFSA a two-year authorisation, noting the establishment of the ALRC-AHEC Inquiry, 'the complex issues involved', and the need to provide a 'breathing space' during which these issues could be debated and government policy developed. The ACCC concluded that:

Ensuring IFSA's members do not require applicants for insurance to undergo genetic testing, and that applicants will not be indirectly influenced into undergoing such tests, is likely to result in benefit to the public. In particular, the Commission considers that there is public benefit in avoiding insurer-initiated coercion to undertake genetic testing.¹⁷

15 See *Trade Practices Act 1974* (Cth) s 88(1), concerning arrangements that may have the effect of substantially lessening competition, within the meaning of s 45 of the Act.

16 Ibid, ss 90(7), 90(8). While there is some variation in the language of the subsections, the ACCC has adopted the view of the Trade Practices Tribunal that the practical application of the tests is the same: *Re Media Council of Australia* (No. 2) (1987) ATPR 40-774, 48,418.

17 Australian Competition and Consumer Commission, *Determination re Applications for Authorisation Lodged by Investment and Financial Services Association (IFSA) in Relation to Clauses 2 and 4 of its Draft Policy on Genetic Testing* (2000), 15.

23.30 Since the ACCC determination, IFSA has expanded the draft policy and formalised it into an industry standard (IFSA Standard 11.00 — Genetics Testing Policy). The purpose of the IFSA Genetics Testing Policy is to specify standards for handling genetic test results to be adopted by insurers in the operation of their business.¹⁸

23.31 The key elements of the IFSA Genetics Testing Policy are as follows:

- Insurers will not initiate any genetic tests on applicants for insurance.
- Insurers may request that all existing genetic test results be made available to the insurer for the purposes of classifying the risk.
- Insurers will not use genetic tests as the basis of ‘preferred risk underwriting’ (offering individuals insurance at a lower than standard premium rate).
- Members must provide their employees and authorised representatives with sufficient information and training so that they understand the content and meaning of the Standard so far as it relates to their particular jobs and responsibilities.
- Insurers will ensure that results of existing genetic tests are obtained only with the written consent of the tested individual.
- The results of a genetic test will be used only in the assessment of an insurance application in respect of the individual on whom the test was conducted.
- Insurers will ensure that strict standards of confidentiality apply to the handling and storage of the results of genetic tests.
- Insurers will provide reasons for offering modifications or rejections to applicants in relation to either new applications or requests for increases on existing policies.
- Insurers will have a competent and efficient internal dispute resolution system to deal with complaints relating to underwriting decisions involving a genetic test result.¹⁹

18 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

19 Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

23.32 The IFSA Genetics Testing Policy is an internal industry standard that is administered by IFSA. Compliance with the policy is the responsibility of each insurance company that is a member of IFSA. Member companies must certify compliance with the policy annually according to the terms of the IFSA Code of Conduct and Code of Ethics. However, as IFSA is not a regulator, it has indicated that its monitoring of compliance will be done with a 'minimum of formality'.²⁰ The IFSA Genetics Testing Policy is also referred to in Chapter 24.

20 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

24. Genetic Discrimination in Insurance

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Introduction

24.1 Mutually rated insurance is based on a process of underwriting, which involves differentiating between individuals on the basis of the risk that they would bring to the insurance pool if their application were accepted. The same insurance product may be offered on different terms to different individuals depending on the insurer's assessment of their level of risk.

24.2 The Institute of Actuaries of Australia has explained the probabilistic nature of underwriting in the following terms:

The probabilistic nature of underwriting decisions is worth emphasising. It is well accepted, based on analysis of groups of smokers and non-smokers, that smokers will on average experience heavier mortality than non-smokers. This does not mean that every smoker will die of a smoking related disease. Some will survive to high ages despite the increased mortality risk they have exposed themselves to by smoking. Nevertheless, because their expected or average probability of death is higher, Australian life insurance companies will almost always charge higher premiums under voluntary life policies for smokers than for non-smokers. It is similar with the predictive nature of medical test results, such as high blood pressure, high cholesterol or a positive test for a genetic disorder. Where the risk is higher in probability terms, then the life insurance company is likely to underwrite a higher than normal rating factor for that risk.¹

24.3 The process of evaluating risk for the purpose of underwriting is not confined to genetic information — a person's genetic status is one of many factors relevant to his or her life prospects. In the words of the Institute of Actuaries of Australia:

Many factors influence a person's progress through life. Genetics is one of these influences, as are a host of other factors. These include schooling, nutrition, hygiene, housing conditions, family wealth, marital status, travel, the place of residence, amount of exercise undertaken and other lifestyle choices, water quality, environment, medical services, neighbours, weather, accidents and acts of God such as fires and floods. Depending how the cards fall, everyone will find that some of these factors will be beneficial for them but others will be harmful. We believe that human genetic information should be considered in this context.²

24.4 The differentiation between individuals on the basis of their genetic status for the purpose of insurance was a principal factor underlying the establishment of this Inquiry. From one perspective, this process of differentiation constitutes a form of discrimination — it involves treating people differently on account of their genetic status.³ However, such discriminatory practices are largely exempt from the provisions of Australian anti-discrimination legislation. The exemptions recognise

¹ Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

² Ibid.

³ M Otłowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 15.

that differentiating between individuals is fundamental to the market in mutually rated insurance products — at least where the decision making process is based on actuarial and statistical data or is otherwise reasonable.

24.5 By contrast, and as discussed in IP 26, private health insurance in Australia is community rated.⁴ Insurers are prevented from using individual characteristics, such as genetic status, to rate individual risk. For this reason, the discussion and proposals in this chapter focus on those sectors of the insurance industry that offer mutually rated products in which health information is collected and used. The products that fall within this description are principally life products, but some general insurance products (such as sickness and accident insurance) are also included.

24.6 A large number of submissions received by the Inquiry expressed a range of concerns about discrimination based on the use of genetic information in insurance.⁵ A number of submissions also reported actual cases of alleged genetic discrimination in insurance. This chapter considers these cases and evaluates whether the existing regulatory framework is adequate to protect such individuals from unfair discrimination in the insurance context.

Evidence of genetic discrimination

24.7 In 2001, Dr Kristine Barlow-Stewart and David Keays published research that identified 48 cases in Australia of alleged discrimination based on genetic information. Most case studies were in the areas of life insurance, income

4 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, 316–318. For a discussion of the use of genetic information in health insurance see M Otlowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 9–13.

5 F Richards, *Submission G044*, 14 January 2002; *Confidential Submission G030CON*, 17 December 2001; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; UnitingCare NSW & ACT, *Submission G052*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002; I Turnbull, *Submission G059*, 14 January 2002; D Pawlukowski, *Submission G067*, 15 January 2002; A Mangos, *Submission G068*, 7 January 2002; F Macrae, *Submission G069*, 14 January 2002; C Roberts, *Submission G072*, 13 January 2002; *Confidential Submission G075CON*, 6 January 2002; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002; Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; New South Wales Nurses' Association, *Submission G090*, 21 January 2002; Australian Medical Association, *Submission G091*, 29 January 2002; New South Wales Health Department, *Submission G092*, 25 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; National Council of Women Australia, *Submission G095*, 31 January 2002; J Kirk, *Submission G096*, 30 January 2002; Australian Huntington's Disease Association (Tas) Inc, *Submission G098*, 11 February 2002; R Richards, *Submission G101*, 24 February 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; K Liddell, *Submission G147*, 10 April 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; D Keays, *Submission G152*, 14 April 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002; M Otlowski, *Submission G159*, 24 April 2002; Queensland Government, *Submission G161*, 16 May 2002.

protection insurance and trauma insurance. In these cases, applicants reported their concerns that insurers' decisions or actions were inappropriate, based on misinformation or a lack of understanding of genetic information and the nature of genetic disorders.⁶

24.8 The submission to this Inquiry by the Investment and Financial Services Association (IFSA) — the peak body of life insurers — has questioned the findings of Barlow-Stewart and Keays. IFSA's submission indicated that the findings are at odds with the industry's own research findings, which show that life insurers have received no complaints with respect to underwriting decisions involving genetic test results.⁷

24.9 David Keays, in his submission to the Inquiry, included the following additional three case studies identifying alleged discrimination.

Robert is 34 years of age and is employed as a medical specialist. He has a family history of the disease myotonic dystrophy, which his mother suffered from. Myotonic dystrophy is characterised by muscle weakness, myotonia (difficulty relaxing muscles after contraction), cataract formation and cardiac abnormalities. Robert required some expensive equipment for his practice. To purchase this equipment he required a bank loan that was subject to income protection insurance. Accordingly, Robert applied for income protection insurance. In applying for insurance Robert disclosed his family history of myotonic dystrophy. The insurance company was not prepared to offer him income insurance based on his family history. He approached the insurance company objecting to the rejection of insurance. He was subsequently told by the insurance company that he would only be considered for insurance if he underwent genetic testing and was negative. Robert did not wish to undergo genetic testing but could not purchase the equipment he required for his practice unless he did. In 1998 he reluctantly underwent a genetic test, the result was negative and he was able to obtain insurance and purchase the necessary equipment. ...

Brett is 43 years of age, a healthy individual who is employed as an information technology consultant in New South Wales. In 1998 Brett underwent a genetic test for Charcot-Marie Tooth disease (CMT) to assist in the diagnosis of a family member. CMT is a hereditary neuropathy characterised by distal muscle weakness and atrophy, mild to moderate sensory loss and depressed tendon reflexes. Like many genetic diseases its severity varies significantly, some individuals are unaware they suffer from it. Prior to the genetic test Brett had not been diagnosed with CMT because he suffers from very mild symptoms. The genetic test however, showed that he had inherited the gene that causes CMT. This information was used in the diagnosis of his son who suffers from severe CMT. Brett subsequently applied for income protection insurance in 1999. In good faith he revealed the result of his genetic test. He was denied insurance. When questioning why his application was rejected he was told that it was because he had a positive genetic test for CMT. ...

6 See K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 254–256.

7 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

Andrea is 57 years of age and is employed as a beauty consultant. She has a history of Huntington's disease in the family. In the 1980's Andrea invested in a life insurance policy, but in response to advice from a financial consultant she rolled her life policy into superannuation. In 1996 she elected to undergo a genetic test for Huntington's disease. The result was positive. Currently she suffers from no symptoms of the disease, but it is only a matter of time before Andrea begins to develop the dementia and loss of motor control characteristic of Huntington's. In 1999 Andrea and her husband decided to purchase a house. The home loan was subject to a requirement that she have life insurance to cover the mortgage in the event of death. Andrea applied for life insurance revealing her positive genetic test. Her application for insurance was denied based on her positive genetic test. As a result the bank would not lend Andrea the funds she required to purchase a home. Fortunately her husband was able to obtain a loan.⁸

24.10 The author of a confidential submission stated that he was denied life insurance, and only provided with disability insurance on unfavourable terms, based on his family medical history of Huntington's disease. The author stated that the insurance companies he approached were provided with a genetic test result indicating that the applicant was not at risk for the disease but refused to take the genetic test result into consideration. The author indicated that this situation has severely impaired his ability to obtain loans.⁹

24.11 The Association of Genetic Support of Australasia briefly referred to two cases of alleged genetic discrimination in its submission to the Inquiry:

There is discrimination occurring in the area of insurance. A family applied for life insurance for their child with Marfan syndrome and was refused. A carrier of Fabry's disease with a specialist report stating normal life expectancy was refused life insurance.¹⁰

24.12 The Inquiry has also received submissions from individuals that suggest that the fear of genetic discrimination in life insurance has led them to avoid seeking genetic testing for health purposes.¹¹ A number of health professionals stated that some patients even hesitate to consult clinical genetics services due to the fear of negative consequences in insurance.¹² In one case, reported during public consultations, a health professional had counselled a patient to seek life insurance prior to undergoing genetic testing.¹³

24.13 Individual case studies and anecdotal accounts have provided a valuable sources of information to the Inquiry in assessing genetic discrimination in insurance, but there would appear to be a need for further empirical research. To

⁸ D Keays, *Submission G152*, 14 April 2002.

⁹ *Confidential Submission G046CON*, 26 December 2001.

¹⁰ Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002.

¹¹ Melbourne, *Public Meeting*, 22 November 2001; *Confidential Submission G066CON*, 10 January 2002; *Confidential Submission G025CON*, 13 December 2001.

¹² J Kirk, *Submission G096*, 30 January 2002, F Macrae, *Submission G069*, 14 January 2002.

¹³ Genetic Support Network of Victoria, *Consultation*, Melbourne, 22 November 2001.

this end, Associate Professor Margaret Otlowski (Faculty of Law, University of Tasmania), Dr Sandra Taylor (School of Social Work and Social Policy, University of Queensland) and Dr Kristine Barlow-Stewart (NSW Genetics Education Program) are currently conducting research into the nature and extent of genetic discrimination in Australia. This project has been funded by the Australian Research Council and is due to be completed in 2004.

24.14 Genetic information, whether in the form of genetic test results or family medical history, is currently being used by the insurance industry to assess applications for mutually rated insurance products. The case studies examined by the Inquiry indicate that the use of genetic information in insurance sometimes leaves an applicant with the impression that the underwriting decision was not well-informed or fair — even if the insurer's actions are permitted by law. The case studies also suggest that use of genetic information in insurance may have a negative impact on individual and public health outcomes. These issues are discussed further below.

Existing regulatory framework

24.15 The broad framework of anti-discrimination and privacy laws in Australia has been canvassed in Chapters 7 and 8. While those laws impose important limits, the legislation is generally permissive in relation to the genetic information that can be collected and used by insurers for the purpose of underwriting.¹⁴ This is because of the underlying duty of an applicant, both at common law¹⁵ and under legislation,¹⁶ to disclose to the insurer all information that is known, or which reasonably ought to be known, to be relevant to the insurer — including genetic information. This section examines the legislative framework in further detail.

24.16 In addition to legislation, industry standards also play a role in regulating the way the insurance industry collects and uses genetic information. For example, as discussed in Chapter 23, IFSA has developed a Genetic Testing Policy to regulate the collection and use of genetic test results (but not family medical history information).¹⁷ These standards are also broadly permissive: applicants must disclose any existing test results, in accordance with their common law and statutory disclosure requirements, and this information can be used in underwriting. However, the Policy does impose some constraints. Life insurers cannot require applicants to undergo a genetic test, nor indirectly coerce applicants

¹⁴ Privacy regulation in the insurance context is discussed in detail in Ch 25.

¹⁵ *Carter v Boehm* (1766) 3 Burr 1905, 1909 (Mansfield LJ).

¹⁶ *Insurance Contracts Act 1984* (Cth) s 21. See also Australian Law Reform Commission, *Review of the Marine Insurance Act 1909*, Report 91 (2001), ALRC, Sydney, Ch 10.

¹⁷ Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

to take a genetic test by offering ‘preferred risk underwriting’ to those who have favourable genetic test results.¹⁸

Anti-discrimination legislation

24.17 As discussed in Chapter 8, Australia has anti-discrimination legislation at the federal, state and territory levels. Despite differences in detail, all legislation dealing with anti-discrimination embodies the same paradigm for identifying unlawful discrimination. For discrimination to be unlawful, an act or omission must be:

- based on one of the grounds or attributes set out in the legislation, such as sex, race or disability;
- fall within an area of activity set out in the legislation, such as employment or the provision of goods and services;
- result in some harm or less favourable treatment, whether by direct or indirect discrimination; and
- not fall within an exception, exemption or defence.

24.18 At the federal level, the *Sex Discrimination Act 1984* (Cth) (SDA), the *Racial Discrimination Act 1975* (Cth) (RDA) and the *Disability Discrimination Act 1992* (Cth) (DDA) contain provisions relevant to discrimination in insurance. All three Acts make it unlawful to discriminate in the provision of goods and services. Subject to the other requirements identified above, it is generally unlawful to discriminate by refusing to provide a good or service, offering a good or service on altered terms or conditions, or by discriminating in the manner in which the good or service is provided.¹⁹ ‘Services’ are defined to include insurance services.²⁰

24.19 The DDA and SDA both contain exceptions relating to the provision of insurance, which allow insurers to discriminate in certain circumstances.²¹ Complaints of discrimination on the basis of genetic information in insurance are, however, most likely to be brought under the DDA and this chapter focuses on the provisions of that Act.

18 This element of the policy is the subject of a temporary ACCC authorisation. See Ch 23.

19 See *Sex Discrimination Act 1984* (Cth) s 22; *Racial Discrimination Act 1975* (Cth) s 13; *Disability Discrimination Act 1992* (Cth) s 24 which are general provisions applying to the supply of goods and services, including insurance.

20 *Sex Discrimination Act 1984* (Cth) s 4(1); *Racial Discrimination Act 1975* (Cth) s 3(1); *Disability Discrimination Act 1992* (Cth) s 4(1).

21 *Disability Discrimination Act 1992* (Cth) s 46; *Sex Discrimination Act 1984* (Cth) s 41.

24.20 The RDA is unique in that it does not provide an exception for discrimination in insurance based on race. The RDA limits the information that insurers are permitted to use in underwriting applications for insurance, despite the actuarial relevance of the information. For example, insurers may not discriminate between applicants on the basis of race even though the life expectancy of indigenous Australians is known to be markedly lower than for the population at large.

State and territory anti-discrimination legislation

24.21 Each State and Territory in Australia has its own anti-discrimination regime and each Act contains its own insurance exception.²² The language of the insurance exceptions varies between jurisdictions but most of the provisions contain elements similar to those in s 46 of the DDA.

24.22 There may, however, be problems of overlap or conflict between federal laws, on the one hand, and state and territory laws, on the other. To address this problem, each federal anti-discrimination Act contains a provision expressly indicating that the federal Act is not to be taken to exclude or limit the operation of any state or territory law capable of operating concurrently with the federal Act. This provision seeks to prevent the paramount operation of federal law over state law by reason of s 109 of the Constitution, in the event of inconsistency. However, such a provision can only cure one kind of constitutional inconsistency — it cannot cure a direct conflict between the operation of a state law and a federal law.²³

24.23 Following the decision of the High Court in *Australian Mutual Provident v Goulden*,²⁴ the insurance provisions in state anti-discrimination legislation may be subject to challenge on the basis that they are inconsistent with federal legislation that regulates how life insurers may determine premiums by reference to actuarial advice and prudent insurance practice. In that case the High Court found that the provision prohibiting disability discrimination in the provision of goods and services in the *Anti-Discrimination Act 1977* (NSW) was invalid to the extent that it was inconsistent with the (now repealed) *Life Insurance Act 1945* (Cth). Because of the possibility that state legislation on this issue remains subject to challenge, future complaints of discrimination on the basis of genetic information in insurance are more likely to be brought under the DDA.²⁵

22 *Discrimination Act 1991* (ACT) s 28; *Anti-Discrimination Act 1992* (NT) s 49; *Anti-Discrimination Act 1977* (NSW) s 49Q; *Anti-Discrimination Act 1991* (Qld) ss 74,75; *Equal Opportunity Act 1984* (SA) s 85; *Anti-discrimination Act 1998* (Tas) s 44; *Equal Opportunity Act 1995* (Vic) s 43; *Equal Opportunity Act 1984* (WA) s 66T.

23 Such provisions can cure only 'cover the field' inconsistency. See *University of Wollongong v Metwally* (1984) 158 CLR 447.

24 *Australian Mutual Provident Society v Goulden* (1986) 160 CLR 330.

25 For a detailed discussion of the High Court's decision and its implications see M Otlowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 19–21.

Disability Discrimination Act

24.24 Section 24 of the DDA provides as follows:

Goods, services and facilities

(1) It is unlawful for a person who, whether for payment or not, provides goods or services, or makes facilities available, to discriminate against another person on the ground of the other person's disability or a disability of any of that other person's associates:

- (a) by refusing to provide the other person with those goods or services or to make those facilities available to the other person; or
- (b) in the terms or conditions on which the first-mentioned person provides the other person with those goods or services or makes those facilities available to the other person; or
- (c) in the manner in which the first-mentioned person provides the other person with those goods or services or makes those facilities available to the other person.

(2) This section does not render it unlawful to discriminate against a person on the ground of the person's disability if the provision of the goods or services, or making facilities available, would impose unjustifiable hardship on the person who provides the goods or services or makes the facilities available.

24.25 As noted above, the insurance industry operates by making distinctions between risks. To that end, insurers may offer the same insurance product to different individuals on different terms, or may refuse to offer some products to certain individuals. Section 46 of the DDA recognises the nature of mutually rated insurance and provides the following exception:

Superannuation and insurance

(1) This Part does not render it unlawful for a person to discriminate against another person, on the ground of the other person's disability, by refusing to offer the other person:

- (a) an annuity; or
- (b) a life insurance policy; or
- (c) a policy of insurance against accident or any other policy of insurance; or
- (d) membership of a superannuation or provident fund; or
- (e) membership of a superannuation or provident scheme;

if:

(f) the discrimination:

- (i) is based upon actuarial or statistical data on which it is reasonable for the first-mentioned person to rely; and

(ii) is reasonable having regard to the matter of the data and other relevant factors;
or

(g) in a case where no such actuarial or statistical data is available and cannot reasonably be obtained—the discrimination is reasonable having regard to any other relevant factors.

24.26 The same exception applies both to the refusal to offer insurance (s 46(1)) and to the terms or conditions on which it is offered (s 46(2)).

24.27 According to the *Guidelines for Providers of Insurance and Superannuation* issued by the Human Rights and Equal Opportunity Commission (HREOC) pursuant to s 67(1)(k) of the DDA, actuarial or statistical data upon which insurers may reasonably rely include underwriting manuals, local data (for example, census statistics), relevant overseas studies, and relevant domestic and international insurance experience.²⁶

24.28 Where there are no relevant statistics or actuarial data available, and these cannot reasonably be obtained, insurers are required to show that discrimination is ‘reasonable’ based on other factors. HREOC has suggested a number of factors that insurers may seek to rely on, including:

- medical opinion;
- opinions from other professional groups;
- actuarial advice or opinion;
- relevant information about the individual seeking insurance; and
- commercial judgment.²⁷

Use of genetic information in underwriting

24.29 Submissions received by the Inquiry identified a range of issues and problems related to the use of genetic information in underwriting. On the one hand, allowing unlimited use of genetic information in this context gave rise to concerns about the creation of a ‘genetic underclass’ that would be denied access to insurance and other related benefits. Concern was also expressed about the negative impact that the use of genetic information by insurers may have on individual and public health outcomes. On the other hand, concern was expressed that there was little or no justification for drawing a distinction between genetic

26 Human Rights and Equal Opportunity Commission, *Guidelines for Providers of Insurance and Superannuation*, <http://www.hreoc.gov.au/disability_rights/standards/Insurance/insurance_adv.html>, 27 August 2001.

27 Ibid.

and other health information in the voluntary, mutually rated, personal insurance market and that prohibiting the use of genetic information would threaten the viability of that market. Each of these issues is discussed below.

Equitable access to risk rated insurance products

24.30 A number of submissions expressed concern that allowing insurers access to genetic information would effectively limit the availability of insurance based on genetic status, creating a 'genetic underclass'.²⁸ David Keays expressed the view that:

The cascading discrimination that can result from a genetic test has the potential to foster the creation of a genetic underclass. A group of people who already have the misfortune of inheriting genetic mutations, who then suffer discrimination at the hands of insurance companies, which then limits their opportunity and freedom. Furthermore, because genetic characteristics are passed from one generation to the next, so too is the discrimination that accompanies it.²⁹

24.31 Similarly, the Androgen Insensitivity Syndrome Support Group Australia submitted that:

Basing access to insurance on outcomes of genetic testing also threatens to deny access in some cases to those who need it most. Discrimination against minority groups with genetic conditions so that the majority may enjoy lower premiums, is socially irresponsible and could be considered indicative of a general lowering of social services. To reduce Government based social services and increasingly rely on the private sector to replace those services on one hand, whilst on the other hand allowing providers of those services to apply them in a discriminatory manner or place them out of financial reach of those who need them, has the potential to create a genetic underclass problem never before seen.³⁰

24.32 According to one commentator, the most significant impact of genetics in insurance is likely to be that, as genetic testing becomes cheaper and more accurate, it will enable insurers to establish more detailed and individualised risk assessments that may well operate to reduce insurance pools.³¹

24.33 The IFSA submission noted, however, that:

While insurance is provided by commercial enterprises, there will always be a group of people who cannot be offered insurance. Such a situation currently exists, and is not new with the advent of genetic testing. This occurs because for some individuals

28 See D Keays, *Submission G152*, 14 April 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

29 D Keays, *Submission G152*, 14 April 2002.

30 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

31 T Lemmens, 'Private Parties, Public Duties? The Shifting Role of Insurance Companies in the Genetics Era' in A Thompson and R Chadwick (eds), *Genetic Information: Acquisition, Access and Control* (1999) Kluwer Academic/Plenum Publishers, New York, 31, 32.

the risk of claiming is so high or so difficult to assess, that a reasonable premium either cannot be determined or would be prohibitively high.

The issue of access to insurance for all is an issue of equity and is a matter for government. A socialised insurance system would involve significant cross-subsidies between different groups of policy owners and could risk escalating costs and reductions in participation rates as witnessed in the private health system.³²

24.34 In addition, IFSA expressed the view that the use of genetic test information would not significantly impact on the number of individuals who would be uninsurable:

Various community groups have expressed concern that the use of genetics in underwriting will result in a pool of individuals being unable to secure insurance cover, disadvantaging them financially ...

The introduction of new testing technologies, such as genetic testing, does not in itself impact the underlying health of the population. It does not increase the number of people who are likely to develop severe health conditions in the future, and therefore does not impact the number of people who present such a high risk as to be uninsurable. Therefore, it is not expected to increase the number of people who are declined insurance.³³

Impact on individual and public health outcomes

24.35 IP 26 asked whether there is any evidence that the use of genetic information by insurers deters individuals from taking genetic tests for clinical diagnosis or from volunteering to participate in genetic research.³⁴

24.36 A number of submissions suggested that the potential impact of testing on one's ability to acquire insurance does act as a deterrent.³⁵ In addition, several individuals indicated that they had personally been deterred from undertaking genetic testing for health purposes because of possible discriminatory consequences in relation to insurance.³⁶

24.37 The Director of the Familial Cancer Service in New South Wales, Associate Professor Judy Kirk, expressed the following concerns based on her experiences in the provision of cancer screening and prevention:

32 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

33 Ibid.

34 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–8.

35 G Suthers, *Submission G026*, 30 November 2001; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; B Williamson, *Submission G011*, 26 June 2002, *Confidential Submission G066CON*, 10 January 2002; *Confidential Submission G025CON*, 13 December 2001, Centre for Law and Genetics, *Submission G048*, 14 January 2002; C Roberts, *Submission G072*, 13 January 2002.

36 Melbourne, *Public Meeting*, 22 November 2001; *Confidential Submission G066CON*, 10 January 2002; *Confidential Submission G025CON*, 13 December 2001.

In my experience some people hesitate to even consult and seek advice from such a service for fear that they will have future difficulty with insurance. Insurance companies do ask whether a person has seen a doctor in the last X years, and the consultation at a familial cancer service may be in issue (for themselves and for their family, despite the assurances of the IFSA mandatory standard). Furthermore, it has been reported to me that some insurance companies ask whether one 'intends having' a genetic test. I would also comment that current advice to patients may sometimes infer that they should seek insurance cover before a genetic test is done, and this cannot be of benefit to the system if it becomes a widespread approach.³⁷

24.38 The Human Genetics Society of Australasia (HGSA) submitted that:

It is a relatively common occurrence that we see individuals who decline genetic testing when the potential implications of that test on insurability are raised. These of course are only people who get to the point of seeing a clinical geneticist or genetic counsellor. How many people do not even get to that point because of these concerns is something that we do not, and cannot know. The best way to address this issue is for legislation banning the use of genetic tests in underwriting insurance policies.³⁸

24.39 Finlay Macrae, Head of Colorectal Medicine and Genetics at the Royal Melbourne Hospital held a similar view:

Examples of the IFSA policy on insurance interfering with patients decisions to undergo mutational analysis and predictive testing are not uncommon in clinical practice. I believe that there should be no requirement for disclosure of genetic testing information for life policies to a certain threshold level, as is the practice in some European countries.³⁹

24.40 In consultations, the Genetic Support Network of Victoria noted that they were aware of at least one incident of a medical practitioner advising a person not to be genetically tested in case they became ineligible for life insurance.⁴⁰

24.41 IFSA expressed a contrary view in its submission, noting that:

recent IFSA research of consumer perceptions, [found] there was no evidence ... to suggest that people would refuse a genetic test due to fears about adversely affecting their standing with insurers. In fact most people would have any test should that test be recommended by their doctor.⁴¹

24.42 The majority of submissions that addressed this issue supported some degree of regulation of genetic test information in insurance underwriting to overcome negative consequences for patient health and medical research.

37 J Kirk, *Submission G096*, 30 January 2002.

38 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

39 F Macrae, *Submission G069*, 14 January 2002.

40 Genetic Support Network of Victoria, *Consultation*, Melbourne, 22 November 2001.

41 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

Distinguishing genetic from non-genetic health information

24.43 IP 26 asked whether the equitable treatment of all applicants for insurance would be affected by distinguishing among, or restricting the use of, particular types of health information, such as:

- genetic test information;
- other genetic information, such as family medical history; and
- non-genetically linked health risks.⁴²

24.44 Some submissions cautioned against treating genetic test information in an exceptional way when considering the regulation of genetics in insurance.⁴³ IFSA submitted that ‘treating consumers with access to genetic information differently to the remainder of the insured population would introduce inequities between consumers’. The submission included the following example:

Consumer A — Applies for \$1.0m of life insurance coverage. Due to her age and the amount of cover applied for she is required, as standard practice, to undergo an electro-cardiogram (ECG) which identifies an abnormality. Additional investigations confirm that the applicant has severe coronary artery disease. On the basis of this information the applicant’s mortality is classified as being 4 times that of a standard risk.

Consumer B — Applies for \$1.0m of life insurance coverage. This applicant has previously undergone a genetic test which indicates she will develop, with certainty, a specific medical condition which may result in her death within the next 10 years. At present she is asymptomatic. If disclosure of a previous genetic test were excluded from the underwriting process, the applicant would obtain her insurance cover at standard premium rates.

Both applicants were asymptomatic at time of applying for insurance cover. Both applicants have a significant likelihood of claiming within the next 10 years. However because one has been diagnosed by ECG and the other by a genetic test their insurance applications are treated completely differently.

The industry believes that this situation is both illogical and inequitable.⁴⁴

24.45 By contrast, the Centre for Law and Genetics submitted that:

42 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–11.

43 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002; S Raeburn, *Submission G033*, 2 January 2002; G Whittaker, *Submission G085*, 21 January 2002.

44 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

the justifications for making the distinction outweigh the drawbacks of doing so: put another way, the risks of not protecting genetic test information are greater than any risk or problems arising from seeking to draw this distinction. ...

Whilst *prima facie*, it may seem inequitable to treat genetic test information differently from other health information, some of which may also be predictive or of a particularly sensitive nature, it is submitted that there are good reasons for differentiating in view of the greater risks associated with this kind of information. Of particular concern is the risk that predictive genetic test information will be misunderstood and misinterpreted, treated as having greater probative value than it deserves, resulting in unfair discrimination against individuals. To single out this form of information as one category of information that insurers should not be entitled to, at least for the time being, would not affect the equitable treatment of all insurance applicants. Although some may perceive it as unfair that genetic conditions are given 'favourable' treatment, in contrast to other health conditions, this can be justified as necessary because of the particular risks presently associated with this category of predictive genetic test information. In any event, arguments about alleged inequality do not withstand closer scrutiny as all comers will be treated the same in relation to their genetic test information. The fact that the impact of this may be haphazard, benefiting some more than others, does not necessarily make this approach inequitable.⁴⁵

24.46 The Queensland Government emphasised the importance of a proper understanding of different types of health information, whether genetic or otherwise.

It would appear that the key factor that needs to be addressed in utilising information for underwriting purposes is to ensure that insurers and applicants properly appreciate the significance of the information. The question would appear to resolve itself into whether there is proper understanding and education by all members of the insurance industry of the probative value of genetic test information, genetic information in the form of family medical history and those risks which are not in any way linked to genetic characteristics or functions. This is essential for the information to be used appropriately in assessing risks of particular individuals.⁴⁶

Impact on viability of risk rated insurance market

24.47 IP 26 asked to what extent the exclusion of genetic information from underwriting would threaten the viability of the market for personal insurance.⁴⁷ Chapter 22 of this Discussion Paper examined the phenomenon of 'adverse selection' in mutually rated insurance, that is, where risk is under-rated, leading to a disproportionate number of high risk individuals obtaining cover. This can occur where there are information asymmetries between an applicant and an insurer, such as where the insurer does not have access to genetic information to accurately rate

45 Centre for Law and Genetics, *Submission G048*, 14 January 2002. See also, Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

46 Queensland Government, *Submission G161*, 16 May 2002.

47 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–10.

the risk, although the information is known to the applicant. In this environment, the value of recoverable claims may in time exceed the premiums charged because the calculated risk underestimates the true risk.

24.48 IFSA submitted that prohibiting the use of existing genetic information in insurance underwriting would lead to adverse selection and threaten the viability of the life insurance market.⁴⁸

[T]he industry believes that the ability to continue to use the results of *existing* genetic tests in underwriting is important. Inability to do this would be inconsistent with the principles of a risk-rated insurance system. It would expose the industry to the risk of adverse selection and potentially destabilise the system, as well as lead to the inequitable treatment of different classes of policy owners.⁴⁹

24.49 However, a large number of submissions questioned the severity of the likely impact of denying insurers access to existing genetic information.⁵⁰ The Centre for Law and Genetics, for example, submitted that:

Although these [adverse selection] arguments have frequently been made of the damaging effect for the industry if insurers are denied access to genetic test information for underwriting purposes, rarely have they been substantiated. There is in fact evidence (largely from the United Kingdom), to suggest that, whilst there are risks to insurers arising from adverse selection in the event that applicants have access to genetic test information that is not available to the insurer, the risks are greatest in respect of large policies. This research indicates that the risks arising from adverse selection in relation to small to average size policies would not be significant and certainly would not undermine the viability of the industry. This points to the desirability of distinguishing between large policies on the one hand, for which some measures to protect against adverse selection may be warranted, and small to average sized policies, in respect of which the industry could reasonably be expected to absorb the risks associated with adverse selection.⁵¹

24.50 The Human Genetics Society of Australasia submitted that:

whilst there are theoretical reasons why [adverse selection] may happen, the HGSA is not aware of any specific evidence that it does happen with regard to genetic testing ... It is the view of the HGSA that the current role of genetic testing is extremely minor in the overall insurance industry and if it were excluded from the underwriting process, it would have very little impact on the industry. Evidence for this is the fact

48 See also S Raeburn, *Submission G033*, 2 January 2002; Institute of Actuaries of Australia, *Submission G105*, 7 March 2002. See Chapter 22 for discussion about the causes and effects of adverse selection.

49 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

50 Centre for Law and Genetics, *Submission G048*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; D Keays, *Submission G152*, 14 April 2002; F Richards, *Submission G044*, 14 January 2002; M Otlowski, *Submission G159*, 24 April 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002; K Liddell, *Submission G147*, 10 April 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; J MacMillan, *Submission G015*, 19 November 2001; *Confidential Submission G066CON*, 10 January 2002.

51 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

that the insurance industries in countries where a ban has been placed on the use of genetic information for underwriting purposes remain viable.⁵²

24.51 Graham Whittaker, an actuary with expertise in underwriting, suggested that, while the short-term consequences of prohibiting the use of genetic test information may not be significant, it would be important to consider carefully exactly what information was excluded:

In the short term it is unlikely that the viability of the market would be threatened, as the volumes of significant genetic tests are low. However a consequence would be that some individuals would be able to obtain very cheap insurance for a high risk, unfairly, and subsidised by other policyholders. If 'family history' were excluded (which is a type of genetic data) the position would be much more serious.

The question arises, if family history were admissible, but an individual's genetic test results were inadmissible, what would be the consequences? This is a complex hypothetical, and I would like to see the Inquiry take expert evidence should this be a serious consideration.⁵³

24.52 A body of expert opinion in other countries suggests that the adverse selection effects are unlikely to be significant in the current climate, at least where genetic test information alone is excluded.⁵⁴ Tony McGleenan, who was commissioned by the Association of British Insurers to conduct research into the impact of genetic information on the insurance industry, notes in his report that:

actuarial modelling indicates that four factors are crucial in determining whether adverse selection based on genetic information will be damaging to a life insurance company.

- (i) If the results of the genetic test need not be disclosed to the insurer.
- (ii) If the possibility of the condition being present would not have been revealed in any event by other medical information, notably family history.
- (iii) If the additional mortality risk indicated by the genetic test is higher than that in the broad categories already used to classify risk in underwriting.
- (iv) If there is no therapeutic option to improve the healthcare prospects of someone with a positive genetic test.

52 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

53 G Whittaker, *Submission G085*, 21 January 2002.

54 P Harper, 'Genetic Testing, Life Insurance, and Adverse Selection' (1997) 352 *Philosophical Transactions of the Royal Society of London (B series)* 1063; A Macdonald, 'Modeling the Impact of Genetics on Insurance' (1999) 3 *North American Actuarial Journal* 83; A MacDonald, 'How Will Improved Forecasts of Individual Lifetimes Affect Underwriting?' (1997) 352 *Philosophical Transactions of the Royal Society of London (B series)* 1067; A Macdonald, *Human Genetics and Insurance Issues*, Genetics and Insurance Research Centre, <<http://www.ma.hw.ac.uk/~angus/papers/aberdeen.pdf>>, 1 August 2001; A Macdonald, *Genetics and Insurance: What Have We Learned So Far?* (2002), A MacDonald, 'Genetics and Health Costs: Some Actuarial Models' (2002), to appear in *Law Probability and Risk*.

It must be said that currently, given the costs involved in genetic testing, these diagnostic procedures are usually only performed when clinically indicated for some phenotypic reason other than family history. Therefore, in most cases the condition outlined in (ii) above will not be satisfied. The market for genetic testing for the purposes of satisfying personal curiosity is extremely small and is likely to remain so.⁵⁵

24.53 Angus Macdonald, an actuary with experience in developing empirical actuarial models in genetics and insurance in the United Kingdom, notes that:

The most striking feature about this, often heated, debate is the almost total absence of numerical estimates of the cost implications. Actuarial modelling is beginning to provide such numerical estimates, in the first instance to the question of the costs of adverse selection if life insurers did not know genetic test results. The answers point to a sharp distinction between dominant single-gene disorders and multifactorial disorders. The former are rare enough that solutions outwith the free market should be sought, and (with some exceptions) the latter probably will not provide clear and reliable estimates of lifetime risk, distinguishable from lifestyle and environmental factors; they might therefore not meet criteria of accuracy and reliability such as those that govern discriminatory pricing in respect of disability.⁵⁶

24.54 In its final report, the United Kingdom Human Genetics Commission concluded that:

recent [actuarial] modelling has shown that a moratorium that extended to family history (as well as genetic test results) would be likely to have a large impact on insurance premiums and affordable access to 'essential' insurance. On the other hand, we have also heard that restricting access to family history information might have only a small impact on insurance premiums in most markets in comparison with the commercial variations that already exist. We do not at present recommend that the insurance moratorium should be extended to the use of family history information.⁵⁷

Options for reform

24.55 IP 26 asked whether practical and cost effective mechanisms could be introduced in the mutually rated personal insurance market to enhance access and equity for persons who might otherwise be disadvantaged because of their genetic status.⁵⁸

24.56 The Inquiry received a large number of submissions recommending further regulation of this aspect of underwriting, including some that suggested limited use of genetic information for specific purposes and others that suggested a

55 T McGleenan, *Insurance and Genetic Information* (2001), Association of British Insurers, London.

56 A MacDonald, 'Genetics and Health Costs: Some Actuarial Models' (2002) to appear in *Law Probability and Risk*, 1.

57 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 124.

58 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–12.

complete prohibition on use.⁵⁹ On the other hand, IFSA, the Institute of Actuaries of Australia and a number of personal submissions opposed any significant change in the collection and use of genetic information for the purposes of underwriting.⁶⁰

24.57 In this section the Inquiry examines the following five options:

- maintaining the status quo;
- introducing a two-tier system;
- prohibiting the use of genetic information in underwriting;
- developing specialised insurance products; and
- cross-subsidising poorer risks through an industry or government scheme.

Maintaining the status quo

24.58 The first option to consider is the maintenance of the status quo. Several submissions expressed the view that there should be no change in Australian law as it relates to the collection and use of genetic test information for underwriting. IFSA's submission stated:

59 C Hogan, *Submission G001*, 6 February 2001; J MacMillan, *Submission G015*, 19 November 2001; F Richards, *Submission G044*, 14 January 2002; *Confidential Submission G046CON*, 26 December 2001; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; *Confidential Submission G051CON*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002; *Confidential Submission G066CON*, 10 January 2002; D Pawlukowski, *Submission G067*, 15 January 2002; F Macrae, *Submission G069*, 14 January 2002; C Roberts, *Submission G072*, 13 January 2002; Womens Health Victoria, *Submission G076*, 3 January 2002; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002; Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; New South Wales Nurses' Association, *Submission G090*, 21 January 2002; New South Wales Health Department, *Submission G092*, 25 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; National Council of Women Australia, *Submission G095*, 31 January 2002; Friedreich's Ataxia Association of NSW, *Submission G102*, 22 February 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Australian Privacy Charter Council, *Submission G120*, 18 March 2002; Christian Science Committee on Publication, *Submission G127*, 19 March 2002; C Roberts, *Submission G130*, 18 March 2002; *Confidential Submission G133CON*, 17 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002; Mucopolysaccharide and Related Diseases Society Australia Ltd, *Submission G136*, 20 March 2002; G Parasivam, *Submission G140*, 19 March 2002; Haemophilia Foundation Victoria, *Submission G145*, 25 March 2002; K Liddell, *Submission G147*, 10 April 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; D Keays, *Submission G152*, 14 April 2002; M Otlowski, *Submission G159*, 24 April 2002; Queensland Government, *Submission G161*, 16 May 2002.

60 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002; Institute of Actuaries of Australia, *Submission G105*, 7 March 2002; G Whittaker, *Submission G085*, 21 January 2002; S Raeburn, *Submission G033*, 2 January 2002; N Renton, *Submission G038*, 14 January 2002. See also Insurance Council of Australia, *Submission G010*, 27 June 2001.

The industry views the use of genetic test results in underwriting as an integral part of the medical information currently used, with the important exception that an insurer will not ask an applicant to undergo a genetic test. One type of information does not replace the other, but rather complements it.

The industry supports the current position under law, which is that where genetic testing data relevant to the application is already available to the applicant, then it should be provided to the insurer to assist underwriting i.e. the same as all other knowledge which the applicant has about their health history.⁶¹

24.59 The Institute of Actuaries of Australia also supported the existing framework:

The IAAust believes the framework currently in place is adequate as the outcomes achieved by existing legislation are internally consistent and are also consistent with the objectives of Government (as codified within the present legislation).⁶²

24.60 The Institute went on to identify a range of possible disadvantages that may arise with a move away from the current system:

- The times at which consumers can gain access to insurance coverage are likely to be limited.
- Risk premiums may be expected to be correspondingly higher under these alternative acceptance terms than for fully underwritten business.
- Maximum amounts of cover available may be lower.
- There are likely to be a smaller number of 'substandard' risk factors that will be acceptable to the insurer.
- Claims may only be accepted that arise in a limited number of circumstances. For example, claims may be restricted to accident only causes for the first few years of the contract, or claims for pre-existing risks may be precluded.⁶³

Introducing a two-tier system

24.61 The second option for consideration is the introduction of a two-tier system, which would allow individuals to purchase insurance up to a specified monetary limit without an obligation to disclose genetic information. Once the sum insured exceeded the threshold, full disclosure would be required. Different views might be taken about whether the non-disclosure of information below the threshold applies only to genetic test information, or whether it extends to family medical history.

⁶¹ Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

⁶² Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

⁶³ *Ibid.*, 33.

24.62 The two-tier system attracted some support in submissions on the basis that it would go some way to address consumers' concerns by providing access to a basic amount of insurance. It was also thought to go some way to meet insurers' concerns if the monetary limit was set below the level at which the effects of adverse selection might become apparent.⁶⁴ Associate Professor John MacMillan, Director of the Queensland Clinical Genetics Service, submitted that:

In the case of genetic testing and insurance I believe that a basic level of insurance, regulated by the state not the insurers, should be made available to all irrespective of any genetic test result. This would not expose the industry to adverse selection and would spread the risk and cost over the whole population. Levels above the regulated threshold would need justification in any case and the need for a genetic test could be decided by a body established for that purpose.⁶⁵

24.63 Some European jurisdictions have adopted various forms of the two-tier system. The monetary limits vary depending on the type of insurance purchased. In the United Kingdom, for example, the limit for term life insurance is set at a higher level than other insurance products (for example, trauma insurance and disability income protection insurance) because these other products are more vulnerable to the effects of adverse selection.⁶⁶

24.64 The type of genetic information protected also varies between jurisdictions. In Sweden, the two-tier system applies to the use of genetic test results and family history information, while in the United Kingdom the system applies only to genetic tests, defined as chromosomal cytogenetic tests and molecular DNA tests.⁶⁷

24.65 The method of implementation also varies. The United Kingdom insurance industry has opted for a self-imposed industry scheme to run for five years. In Ireland, law makers are considering a Bill that would impose a two-tier system with respect to the use of family medical history information.⁶⁸

24.66 The monetary threshold varies significantly between countries. For example, the threshold for term life policies ranges from £500,000 (approximately AUD \$1.4m) in the United Kingdom to €60,000 (approximately AUD \$110,000) in Sweden. The difference in the threshold appears to reflect differences in the insurance market and the type of genetic information protected under the threshold. In some countries with a two-tier system, the threshold was initially selected by reference to the average cost of housing because life insurance was generally required for the purpose of obtaining a mortgage.

64 See M Otlowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart.

65 J MacMillan, *Submission G015*, 19 November 2001.

66 See Association of British Insurers, *Submission G053*, 15 January 2002.

67 Ibid.

68 Disability Bill 2001 (Ireland): see the Irish Parliamentary website: <http://www.irlgov.ie/bills28/bills/2001/6801/default.htm>. The Bill imposes a legislative ban on the use of genetic test information.

24.67 The Inquiry has received a number of submissions supporting the adoption of a two-tier approach in Australia.⁶⁹ There are two ways in which a two-tier system could be implemented:

- through the development of industry codes or standards; or
- through legislative amendment in relation to both the collection and use of genetic information by insurers. This could be achieved, for example, by altering the insured's duty of disclosure in the *Insurance Contracts Act 1984* (Cth), and by amending the insurance exemption in the DDA.

24.68 A number of submissions that addressed this issue favoured implementation through industry codes, coupled with independent government oversight and approval of genetic tests. Submissions noted that industry codes would be an effective strategy in the short-term and would retain sufficient flexibility to develop long-term policy at a time when the number of genetic tests being undertaken is small.⁷⁰

24.69 Privacy NSW, for example, recommended

the introduction of a moratorium on the use of genetic information obtained by genetic testing, to be reviewed in 3–5 years, unless a test for a specific condition is approved in the interim by the Genetics Advisory Committee when the moratorium may be lifted in respect to that test.

To address adverse selection concerns, a ceiling policy value should be applied, above which some use of genetic testing information should be allowable.⁷¹

24.70 The Centre for Law and Genetics recommended that:

A 'ceiling' model along the lines suggested ... is readily applicable to life insurance and could also be adapted to disability and related forms of insurance. Such an approach could be accommodated within existing insurance legislation (*Insurance Contracts Act 1984* (Cth)) as a qualification on the usual disclosure obligations: the alternative, and arguably preferable option, would be for this to be dealt with by way of an industry Code or moratorium.⁷²

⁶⁹ See eg Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Association of British Insurers, *Submission G053*, 15 January 2002; F Macrae, *Submission G069*, 14 January 2002; Department of Human Services Victoria Genetics Advisory Committee, *Submission G089*, 24 January 2002; F Richards, *Submission G044*, 14 January 2002; New South Wales Health Department, *Submission G092*, 25 January 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002, 20; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

⁷⁰ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; M Otlowski, *Submission G159*, 24 April 2002.

⁷¹ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

⁷² Centre for Law and Genetics, *Submission G048*, 14 January 2002.

24.71 In addition, the Centre for Law and Genetics noted that:

One of the key advantages of at least delaying the use of genetic test information for the purposes of insurance underwriting (eg through an industry moratorium) is that it permits time for the scientific and actuarial relevance of genetic tests to be established, thus addressing current concerns about the reliability and relevance of information currently used by the industry for underwriting purposes.⁷³

24.72 In its submission to the Inquiry, the Association of British Insurers set out the rationale for the five year moratorium and two-tier system adopted by insurers in the United Kingdom:

The purpose of the five year moratorium, as set out in our press release, is to enable there to be a rational and informed discussion about the best way forward for the UK on genetics and insurance in the medium term. It does so by balancing the desire of those faced by genetic disadvantage to be able to access life and health insurance, with the insurance industry's need to protect itself against the highest levels of adverse selection.⁷⁴

24.73 The Queensland Government submitted that, if a two-tier system were recommended, it should apply only to genetic test results, and not family medical history information.⁷⁵

24.74 Finally, the Centre for Law and Genetics noted that, where approval for the use of genetic tests is required, or where a moratorium is in place

insurers should continue to be able to take account of negative test results in the calculation of premiums (ie where it is to the benefit of the applicant in countering unfavourable family history information).⁷⁶

Prohibiting the use of genetic information

24.75 The third option for consideration is a prohibition on the use of genetic information in insurance. This option also received some support in submissions.⁷⁷ The Androgen Insensitivity Syndrome Support Group of Australia submitted that:

⁷³ Ibid.

⁷⁴ Association of British Insurers, *Submission G053*, 15 January 2002.

⁷⁵ Queensland Government, *Submission G161*, 16 May 2002. See also M Otlowski, *Submission G159*, 24 April 2002.

⁷⁶ Centre for Law and Genetics, *Submission G048*, 14 January 2002.

⁷⁷ Queensland Government, *Submission G161*, 16 May 2002; *Confidential Submission G051CON*, 14 January 2002; *Confidential Submission G066CON*, 10 January 2002; C Roberts, *Submission G072*, 13 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Christian Science Committee on Publication, *Submission G127*, 19 March 2002; *Confidential Submission G133CON*, 17 March 2002; Association of Genetic Support of Australasia, *Submission G135*, 19 March 2002; Haemophilia Foundation Victoria, *Submission G145*, 25 March 2002.

Refusal to undertake genetic testing or to provide genetic information should not be grounds for discriminatory practices in the fields of employment or insurance. There seems to be emphasis on questions of potential discrimination once information is disclosed, why must it even be disclosed in the first instance? Many areas of law enshrine the right to inaction, including criminal law.⁷⁸

24.76 The Genetic Support Council of Western Australia stated:

The genetic support groups were strongly opposed to the idea that their genetic information could be used by insurance companies for underwriting purposes. The groups felt that insurance companies should not be legally allowed to request or use genetic information. This view stems from the concern that insurance companies may not understand the range of genetic tests available, such that a test for a predisposition to a condition not yet present may be treated in the same manner as a diagnosis of a current debilitating condition.⁷⁹

24.77 The Haemophilia Foundation of Victoria stated:

There was a strong and unanimous feeling that insurance companies should NOT have access to genetic information under ANY circumstance. While it is fair that they know of pre-existing conditions, a predisposition to a condition should not have to be declared, even if tests have been conducted and results known. No one has perfect genes!⁸⁰

24.78 IFSA did not support a prohibition on the use of genetic information for the following reasons:

The major disadvantage of a complete ban is that it undermines the basic principles of a voluntary, risk-rated insurance system. Such an approach exposes the industry to the risk of adverse selection and potentially destabilises the system. The main advantage of the approach is that it potentially provides greater access to life insurance to those who are aware of an unfavourable genetic test result. However, the industry believes this preferential treatment is inequitable, as other consumers bear the additional cost.⁸¹

Developing specialised insurance products

24.79 A fourth option for consideration is development by the insurance industry of specialised products that cater for the insurance needs of individuals with genetic disorders or predispositions. The Centre for Law and Genetics submitted that:

We believe that there is definitely merit in encouraging insurers, agents and brokers to specialise in designing products and handling coverage for persons with a higher level of risk due to genetic factors. It is important that the legitimate insurance needs of this category of the population are met and that their difficulties are not compounded

78 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

79 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

80 Haemophilia Foundation Victoria, *Submission G145*, 25 March 2002.

81 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

through insensitive treatment. Development of products with the needs of those at increased risk due to genetic factors in mind and ensuring that those handling coverage for such persons are specialised in the area, would be a way of achieving this objective on terms that are also compatible with the viability of the insurance industry. This strategy could augment the protection provided by a ceiling approach, as recommended above, or possibly be an alternative to it.⁸²

24.80 The Human Genetics Society of Australasia submitted that:

If the overall decision is that insurers are allowed to use genetic information to underwrite policies, it is vital that they produce products that allow those with a genetic predisposition to disease to avail themselves of insurance, including:

1. Having policies below a certain amount of money for which questions about family history and genetic testing are not asked.
2. Having policies that allow coverage for all eventualities other than the genetic illness for which the person is at risk.
3. Having policies with a time limit may be appropriate in some instances.⁸³

24.81 The New South Wales Branch of the Australian Huntington's Disease Association expressed the concern that:

Although it may be possible to design products for those with positive family histories of genetic conditions or positive genetic test results, the cost could be prohibitive for the average Australian family.⁸⁴

24.82 The Institute of Actuaries of Australia submitted that there are a number of alternative products already available to those at higher risk:

Superannuation: The mandatory Superannuation Guarantee Contributions (SGC) provide every employee in Australia with a minimum level of superannuation benefits. These superannuation facilities almost invariably carry a certain amount of life cover. The only entry requirement is that the person covered be fit enough to attend work on the start date. Thus, most people who are fit enough to obtain employment at present have access to some insurance regardless of their predisposition for future health problems. ... Once obtained, superannuation insurance covers can often be maintained even after the employee leaves employment, under continuation cover terms.

Consumer credit insurance: People who buy goods under hire purchase can often obtain insurance to cover the remaining repayment instalments in the event of their prior death. This cover has varying terms from company to company. Sometimes it is offered automatically, without the need to provide evidence of good health.

82 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

83 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

84 Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002.

Credit card offers: Credit card providers, and other organisations including large chains of retail shops, sometimes make offers of simple entry insurance policies. Some of these may have an initial period of accident only cover, say three years, before full cover commences. This prevents a person who may be terminally ill from obtaining cover, while providing insurance to most people, including those who have poor prospects beyond medium term survival.⁸⁵

Cross-subsidising poorer risks

24.83 A final option is the establishment of scheme whereby individuals with poorer risks, who may not otherwise be able to obtain insurance, are directly subsidised for the purpose of obtaining insurance. Depending on the model chosen, the subsidy might come either from government (with cross-subsidisation from taxpayers) or from the insurance industry (with cross-subsidisation from other insureds).

24.84 In the United Kingdom, the recent report of the Human Genetics Commission noted the development of detailed models for the creation of a re-insurance pool, which would provide insurance to poorer risks through a partnership between insurers and government.

24.85 Another model referred to by the Human Genetics Commission was an industry-funded risk pooling system based on the United Kingdom Motor Insurance Bureau model:

A new "Central Insurance Bureau" (CIB) would underwrite life and health insurance for those who cannot obtain insurance because of an adverse genetic test result. Insurance companies would have to be members of the CIB in order to underwrite life and health insurance in the UK. It would be funded by a levy on all life and health insurance of up to 5% of premiums.⁸⁶

24.86 In relation to the idea that government should assume some level of responsibility for providing a basic level of personal insurance cover the Queensland Government submitted that:

The notion of providing basic cover through government-run programs similar to a national medical/hospital insurance scheme, would require considerable resources and depend on the willingness of society to pay for the premiums through increased taxation. It raises the question of how much compensation and taxation the community would be willing to provide.⁸⁷

⁸⁵ Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

⁸⁶ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 135.

⁸⁷ Queensland Government, *Submission G161*, 16 May 2002.

Inquiry's views

24.87 The Inquiry recognises the range of genuine and significant concerns raised by the use of genetic information in underwriting mutually rated personal insurance. However, for reasons explained below, the Inquiry's preliminary view is that a shift away from the fundamental principles of voluntary risk-rated insurance, based on parity of information between the applicant and the insured, is not warranted at the present time.

24.88 Within the last ten years, many countries have begun to confront the challenges posed by the use of genetic information in underwriting. Different approaches have been taken in different jurisdictions, and some countries have experimented with a number of models within a relatively short period of time. The variety of responses suggests that this shared problem has no universal solution that is likely to commend itself to all. Account must be taken of important differences between insurance markets and between social objectives when comparing jurisdictions.

24.89 The consequences of changing the framework for regulating the use of genetic information in underwriting are likely to take considerable time to manifest themselves. In Australia at present, the number of cases in which genetic test information is used to underwrite personal insurance is quite small (see Chapter 23). Moreover, the actuarial data on which underwriting is generally based are concerned with long-term trends of morbidity and mortality, particularly in relation to products such as term life insurance. A thorough evaluation of new regulatory structures is thus likely to take some time. In this environment, much can be gained by monitoring developments in countries that have begun to experiment with alternative approaches. To this end, the Inquiry considers that the proposed Human Genetics Commission of Australia should monitor the experience of the insurance industry in using genetic information in underwriting, both in Australia and overseas, in order to review Australian insurance practices at a later time, if the need arises.

24.90 There are a number of reasons for the Inquiry's preliminary view that there should be no fundamental change to the basis of underwriting applications that involve genetic information. These are set out below in summary form.

- A contract of insurance is a private commercial relationship between an insured and an insurer by which the former agrees to pay a regular premium in exchange for a payout on the occurrence of a defined event. Although insurance can provide insureds and their families with significant financial support in adverse circumstances, private insurers should not be expected to provide a social safety net for Australians regardless of their genetic status — that function is more appropriately performed by the social security system and the public health system.

- Australians do not appear to regard private insurance of the kind presently in question as an essential good. While accurate statistics are not available, it would appear to be common knowledge that not all, or even most, adults have voluntary life insurance.⁸⁸ This suggests that most Australians consider life insurance to be an option rather than a necessity, and may reflect the fact that many other forms of investment and financial services are available. These can provide individuals with financial security for the future, and are not risk rated by reference to genetic status.
- A departure from a system of equality of information between applicants and insureds raises significant issues of equity. If high-risk individuals can join an insurance pool at standard rates, the increased claims by those individuals must ultimately be borne by others. In the absence of a government subsidy, that cost will be borne by other insureds in the insurance pool in the form of higher premiums. This gives rise to inequities because individuals in the pool do not contribute in accordance with the risk they bring to the pool.⁸⁹
- The legal principles upon which personal insurance is currently underwritten do not prevent an individual from obtaining insurance at standard rates merely because of his or her genetic status, so long as that status is unknown to the applicant. The present law targets decision making on the basis of differential information; it does not target decision making on the basis of underlying genetic status as such. A useful analogy is to ask: can a person insure a house against loss by fire while it is burning down? If neither the applicant nor the insurer knows that the house is on fire, there may be no difficulty. However, if the applicant possesses this information and the insurer does not, there is an inherent inequity — others in the pool will have to bear a loss that was known to the applicant at the time of contracting.
- Giving more favourable underwriting treatment to applicants because of the genetic basis of their disease creates an arbitrary distinction between individuals according to the source of their ill-health or disability. There is a grey zone between genetic information and other health information. It is not clear, for example, why a person who has acquired an infectious disease should be treated less favourably in their access to insurance than a person whose disease has a genetic basis. Similarly, it is not clear why a person suffering from a cancer that is not (currently) known to be genetically-linked should be treated less favourably than a person suffering from a cancer that

88 Statistics produced by the Insurance and Superannuation Commission in 1996 suggested that about one-third of Australians had life insurance. However, the reliability of the data has been questioned by IFSA.

89 See eg comments by L Ralph in Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), The Parliament of Australia 35. See also R Pokorski quoted in T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 384.

is. It is for these reasons that the Inquiry rejects the idea of ‘genetic exceptionalism’ — that is, the idea that genetic information is so fundamentally different from, and more powerful than, all other forms of personal health information that it requires different and higher levels of legal protection (see Chapter 6).

- Finally, although the number of applications for life insurance involving genetic test information is currently quite small, it is important to adopt policies that are sufficiently robust to endure in the longer term. As genetic tests become cheaper and more widely used, and as our knowledge of the genetic basis of common disorders such as asthma, diabetes and depression expands, the relevance of genetic test information is likely to grow. If insurers were denied access to that class of information in underwriting, the disparity in the information known to the applicant and the insurer would grow, enhancing the prospect of adverse selection.

24.91 In light of these considerations, the Inquiry has formed the preliminary view that there is no demonstrated need to depart from the fundamental principle underlying the market in voluntary, mutually rated personal insurance in Australia, namely, equality of information between the applicant and the insurer. However, given developments in other jurisdictions, including the introduction of two-tier systems in some European countries, the Inquiry is of the view that the proposed HGCA should keep this matter under review. The proposals in this chapter reflect these preliminary views but the Inquiry invites further comment on these matters, particularly in relation to alternative options for reform identified above.

24.92 The Inquiry recognises, however, that many of the concerns raised in submissions relate to the way in which insurers use, or are perceived to use, genetic information in underwriting. Subsequent sections of this chapter address a range of issues that are directed toward ensuring that the use of genetic information by insurers is fair and transparent, and that insurers are kept to the terms of the exemption granted to them by anti-discrimination laws.

Proposal 24–1. Although there is no demonstrated justification for departing from the fundamental principle underlying the market in voluntary, mutually rated personal insurance (namely, equality of information between the applicant and the insurer), where the underwriting of such insurance involves the use of human genetic information, the process of underwriting should be subject to the qualifications identified in Proposals 24–3 to 24–9 below.

Proposal 24–2. The proposed HGCA should monitor the experience of the insurance industry in using genetic information in underwriting, both in Australia and overseas, with a view to reviewing Australian insurance practices at a later time.

Question 24–1. Should there be a fundamental change to the way in which genetic information is used to underwrite personal insurance, such as the introduction of a two-tier system; a prohibition on the use of genetic information; or a public subsidy for poorer risks?

Testing children and access to insurance

24.93 At a public meeting held by the Inquiry in Parramatta, Sydney, a concerned health professional employed at a children's hospital identified a further issue related to the use of genetic information by insurers. The issue was whether an individual should be obliged to disclose the results of a genetic test conducted on them as a child, as a result of a decision made on their behalf by a parent or guardian, when they seek insurance later in life.⁹⁰

24.94 A related issue is whether parents may be unduly influenced by the use of genetic information in underwriting when making decisions on behalf of a child. In particular, would parents decline to consent to a genetic test being conducted on their child, when the test is in the best interests of the child's health, but may have adverse repercussions for insurance? This concern was highlighted in the following submission received by the Inquiry:

From a personal point of view, I did not register my son's disability as I didn't want any insurance companies to discriminate against him or in the future any of his children or their children. Even if I wanted to, I would not have a genetic test undertaken on my son due to the same reason — lack of confidentiality and possible future discrimination.⁹¹

24.95 At a public meeting held in Melbourne, a member of the public explained the choices that parents face when deciding whether to genetically test children for clinical management:

I have now submitted my DNA for testing, and it's important from my children's point of view that they know whether they have Marfan Syndrome. If they do then we can treat them early and perhaps prevent a premature death. Who should get the right to that information? My personal view at the moment is that they should not even be told themselves. They're at a young age that they are being genetically tested because they can then answer honestly on a form they have never been genetically tested. If they do say they have Marfan's Syndrome they will be discriminated against quite

⁹⁰ Parramatta Public Meeting, 13 March 2002.

⁹¹ Confidential Submission G025CON, 13 December 2001.

clearly by companies whose responsibilities are to shareholders and not to the customer.⁹²

24.96 The Inquiry notes that the general approach in clinical genetics is not to perform predictive genetic testing on children unless ‘the result is likely to be of direct benefit to the child through medical surveillance or intervention’.⁹³ The Human Genetics Society of Australasia noted that:

there is particular concern in regard to predictive testing of children, where many health professionals are willing to perform such tests in response to parental request, without due attention to the long-term interests of the child.⁹⁴

24.97 As discussed in Chapter 23, an applicant for insurance is obliged to disclose every matter that is known to be relevant, or which reasonably ought to be known to be relevant, to the insurer. Where an individual is aware that he or she underwent a genetic test as a child, that individual is obliged under the current law to disclose the results for insurance purposes. As a result, while the circumstances in which children undergo predictive genetic testing may be limited in practice, the potential for adverse insurance consequences still exists.

24.98 Margaret Otlowski has commented that:

in view of the strong terms of the *United Nations Convention on the Rights of the Child*, to which Australia is a party, it is essential that the interests of children are not compromised and that decisions whether to subject a child to genetic testing can freely be made on the basis of medical advice, without fear of later repercussions for the child. Moreover, where genetic testing has been undertaken on a person whilst a minor, (ie at a time that they are not in a position to personally give a full and informed consent to testing), one may question the fairness of requiring that person in later life to disclose to insurers information about the results of those tests. An unqualified obligation to disclose existing genetic test information clearly presents problems for individuals in these circumstances.⁹⁵

24.99 The Australian Medical Association submitted that:

Individual[s] should be given the option to have their childhood genetic test declared ‘null and void’ to insurers when that individual reaches the legal age of consent.⁹⁶

24.100 The Inquiry notes that adults are generally capable of making a voluntary and informed decision about whether or not to provide a genetic sample and submit it for testing. One of the factors considered in that decision making process may be the potential impact of the test results on the individual’s prospects of obtaining

92 Melbourne, *Public Meeting*, 22 November 2001.

93 See Human Genetics Society of Australasia, *Predictive Testing in Children and Adolescents* (1999), Alexandria.

94 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

95 M Otlowski, *Discussion Paper No 1: Implications of the Human Genome Project for Australian Insurance Law and Practice* (1997) Centre for Genetics and the Law, 44.

96 Australian Medical Association, *Submission G091*, 29 January 2002.

insurance. That freedom of choice is not available to a child, for whom a decision is made by a parent or guardian. The Inquiry is interested in receiving further comment about whether an individual's obligation of disclosure should be limited in relation to genetic tests undertaken while the individual was a child.

Question 24–2. Should an adult applicant for insurance be obliged to disclose the result of a genetic test undertaken while that person was a child?

Scientific reliability and actuarial relevance

24.101 As noted above, s 46 of the DDA provides an exception from the operation of the disability discrimination provisions in relation to insurance. The effect of the exception is to enable insurers to discriminate where (a) the discrimination is based upon actuarial or statistical data and is reasonable, or (b) in the absence of actuarial or statistical data, the discrimination is reasonable having regard to any other relevant factors.

24.102 In seeking to rely on genetic information to discriminate between individuals for the purposes of underwriting, insurers must therefore be able to demonstrate either the actuarial or statistical basis of their decision or the reasonableness of their actions. Where the scientific reliability or actuarial relevance of genetic information is doubtful, its use in underwriting may take insurers outside the scope of the exemption and render their discriminatory conduct unlawful.

24.103 Although questions of relevance and reasonableness often arise in relation to genetic information derived from new genetic tests, the use of family medical history is also of concern. This has been recognised by the United Kingdom's Human Genetics Commission and by its House of Commons Science and Technology Committee.⁹⁷ In its final report, the Human Genetics Commission recommended that the government continue to monitor the evidence used by the insurance industry to justify its use of family medical history in underwriting.⁹⁸

24.104 In establishing whether it is reasonable for insurers to rely on genetic information in underwriting, two main issues arise — the scientific reliability of the genetic information and its actuarial relevance. The first factor relates to the link between the existence of a genetic mutation and the expression of a particular disorder; the second relates to the link between the expression of disease and increased morbidity or mortality.

⁹⁷ Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London.

⁹⁸ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 124.

24.105 As discussed in Chapter 6, the genetic expression of a disease does not lead to the certain development of that disease, except in a number of rare monogenic disorders. Yet, a number of submissions expressed the concern that:

genetic information is often credited with greater probative value than it deserves, and in many cases it is treated as if it was medical fact rather than mere prediction.⁹⁹

24.106 For example, a genetic test that indicates a recessive predisposition to a multifactorial disorder will not be as scientifically reliable in terms of predicting health outcomes as a genetic test for a dominant single-gene disorder. As Martin Bobrow has noted:

[G]enetic tests are very good at distinguishing those who carry a particular gene from those who do not. They are somewhat less accurate at identifying those who will and will not eventually get the disease.¹⁰⁰

24.107 Moreover, the expression of a genetic disease or disorder may or may not have a bearing on an individual's mortality or morbidity, particularly where the condition may be treated effectively. It is the role of actuaries to determine the actuarial significance of a particular genetic disease by analysing health data collected from large numbers of individuals. The data enable actuaries to calculate the risk that an applicant with a particular condition will make a claim, if insurance were granted.

24.108 The importance of the statistical link between genetic test results and the occurrence of death or illness has been emphasised by Margaret Otłowski:

There are definite limits to the extent of clinical knowledge and it is not uncommon to find disagreement amongst experts regarding the interpretation of genetic test information. It logically follows that there is greater uncertainty about its relevance in the calculation of risk for the purpose of insurance underwriting. Moreover, in order for sound prediction of disease or lowered life expectation to be made on the basis of a genetic result, statistical information linking a given test result to the occurrence of some disorder will be required: without this additional information which connects genetic test results and the incidence of disease or death, these results lack actuarial import. Thus, the process of establishing relationships between genetic indicators and the economic costs of the risk identified is a painstaking one that must develop separately for each genetic condition.¹⁰¹

24.109 In its submission, the Institute of Actuaries of Australia described the way in which actuarial data used in underwriting is compiled over time:

99 M Otłowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 37.

100 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xvi.

101 M Otłowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 37.

In the early days statistics will be scanty. The development will be experimental at first. The impact of it on life rating factors will at that stage be based mostly on informed opinion. Only after scientific papers have been published will the development be put into widespread use. With familiarity, the development will be further refined and the results re-evaluated. This will lead to another round of medico-actuarial analysis, this time with a larger pool of statistics to work with. So the new development will work its way through a classic learning curve, with the level of confidence in it steadily growing.

This is the way that life insurers have always assessed new medical information for use in underwriting. IAAust sees no reason why insurers would not follow the same pattern with genetic information.¹⁰²

Interpretation and use of genetic test information

24.110 A large number of submissions expressed unease with the insurance industry's present ability to accurately interpret genetic test information, both scientifically and actuarially.¹⁰³ Privacy NSW submitted that:

Evidence indicates that the insurance industry generally does not yet have the information which would be needed to make actuarially sound use of genetic test results.¹⁰⁴

24.111 The Human Genetics Society of Australasia submitted that:

there is inadequate scientific data for interpreting the majority of genetic tests for the purposes of insurance underwriting at this time. The interpretation of data needs to be undertaken by experts in the area, based on published data. It often takes many years following the discovery of a gene to understand the significance of a result, and sometimes even then specific results cannot be interpreted with certainty.¹⁰⁵

24.112 Fiona Richards submitted that:

¹⁰² Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

¹⁰³ F Richards, *Submission G044*, 14 January 2002; Thyroid Australia Ltd, *Submission G045*, 10 January 2002; *Confidential Submission G046CON*, 26 December 2001; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; UnitingCare NSW & ACT, *Submission G052*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; J Boyle, *Submission G057*, 14 January 2002; D Pawlukowski, *Submission G067*, 15 January 2002; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002; New South Wales Health Department, *Submission G092*, 25 January 2002; New South Wales Genetics Service Advisory Committee, *Submission G094*, 25 January 2002; National Council of Women Australia, *Submission G095*, 31 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Neurofibromatosis Association of Australia Inc, *Submission G121*, 18 March 2002; K Liddell, *Submission G147*, 10 April 2002; Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002; D Keays, *Submission G152*, 14 April 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002; M Otlowski, *Submission G159*, 24 April 2002; Queensland Government, *Submission G161*, 16 May 2002.

¹⁰⁴ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

¹⁰⁵ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

I suspect that most insurance companies are not aware of the implications of intermediate range results in [Huntington's disease] testing — this is a complex area which requires highly specialised knowledge. An advisory body would be able to provide this updated information to insurers and assist with interpretation of complex results.¹⁰⁶

24.113 Where the scientific reliability or actuarial relevance of genetic information is uncertain, its use may result in unlawful or otherwise unjustifiable discrimination. The Centre for Law and Genetics stated in its submission that:

In many cases, insurers would probably be able to justify their decisions to load premiums or decline cover on the basis of actuarial or statistical data. But given the broad range of genetic conditions and the increasing number of genetic tests that are available, serious concerns are being raised about the reliability of the actuarial data that is currently being used by insurers to make their underwriting decisions, raising doubts about the lawfulness of their decision-making. Indeed, many have argued that there is presently insufficiently reliable actuarial, statistical or other data available to allow use of genetic test information for underwriting purposes.¹⁰⁷

24.114 A decision of the Human Rights and Equal Opportunity Commission in 2000, involving the interpretation of the equivalent insurance exemption in the SDA, has highlighted both the need for data to come from a source on which it is reasonable to rely, and the breadth of the data that may be so used.¹⁰⁸ In that case the claimant alleged that a 24% loading on the premium for her income protection policy amounted to unlawful discrimination by a life insurer on the ground of sex. Commissioner McEvoy held that the onus was on the insurer to bring itself within the terms of the insurance exemption. However, in the circumstances of the case, McEvoy C was satisfied that the insurer had based the discrimination upon actuarial or statistical data from a source on which it was reasonable to rely. Commenting on the types of information upon which an insurer might rely, McEvoy C stated:

I accept the [life insurer's] submission that actuarial data is not the only relevant data: section 41(1)(c) refers also to 'statistical data', and I accept that this comprehends a wider range of data than 'actuarial data', including statistical comparisons between commission rates paid by various life offices to agents, comparative premium rates charged for similar policies, and differential profiles of policy holders as between life offices, such as contained in the Report of the Disability Committee of the Institute of Actuaries of Australia.¹⁰⁹

24.115 In the case of discrimination on the basis of genetic test information, Margaret Otowski has stated that:

¹⁰⁶ F Richards, *Submission G044*, 14 January 2002.

¹⁰⁷ Centre for Law and Genetics, *Submission G048*, 14 January 2002.

¹⁰⁸ *D v A Registered Life Insurer* (Unreported, Human Rights and Equal Opportunity Commission, Commissioner K McEvoy, 11 February 2000).

¹⁰⁹ *Ibid.*

One can conclude that rejection of a person's application, or other decisions by insurers that are disadvantageous to the applicant (eg imposing higher premiums or attaching other conditions), based on a misinterpretation of genetic test information would amount to unlawful discrimination. Further, it should be noted that in the case of new tests, even if accurately interpreted, there will often not be sufficient actuarial, statistical or other relevant data to be sure on these grounds, which are the only grounds provided for under the Commonwealth *Disability Discrimination Act 1992*, to justify rejection of a person's application for life or other personal insurance, or to charge a higher than normal premium. Individuals could, in these circumstances, bring proceedings under anti-discrimination legislation, although not all individuals facing unlawful genetic discrimination would necessarily be willing to do so.¹¹⁰

Use of family medical history information

24.116 Although many submissions focussed on the interpretation of genetic test results, the Inquiry also received submissions expressing concern about the use of family medical history information in underwriting.

24.117 The Human Genetic Society of Australasia identified the difficult task faced by underwriters in keeping up to date with rapidly changing medical knowledge.

The current situation, whereby the insurance industry works under an industry standard if the company is a member of the Investment and Financial Services Association (IFSA), is open to incorrect underwriting decisions being made by the industry that can greatly discriminate against individuals. This is not only based on genetic testing, but the use of family history. The HGSA is aware of examples where this is the case ... Many of these cases are the result of the fact that individual underwriters do not have access to the latest data and rely on manuals that, because of the rapidity of increasing knowledge in genetic illness, cannot keep up with advances in this area.¹¹¹

24.118 The New South Wales Anti-Discrimination Board submitted that:

In our view use of family medical history, whether or not such information can amount to genetic information, should be subject to greater scrutiny to determine whether or not the information used in the underwriting process is scientifically reliable and actuarially relevant. The independent body we propose above should play a role in evaluating the scientific reliability and actuarial relevance of both genetic and non-genetic information.¹¹²

24.119 A related issue is the way in which insurers deal with the interaction between family medical history information and genetic test information. As noted above, the Inquiry received one submission reporting an incident in which insurers appeared to underwrite on the basis of the applicant's family medical history of

110 M Otlowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (2001) Centre for Law and Genetics, Hobart, 39–40.

111 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

112 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

Huntington's disease, despite the provision of genetic test results that showed that the applicant did not have the genetic mutation for that disease.¹¹³

24.120 The Human Genetics Society of Australasia submitted that:

In the setting where a person has had a genetic test for a familial condition and they have been shown not to have the mutation, this should negate the effect that their family history has on the loading. The basis for this recommendation is that where a family mutation is not present, the evidence is clear that that individual is either at the same risk of the condition in question as others in the community or not at risk at all.¹¹⁴

Independent oversight and approval of genetic tests

24.121 The majority of submissions that considered this issue supported the view that an independent body comprised of experts should oversee the use of genetic test information in underwriting.

24.122 Margaret Otlowski submitted that:

The best solution would be for the creation of an independent multi-disciplinary expert body as has been established in the United Kingdom in the form of the Genetics and Insurance Committee (GAIC) to hear and determine applications for approval of specific genetic tests in insurance, having regard to the scientific and actuarial relevance of the tests. This is particularly important in Australia, where, by the industry's own admission, much more work needs to be done to examine the impact of genetic testing on actuarial modelling.¹¹⁵

24.123 David Keays submitted that:

It is argued that insurers should not be permitted to discriminate on the basis of genetic test results unless they are charged with reliable scientific evidence that can be translated into statistical relevance. An independent body comprised of actuaries, scientists, clinical geneticists and lawyers could monitor developments and authorise discrimination with respect to specific genetic tests when reliable scientific evidence is available.¹¹⁶

24.124 The NSW Anti-Discrimination Board submitted that:

There is a need to establish an independent body to evaluate the scientific reliability and actuarial relevance of genetic information before it is used for underwriting. The UK Genetics and Insurance Committee (GAIC) provides a useful model. In light of the above discussion, we consider that such a body should not be limited to evaluating genetic information only and should also have a role in examining the scientific reliability and actuarial relevance of health research information generally. We

113 Confidential Submission G046CON, 26 December 2001.

114 Human Genetics Society of Australasia, Submission G050, 14 January 2002.

115 M Otlowski, Submission G159, 24 April 2002.

116 D Keays, Submission G152, 14 April 2002.

propose that this body should have the power to assess whether the research upon which actuarial data is based, whether currently in use or proposed for use in the future, is sufficiently current and appropriate to be relied upon in the Australian context for the purposes of determining risk.¹¹⁷

24.125 The Centre for Law and Genetics stated that:

The prospects of ensuring that accurate and reliable information is uniformly available to agents and brokers would be greatly enhanced if this responsibility was shared between the insurance industry and government, through the work of an expert committee established for the specific purpose of evaluating the scientific and actuarial relevance of genetic tests proposed for use by the insurance industry in setting insurance premiums, along the lines of the *Genetics and Insurance Committee* (GAIC) established in the United Kingdom.¹¹⁸

24.126 A number of submissions also expressed support for the inclusion of family medical history information in the remit of the independent expert body. Privacy NSW submitted that:

Questions have been raised about the accuracy of actuarial decisions based on family history information. Ideally, if a Genetics Advisory Committee is formed, the safest option is to include family history information in the proposed moratorium on the use of genetic testing information. Alternatively, if family history information continues to be used, the Genetics Advisory Committee should assess the way it is used in the light of progress in genetics. Proposers should be provided with appropriate information to assist them to understand how this information may affect their applications.¹¹⁹

24.127 The NSW Anti-Discrimination Board proposed an even wider role for an independent body, suggesting that it should be established to evaluate the scientific reliability and actuarial relevance of:

- genetic information proposed for use by the insurance industry before genetic information is used for underwriting; and
- non-genetic information whether used or proposed for use by the insurance industry for underwriting.¹²⁰

24.128 The Institute of Actuaries, however, took a different view:

Government has not usually involved itself in examining, testing or approving the use that is made of medical or other information in underwriting. These would be daunting tasks to undertake. In effect they would require Government to establish some form of central Government Underwriting Department. This would require a set of skills we do not believe is currently available within the Public Service. There is no

117 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

118 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

119 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

120 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

case for this made in the Issues Paper and it is not a course that IAAust would support.¹²¹

Inquiry's views

24.129 The purpose of federal anti-discrimination law is to promote a more equitable society by preventing unfair discrimination against individuals on a number of stated grounds. This policy is stated in the DDA, for example, in the following terms:

The objects of this Act are:

- (a) to eliminate, as far as possible, discrimination against persons on the ground of disability in the areas of ... the provision of goods, facilities, services ...
- (b) to ensure, as far as practicable, that persons with disabilities have the same rights to equality before the law as the rest of the community; and
- (c) to promote recognition and acceptance within the community of the principle that persons with disabilities have the same fundamental rights as the rest of the community.¹²²

24.130 In exempting insurers from the operation of the DDA, the legislature has recognised that differentiation between individuals goes to the very nature of mutually rated insurance business. However, the exemption from the general proscriptions of the Act is expressly confined to discrimination based on reasonable actuarial or statistical data, or (where no actuarial or statistical data is available) to discrimination that is otherwise reasonable. If neither test is satisfied, the inherently discriminatory conduct of insurers in underwriting mutually rated insurance will be unlawful.

24.131 The Inquiry notes the strength of disquiet that has been identified in consultations and submissions in relation to the use of genetic test results and family medical history in underwriting. Common to both types of genetic information is a concern that our understanding of the genetic basis of disease is changing rapidly, and that this presents a serious challenge for underwriters in establishing the necessary links between genetic mutation and disease, on the one hand, and between disease and mortality and morbidity, on the other. In addition, our experience with genetic test information is relatively new, so that there has been no deep accumulation understandings, cases and precedents upon which to base underwriting decisions.

24.132 The exemption in the DDA already recognises that actuarial or statistical data may not be available in some cases. In such circumstances, the legislation

¹²¹ Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

¹²² *Disability Discrimination Act 1992* (Cth) s 3.

requires the discrimination to be ‘reasonable having regard to any other relevant factors’ if it is to enjoy the benefit of the exemption. The submissions received by the Inquiry demonstrate that different views may be taken as to what is reasonable, reflecting the different interests of stakeholders in making the assessment. Applicants wish to ensure that they are afforded access to insurance on just terms and are not penalised by reason of their genetic status, over which they have no control. Insurers wish to ensure that, at the same time as attracting new customers, they do not consistently under-rate risks, thereby jeopardising the stability of the insurance pool and the long-term viability of their business. The latter concern is a real one, as evidenced by the collapse of some general insurance businesses in Australia in recent times.

24.133 Apart from a slow and costly formal review by a court or tribunal, the present system offers no independent oversight of whether the discriminatory use of genetic information is based on reasonable actuarial or statistical data, or is otherwise reasonable. Insurers themselves determine which genetic information is considered to be scientifically reliable and actuarially relevant, and then apply this information in particular ways to underwrite individual applications. From the perspective of an applicant who has received an unfavourable underwriting decision, this practice may give rise to dissatisfaction — even if the decision may be sound in fact and falls within the terms of the insurance exemption.

24.134 In the light of these considerations, the Inquiry has formed the preliminary view that some degree of independent oversight of the use of predictive genetic test information in underwriting is needed. Oversight by an independent expert body would help to ensure that the use of genetic test information in underwriting is either firmly based on actuarial or statistical data or that it appears to be reasonable, in the absence of such data.

24.135 In making this proposal, the Inquiry is not suggesting that insurers currently use genetic information to underwrite applications in a manner that falls outside the terms of the exemption in s 46 of the DDA or equivalent legislation. Such a claim could only be substantiated by a thorough investigation of the facts of particular cases. Rather, it is the Inquiry’s present view that independent oversight would help to build public confidence that genetic information is being used to discriminate only in the limited circumstances permitted by law. By utilising the advice of an independent body, an insurer’s use of genetic information in underwriting may be seen to be transparent and based on objective information. In this context, the Inquiry recalls the note of caution sounded by the United Kingdom’s House of Commons Science and Technology Committee:

We regret that the insurance industry insisted on using genetic tests before their reliability had been fully established. In hindsight it would have been better if the

insurance industry had proceeded far more cautiously in this difficult area, which at present can bring them little financial return but a great deal of adverse publicity.¹²³

24.136 The Inquiry envisages that an independent body would have a role in standard-setting for the industry, but would not be involved in making or reviewing individual underwriting decisions. The Inquiry notes the concerns raised by the Institute of Actuaries of Australia in regard to the actuarial skills ‘currently available within the Public Service’. As discussed in Chapter 3, the Inquiry proposes the establishment of a national standing body on human genetics — the Human Genetics Commission of Australia (HGCA) — with a balanced and broad-based membership, including both expert and community representation. The Inquiry is of the view that a body established in accordance with the proposals in Chapter 3 would have the levels of expertise and authority necessary to provide appropriate oversight through the approval of particular predictive genetic tests for use in underwriting. The Inquiry envisages that the approval process would be a public one involving consultation with relevant stakeholders, including consumers, insurers and actuaries.

24.137 Different views have been expressed about how a system that requires HGCA approval might be implemented. One option would be for the insurance industry to amend its industry codes to prohibit the use of results from a genetic test unless the test had been approved for use in underwriting by the HGCA. Such an approach could be implemented, for example, by amendment to IFSA’s Genetic Testing Policy. An alternative approach would be to give effect to the proposal through legislation. For example, anti-discrimination legislation could be amended to make it lawful for an insurer to discriminate on the basis of information obtained from a genetic test approved by the HGCA.¹²⁴ A complementary change might be to amend the *Insurance Contracts Act 1984* (Cth) so that an applicant’s duty of disclosure in relation to predictive genetic tests is limited to results of tests approved for use by the HGCA. The Inquiry has no view at present as to how best to implement Proposal 24–2 and accordingly invites further comment in relation to this issue.

24.138 Chapter 23 noted that family medical history, as a form of predictive genetic information, has been used by insurers for the purpose of underwriting for many decades. Consequently, the industry has had a long period in which to collect statistical data and assess its actuarial relevance, particularly when compared with genetic test information. However, the use made of family medical history is in some ways more abstract and subjective than genetic test information. In particular, problems may arise because of the quality of the data collected about genetic

123 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000-1), The Stationery Office Limited, London, xxvi.

124 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

relatives, missing information, or the lack of medical understanding about the genetic influences on common diseases.

24.139 The Inquiry has noted previously that current industry policies on the use of genetic information in underwriting, such as IFSA's Genetic Testing Policy, do not address the use of family medical history. This is also true of most European two-tier systems. The Inquiry does not propose that the HGCA be asked to approve the use of the family medical history for underwriting purposes because such an approach is likely to be impractical, given the variability of circumstances in which family medical history may be relevant. However, the Inquiry is of the view that insurers, through their peak bodies, should develop industry policies on the use of family medical history in underwriting to ensure that discrimination based on such information is scientifically reliable and actuarially relevant. Such policies should be developed in consultation with the proposed HGCA.

Proposal 24–3. No predictive genetic test should be used by insurers in underwriting mutually rated insurance unless the test has been approved for that purpose by the proposed HGCA.

Question 24–3. Would Proposal 24–3 be implemented most effectively through an industry code or legislation? If the latter, should this be through amendment to: (a) the insurance exemption in anti-discrimination legislation; (b) the duty of disclosure in the *Insurance Contracts Act 1984* (Cth); or (c) both?

Proposal 24–4. The insurance industry, through its peak bodies and in consultation with the proposed HGCA, should develop and publish policies on the use of family medical history for underwriting mutually rated insurance.

Insurer's duty to provide reasons

24.140 In IP 26 the Inquiry asked whether insurers should be required to provide applicants with information and data to support unfavourable underwriting decisions based on genetic information.¹²⁵

24.141 The Inquiry received a number of submissions expressing the view that the reasons provided by insurers for unfavourable underwriting decisions are, from an applicant's point of view, generally inadequate. Moreover, the mechanisms for

¹²⁵ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–2.

obtaining reasons were seen in some circumstances to be unduly onerous. The NSW Anti-Discrimination Board expressed a common view in the following passage from its submission:

Without an adequate independent mechanism for evaluating the scientific reliability and actuarial relevance of genetic information, an onerous burden will fall to individuals to lodge complaints under anti-discrimination legislation in order to test the actuarial relevance of the genetic information upon which the insurers seek to rely and the accuracy of the interpretation of that information in the underwriting process. To allow the scientific reliability and actuarial relevance of predictive genetic test information to be determined on a case by case basis is totally inadequate to address the complexities of determining the use of genetic information when applied to risk rating for insurance purposes.¹²⁶

Current law and practice

24.142 The extent to which an applicant is given reasons for an adverse underwriting decision is currently regulated in three ways:

- s 75 of the *Insurance Contracts Act 1984* (Cth) imposes a duty on insurers to give applicants written reasons for an unfavourable underwriting decision, where requested to do so;
- s 107 of the DDA enables the President of the Human Rights and Equal Opportunity Commission (HREOC) to require an insurer to disclose the source of the actuarial or statistical data on which a discriminatory act was based; and
- IFSA's Genetic Testing Policy requires members to give reasons in a clear and meaningful way in respect of adverse decisions based on genetic test information.

24.143 The first and second methods apply to underwriting decisions irrespective of whether they use genetic information. The third is specific to genetic information, but is confined to genetic test information to the exclusion of family medical history. Each of these provisions is described in more detail below.

24.144 Section 75(1) of the *Insurance Contracts Act* currently provides:

Where an insurer:

- (a) does not accept an offer to enter into a contract of insurance;
- (b) cancels a contract of insurance;

126 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

(c) indicates to the insured that the insurer does not propose to renew the insurance cover provided under a contract of insurance; or

(d) by reason of some special risk relating to the insured or to the subject-matter of the contract, offers insurance cover to the insured on terms that are less advantageous to the insured than the terms that the insurer would otherwise offer;

the insurer shall, if the insured so requests in writing given to the insurer, give to the insured a statement in writing setting out the insurer's reasons for not accepting the offer, for cancelling the contract, for not renewing the insurance cover or for offering insurance cover on less advantageous terms, as the case may be.

24.145 Section 107 of the DDA provides a legal mechanism for HREOC to obtain access to 'the source of the actuarial and statistical data' used in assessing an individual's insurance application. Section 107 provides:

If a person has engaged in an act of discrimination that would, apart from section 46 be unlawful, the President or the Commission may, by notice in writing served on the person as prescribed, require the person within 28 days after service of the notice on the person, to disclose to the President or to the Commission, as the case may be, the source of the actuarial or statistical data on which the act of discrimination was based and, where the President or the Commission, as the case may be, makes such a requirement of a person, the person must not, without reasonable excuse, fail to comply with the requirement.

Penalty: \$1,000.

24.146 IFSA's Genetic Testing Policy addresses the issue of providing reasons to an applicant in the following terms:

11. All underwriting decisions, involving a genetic test, whether or not the test was a significant factor in the decision, should be thoroughly documented, so that adequate information can be provided to the applicant on request. ...

12. Insurers will provide reasons for offering modifications or rejections to applicants in relation to either new applications or requests for increases on existing policies.¹²⁷

24.147 The explanatory notes to the last quoted rule go on to say that members will inform applicants 'in a clear and meaningful way' of the reasons for the decision; reasons may be given to the applicant's doctor in appropriate cases; and members will include information on how an applicant can lodge a complaint in relation to the decision.

Consultations and submissions

24.148 A number of submissions were critical of s 75 of the *Insurance Contracts Act*. Margaret Otlowksi, for example, noted that:

¹²⁷ Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

Under the *Insurance Contracts Act* — individuals can request in writing that they be given written reasons. There are, however, questions about the scope of this provision and whether it would entitle an individual to details of the actuarial or statistical data (or other data) relied on by the insurance company in reaching its decision.¹²⁸

24.149 The Human Genetics Society of Australasia recommended that the insurance industry be compelled by law to provide an explanation for loading or refusal of policies in every case:

This explanation should be provided to the individual and any third party nominated by the individual such as their medical practitioner. Any decision to refuse, or to load, an insurance policy based on the genetic test result must be justified by reference to appropriate medical literature, and appropriate peer review studies.¹²⁹

24.150 Other submissions directed criticisms toward s 107 of the DDA. The Centre for Law and Genetics noted the practical need to lodge a complaint with HREOC in order to invoke the Commission's power under s 107, with the consequence that the desired information may come too late:

At present, the only sure means by which an individual can gain access to relevant actuarial and/or statistical data is by lodging a complaint with the Human Rights and Equal Opportunity Commission under the *Disability Discrimination Act 1992* (Cth), thereby invoking the power in the Commission under s 107 of the Act to require a person who is *prima facie* in breach of the prohibition against unlawful discrimination to disclose to the commission the source of the actuarial or statistical data on which the act of discrimination was based. This seems an unduly onerous and impractical approach, particularly in view of the fact that the availability of this information may well be influential in deciding whether or not to bring proceedings under the *Disability Discrimination Act* (or equivalent state or territory legislation).¹³⁰

24.151 Similarly, the NSW Anti-Discrimination Board submitted that:

There are some inadequacies with this provision. First, the provision appears to limit disclosure to the *source* of the data, rather than the data itself. Secondly, the provision only refers to 'disclosure to the President or to the Commission'. As far as we are aware, the terms of the provision have not been used to prevent disclosure of the information to the complainant. However, in the interests of clarity, it should be made clear that complainants are entitled to access the information disclosed to the President or the Commission.

The [*Anti-Discrimination Act 1977* (NSW)] does not enable the President to compel the parties to a complaint to produce documents which may be relevant to the investigation of the complaint. As such, where the respondent seeks to rely upon actuarial and statistic evidence for their decision, the insurer cannot be compelled to provide the information until that matter is before the Administrative Decision Tribunal. It is only then, that the complainant could subpoena the relevant material.

128 M Otlowski, *Submission G159*, 24 April 2002.

129 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002, 30. See also Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

130 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

As a result individuals are often unable to assess the merits of their case until the matter has been referred to the relevant court or tribunal for hearing. We do not consider this appropriate for the reasons outlined in section 5.3 above.¹³¹

24.152 A number of submissions also expressed support for greater transparency in relation to genetic information used in underwriting. The NSW Anti-Discrimination Board stated that:

We strongly disagree with the view expressed by IFSA that the current methods of risk assessment using genetic information are sufficiently transparent and accountable to the public because the DDA provides consumers with the capacity to lodge a complaint and this in turn would mean that the insurer may be required to provide evidence in support of their underwriting decision. We do not consider that it is acceptable for insurance companies to require individuals to lodge a complaint before such information is provided to consumers.

In our view, consumers should have the right to access adequate information about the basis for the insurers decision and the actuarial or statistical evidence on which the insurer has relied in making that decision. It is only with such information that consumers can determine whether to challenge the decision under anti-discrimination legislation.¹³²

24.153 The Centre for Law and Genetics suggested that:

The information provided should include an explanation, in layman's terms, of the reasons for the unfavourable underwriting judgment and the actuarial basis for that decision. To avoid the feedback to the individual being entirely negative, where possible, it would be desirable if information could be provided about alternative insurance products and or options which may be open to the applicant, notwithstanding the genetic information.¹³³

24.154 Other submissions suggested that it may be difficult to disclose the actuarial or statistical data on which an underwriting decision is based for 'commercial in confidence' reasons.¹³⁴ The Institute of Actuaries of Australia, in its submission to the Inquiry, noted that:

if all this information were to be provided on every request, the applicant would most often receive an overwhelming quantity of data that is incomprehensible except to an expert. Life companies prefer to start by giving a plain English explanation that is consumer friendly.¹³⁵

131 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

132 Ibid.

133 Centre for Law and Genetics, *Submission G048*, 14 January 2002. IFSA's Genetics Testing Policy makes provision in this regard. Rule 10.13 states that, if an application is rejected, 'members should endeavour to offer alternative terms (as may be actuarially justifiable) or alternative products': Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

134 M Otlowski, *Submission G159*, 24 April 2002.

135 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

Inquiry's views

24.155 The Inquiry is of the view that applicants are entitled to know the reasons for an adverse underwriting decision. Transparency of decision making has the benefit of building public confidence in the way in which insurers use genetic information in underwriting. It also creates checks and balances by providing consumers with the means of ensuring that the discriminatory acts of insurers fall within the terms of the exemptions permitted by law.

24.156 The Inquiry considers that the reasons provided must be effective for the purposes of consumer understanding and possible review — and they may fail to be so if an insurer provides either too little information or too much. A bare statement that an applicant has been denied insurance because of her family history of a particular genetic disorder is unlikely to satisfy a consumer's wish to understand the basis of an adverse decision. On the other hand, the provision of vast quantities of raw statistical or actuarial data is unlikely to offer an applicant any better understanding.

24.157 The Inquiry regards IFSA's policy for its members as encapsulating the essence of effective reasons: insurers should inform applicants 'in a clear and meaningful way of the reasons for their decision in relation to the application'.¹³⁶ However, much will depend on how such principles are applied in practice.

24.158 With these considerations in mind, the Inquiry has formed the preliminary view that existing legal mechanisms and industry practice may fall short of the desired standard in several respects.

- Section 75 of the *Insurance Contracts Act* imposes a duty on insurers to 'give to the insured a statement in writing setting out the insurer's reasons', but it says nothing of the adequacy of those reasons or the statistical or actuarial basis for the decision.
- Section 107 of the DDA enables HREOC to require an insurer to disclose the source of the actuarial or statistical data on which a discriminatory act was based. However, the section does not indicate that an applicant is entitled to the information so obtained; the section is obscure in so far as it requires disclosure of the 'source' of the data; and disclosure may in any case come too late to be effective.
- IFSA's Genetic Testing Policy provides a sound model in relation to the giving of reasons, but the policy applies only to genetic test information, not

136 Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney, 10.12.1.

to family medical history. Moreover, the success of the policy ultimately will depend upon how it is implemented in practice by individual insurers.

24.159 The interest of consumers in obtaining adequate information about adverse underwriting decisions is not, of course, confined to underwriting based on genetic information. The NSW Anti-Discrimination Board made this point in its submission when referring to the findings of its recent report into Hepatitis C related discrimination.¹³⁷ To that end, the Board expressed support for legislative amendments that would compel insurers to provide consumers with access to adequate information in relation to all unfavourable decisions.¹³⁸ While there may be merit in such a broad approach, in conformity with the terms of reference, the Inquiry's proposals are confined to the situation in which an application has been assessed using the person's genetic information.

Proposal 24–5. The *Insurance Contracts Act 1984* (Cth) should be amended to clarify the nature of the obligation of an insurer to provide written reasons for an unfavourable underwriting decision. Where such a decision is based on genetic information, the insurer should give reasons that are clear and meaningful and that explain the actuarial or statistical basis for the decision.

Proposal 24–6. The *Disability Discrimination Act 1992* (Cth) and related legislation should be amended to clarify the nature of the information required to be disclosed by an insurer and to ensure that the complainant is entitled to access to the information so disclosed.

Proposal 24–7. The insurance industry, through its peak bodies, should develop a policy regarding the provision of reasons by an insurer to an applicant in response to an unfavourable underwriting decision based on family medical history. The policy should ensure that the reasons given are clear and meaningful and that they explain the actuarial or statistical basis for the decision.

Review and appeal mechanisms

Industry regulation

24.160 In its submission to the Inquiry, IFSA described the current review and appeal mechanisms available to unsuccessful applicants for life insurance:

137 NSW Anti-Discrimination Board, *C-change: The Report of the Enquiry into Hepatitis C Related Discrimination* (2001), Sydney.

138 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

All life insurers have complaints handling processes. With the advent of licensing requirements under the *Financial Services Reform Act 2001*, these processes will be required to meet specified minimum standards approved by ASIC and we should therefore see further consistency across the industry.

Should a customer be dissatisfied with an insurer's response then a complaint can be considered by FICS [Financial Industry Complaints Service] at no charge to the customer. Determinations by FICS are binding on the insurer.

FICS does not consider complaints relating to underwriting, so in the case of dissatisfaction with an underwriting decision, the complaint may be referred to the Human Rights and Equal Opportunity Commission (HREOC).

At present, prior to the new licensing requirements, normal industry practice is to provide a consumer who is not satisfied with an insurer's decision with details of the external dispute body that can consider their complaint.¹³⁹

24.161 IFSA's customer brochure on genetic testing in life insurance provides applicants with the following information about monitoring and compliance with the IFSA Genetic Testing Policy:

If you believe that an IFSA member company has breached the provisions of the IFSA Genetic Testing Policy, then contact the IFSA's Senior Policy Manager (Life Insurance). IFSA will review the matter with a view to liaising with the member company to ensure that the Policy has been followed.

If after IFSA has liased on your behalf you are still of the view that you have been subject to discrimination you may take the matter of discrimination up with the Human Rights & Equal Opportunity Commission (HREOC).¹⁴⁰

24.162 Clause 10.14 of IFSA's Genetic Testing Policy requires that:

Insurers will have a competent & efficient internal dispute resolution system to deal with complaints relating to underwriting decisions involving a genetic test result. Responses to any complaints must include a reference to the legal remedies available to the applicant.¹⁴¹

24.163 As of January 2002, IFSA had not received any complaints from consumers in relation to the application of the Genetic Testing Policy.¹⁴²

24.164 The Financial Industry Complaints Service (FICS) is an independent body that was established to assist consumers in the resolution of complaints relating to members of the financial services industry, including life insurers. The FICS scheme is approved by the Australian Securities and Investments Commission (ASIC) in accordance with ASIC Policy Statement 139 — 'Approval

139 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

140 Ibid.

141 Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney, clause 10.14.

142 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

of external complaints resolution schemes'. FICS receives complaints directly from insurance applicants and has the authority to make determinations that are binding on participating life insurers.¹⁴³

24.165 However, as noted in Chapter 23, the FICS rules stipulate that it does not have the power to consider complaints related to 'underwriting or actuarial factors leading to the rejection of an insurance proposal for commercial or medical reasons'.¹⁴⁴ The Inquiry has received advice from FICS indicating that there may be some scope for it to examine the actuarial basis of decisions when a proposal 'was rejected maliciously, or on the basis of incorrect information',¹⁴⁵ but this possibility does not appear to be utilised in practice.

24.166 In addition to the role of FICS in respect of life insurance, the Insurance Enquiries and Complaints Ltd (IEC) handles complaints about general insurance matters. The IEC is also an ASIC approved scheme, which may make determinations that are binding on participating general insurers.¹⁴⁶ Like FICS, the IEC does not generally have the power to consider complaints about an insurer's underwriting decisions.¹⁴⁷

Anti-discrimination legislation

24.167 A complaint of unlawful discrimination based on the use of genetic information by an insurer can be brought before HREOC, which has the power to investigate and conciliate complaints under the DDA.¹⁴⁸ Of the total 789 complaints received by HREOC in relation to alleged unlawful discrimination under the DDA during the period 2000–2001, 19 complaints were received in relation to insurance and superannuation.¹⁴⁹ To-date, HREOC has not received a complaint in relation to the use of genetic test information in insurance.¹⁵⁰

24.168 Once a complaint has been lodged, HREOC has the power to require an insurer to provide actuarial or statistical data in accordance with s 107 of the DDA. As discussed above, a number of submissions raised concerns about the effectiveness of this mechanism.

143 Financial Industry Complaints Service, *Rules* (2002), Melbourne, rules 38, 39.

144 *Ibid*, rule 15.

145 W Ribbands, *Correspondence*, 23 July 2002. See also Financial Industry Complaints Service, *Rules* (2002), Melbourne, rule 15.

146 Insurance Enquiries and Complaints Ltd, *The General Insurance Enquiries and Complaints Scheme: Terms of Reference*, <<http://www.iecltd.com.au/index2.html>>, 26 July 2002.

147 *Ibid*, 2.2(b).

148 *Human Rights and Equal Opportunity Commission Act 1986* (Cth) s 11(1)(aa).

149 Human Rights and Equal Opportunities Commission, *Annual Report 2000–2001*, <http://www.hreoc.gov.au/annrep00_01/chap2.html>, 19 July 2002, Ch 2.

150 D Mason, *Correspondence*, 18 July 2002.

24.169 If a complaint of alleged unlawful discrimination cannot be conciliated, the complainant may apply to have the complaint considered by the Federal Court or the Federal Magistrates Service.

24.170 IFSA expressed the view that the anti-discrimination regime provided an effective mechanism for insurance applicants to pursue their rights:

IFSA believes that existing anti-discrimination laws are adequate. In the past they have allowed people to seek recourse when needed and we see no reason why they should fail where genetic information is concerned. We do not see genetic information as being any different to any other type of information collected for risk assessment.¹⁵¹

24.171 The NSW Anti-Discrimination Board, however, raised the following concerns in relation to relying on the anti-discrimination regime to address consumer complaints in the insurance context:

IFSA's approach also fails to acknowledge the power inequities which exist between individuals and insurance companies. Where an application for insurance is refused, the onus is on the individual to lodge a complaint under anti-discrimination law. This means people have to understand their experience as discrimination, and have sufficient information and resources to use the complaints mechanisms available.

Even if consumers can do so, there is a significant imbalance of power between consumers and the insurance industry, particularly in relation to their respective capacities to bear the costs involved in pursuing a matter to hearing. This can lead to unsatisfactory settlements at conciliation, while in turn conciliated settlements do not produce binding precedents. It is clear that from the HCV Enquiry that there are very real limitations with individual complaint mechanisms in bringing about systemic change.¹⁵²

Awareness of existing complaint mechanisms

24.172 A number of submissions indicated that consumers are not made sufficiently aware of the complaint mechanisms available to them in the area of insurance. The study conducted by Dr Kristine Barlow-Stewart and David Keays noted that:

None of the cases of reported genetic discrimination indicated that they were followed by an exhaustion of the available appeal mechanisms and three individuals stated they were unaware how to appeal against the decision of an insurance company. It is apparent that consumers are unaware of the mechanisms available for redress following discrimination.¹⁵³

151 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

152 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

153 K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 258.

24.173 As noted earlier in this chapter and in Chapter 23, IFSA has taken steps to improve this situation, particularly in relation to the Genetics Testing Policy, which imposes an obligation on members to inform applicants about their legal rights to challenge an unfavourable decision.¹⁵⁴

24.174 The NSW Anti-Discrimination Board submitted that government and anti-discrimination agencies also need to be more active in making individuals aware of their right to lodge a complaint of unlawful discrimination in insurance under anti-discrimination law:

People are less likely to be deterred from undertaking genetic testing if they are confident that their human rights will be protected. In order to instil such confidence in the community, not only must privacy and anti-discrimination laws provide adequate protection, people must understand their rights. We refer you to section 3.3.9 above where we emphasise the important role anti-discrimination agencies can play in educating those affected about their rights. As we have discussed, if complaint handling mechanisms are fraught with delays, people are unlikely to feel confident that anti-discrimination legislation will provide effective redress. Community confidence is also likely to be supported where people are assured that they can access information upon which insurance companies base their decision.

So too, anti-discrimination agencies have a critical role to play in working with employers, insurance companies and other service providers to prevent discrimination.¹⁵⁵

Options for reform

24.175 A number of submissions proposed changes to the existing review and appeal mechanisms available to applicants, drawing particularly on the experience of some overseas jurisdictions.

24.176 In the United Kingdom, the Association of British Insurers (ABI) has established the Genetic Testing — ABI Code of Practice Adjudication Tribunal, which can receive and adjudicate alleged breaches of the ABI Genetic Testing Code of Practice for life insurance and some forms of general insurance. The Code of Practice states in part:

48. If an applicant has concerns about any aspect of his/her application for insurance and the resulting decision, he/she should contact the company using its complaints procedure. If the company cannot satisfy the applicant within a reasonable period of time, and the complaint is about a breach in the Code of Practice, the applicant has the right to refer the case to the independent Genetic Testing — ABI Code of Practice Adjudication Tribunal to which ABI companies agree to be bound. The Tribunal, like other adjudication services, will consider appeals only if the insurer's own complaints mechanism has not resolved the issue to the complainant's satisfaction. The applicant, of course, is free to apply to another insurance company at any time.

¹⁵⁴ Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney, 10.14.2.

¹⁵⁵ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

49. The independent Adjudication Tribunal will comprise individuals who have the confidence of both the insurance industry and the public. Amongst them, they will demonstrate a clear understanding of insurance law and underwriting practice and of genetic science and its clinical implications.

50. The Tribunal will consider a complaint from an individual where the insurance company has allegedly breached the Code of Practice when considering his/her application; there will be no cost to the individual whether or not the complaint is upheld. The Tribunal will be funded by the ABI, if necessary by a special levy on its members. They will take evidence from the insurer as well as the applicant. The Tribunal's decision is binding on the insurer but not on the complainant. Decisions will be analysed so that best practice can be adopted across the industry. The Tribunal will work within terms of reference and to service standards. The Tribunal will publish an annual report which will be available to the public.¹⁵⁶

24.177 The Centre for Law and Genetics supported the establishment of a similar body in Australia:

There should also be a clear avenue of appeal to individuals in circumstances where they disagree with the decision that has been made. Whilst individual insurance companies have their own complaints procedures, options beyond this are presently limited as the Life Insurance Complaints Service [now the Financial Industry Complaints Services] does not have jurisdiction to deal with complaints about the level of premium, or underwriting or actuarial factors leading to the rejection of insurance or the offer of insurance on non-standard terms, which are the sorts of complaints most likely to arise from disputed use of genetic test information. The creation of a robust, independent appeals mechanism as recommended by the Human Genetics Advisory Commission and as now provided for under the Association of British Insurers *Code of Practice* should therefore be a priority.

Such measures would assist in enhancing the accountability of insurers in their use of genetic information and at the same time, would help to promote understanding of the implications of genetic testing in the community.¹⁵⁷

24.178 The Commonwealth Department of Health and Ageing proposed that serious attention should be given to the framework elements of the ABI Genetic Testing Code of Practice, including a complaint and appeal mechanism such as adjudication by the ABI Code of Practice Adjudication Tribunal.¹⁵⁸ It was suggested that IFSA's Genetic Testing Policy, which already includes a number of these elements, could form the basis for further developments in both the life and general insurance industries.

24.179 In consultations, the Swedish Insurance Federation reported that a review board had been established by statute in Sweden to investigate complaints with

156 Association of British Insurers, *Genetic Testing: ABI Code of Practice* (1999), Association of British Insurers, London, Pt 5.

157 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

158 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

regard to the use of genetic information in underwriting.¹⁵⁹ The body had been established to provide a mechanism of review that was independent of the insurer that made the underwriting decision. As of March 2002, the review board had not yet been constituted to hear an appeal.

Inquiry's views

24.180 There is currently a two-tier system for reviewing adverse underwriting decisions, in contrast to the three-tier system applicable to many other kinds of complaints. First, an applicant may seek review by the insurer that made the decision, in accordance with the insurer's internal review procedures. Second, if the complaint is not resolved with the insurer, the applicant may seek external review through a government agency such as HREOC, and ultimately through the courts.

24.181 The difficulties with the first option are that internal review lacks independence, and the adequacy of procedures may vary widely among insurers. The difficulties with the second option are that applicants may be unaware of their right to seek external review; such review may be costly and slow; applicants may have difficulty in ascertaining the information upon which they can base their claim of unlawful discrimination; and the disparity between the capacity of the applicants and insurers to pursue the claim may lead to unsatisfactory settlement outcomes.

24.182 Many of the difficulties identified in relation to external review by a government agency are systemic. They are not specific to complaints regarding the use of genetic information, nor even to complaints against insurers. If solutions to these problems are to be found, it will be necessary to look well beyond the scope of the present Inquiry. As a result, the Inquiry makes no proposals for the reform of the existing system of merits review by anti-discrimination agencies.

24.183 However, on the basis of submissions received by the Inquiry, there does appear to be a gap in the avenues for review and appeal currently available to applicants for insurance where genetic information has been used for underwriting. In relation to insurance complaints other than underwriting, both FICS and the IEC provide an industry-based mechanism for investigating and adjudicating disputes between insurers and insureds. This provides a middle tier of review — one that is independent of the insurer who made the decision but yet avoids some of the difficulties associated with independent agency review. In the light of public concern about the use of genetic information in underwriting, the Inquiry is of the view that it would be appropriate for the industry to develop a robust mechanism for independent industry-based review of adverse underwriting decisions.

159 Swedish Insurance Federation, *Consultation*, Stockholm, 25 March 2002.

24.184 Given the complexity and sensitivity of using genetic information in insurance, it is important that any review body have the expertise to examine both the medical and actuarial dimensions of the underwriting process. One way of achieving this would be to enhance the jurisdiction of FICS (in relation to life insurance) and the IEC (in relation to general insurance) to consider complaints with respect to the underwriting of applications involving genetic information. An alternative would be to establish a separate review body to deal with complaints involving genetic information, such as the United Kingdom's ABI Code of Practice Adjudication Tribunal. In either case, better education will go some way toward meeting concerns about the lack of consumer awareness of available review mechanisms (see below).

Proposal 24–8. The insurance industry, through its peak bodies, should develop appropriate mechanisms for reviewing underwriting decisions involving the use of genetic information. Such reviews should be:

- conducted in a timely and efficient manner;
- undertaken by a panel of individuals, each of whom is independent of the insurer that made the decision;
- carried out by suitably qualified individuals with a demonstrated understanding of insurance law and anti-discrimination law, underwriting practice, and clinical genetics; and
- binding on the insurer but not on the complainant.

Education and training

Authorised representatives' advice

24.185 IP 26 asked whether the information that agents and brokers currently receive from insurers is adequate for them to advise insurance applicants effectively about the implications of genetic information.¹⁶⁰

24.186 The Centre for Law and Genetics submitted that:

Anecdotally one hears accounts which suggest that the information available to agents and brokers on this subject may be less than adequate, or even if adequate, is not well understood by the agents and brokers, and that this, in turn, is reflected in the quality

¹⁶⁰ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 11–1.

and accuracy of the information that they are able to provide. Indeed, it has been suggested that advice given by agents and brokers at the coalface may inappropriately deter individuals who have obtained unfavourable genetic test results or who have a family history of genetic disease from even applying for insurance, on the mistaken belief that their application will not be accepted.¹⁶¹

24.187 In its submission to the Inquiry, IFSA stated:

As an improvement, specifically tailored to educate members and their authorised representatives about the use and handling of genetic information in the context of the application for Life Insurance, IFSA has introduced IFSA Standard No 11.00 'Genetic Testing Policy'. It is mandatory for its members. Members must monitor their staff's and authorised representative's compliance with this Standard, and must take action if there was a breach (Genetic Testing Policy 10.15) The Standard also encourages non-members to follow this standard (Genetic Testing Policy section 5.2).¹⁶²

24.188 Clause 10.4 of the Policy provides:

Members must provide their employees and Authorised Representatives who represent them with sufficient information and training so that those employees and Authorised Representatives can reasonably be expected to understand the content and meaning of this Standard so far as it relates to their particular jobs and responsibilities.

Members' Authorised Representatives must be aware of the need to seek specialist advice before responding to applicants' questions, as the types of genetic test and their potential impact on the applicant differ enormously.

24.189 Several submissions expressed the view that, due to the often complex nature of genetic information, it may be unduly onerous to expect authorised representatives to keep fully abreast of relevant developments in genetics.¹⁶³ It was suggested that:

one possible measure to overcome this difficulty would be the appointment of specialist advisors ... who can be contacted as required by the agents and brokers, or even by the applicants themselves, when they have queries regarding the implications of genetic testing on insurance.¹⁶⁴

24.190 The Institute of Actuaries of Australia submitted that education is an important consideration for those who work with genetic information. However, the Institute also noted that the degree of understanding and training required depends on the context:

161 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

162 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

163 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002; Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

164 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

We see a strong need for all people who are going to be dealing with genetics in their day to day work to understand what they are seeing. Sometimes this will require them to undertake detailed continuing professional education on genetics. This will apply, for example, to members of the medical profession ... or to underwriters and actuaries who are making assessment decisions on applications for life insurance policies ... In other cases, it will be enough to obtain a broad understanding, provided that the persons concerned know their limitations and seek the help of experts when they reach the boundaries of their own knowledge. This is likely to be the case in the employment field ... or for insurance agents and brokers.¹⁶⁵

24.191 The Human Genetics Society of Australasia expressed concern about the specificity of advice that agents and brokers might be required to give:

The HGSA believes, given the sensitivity of genetic information and the complexity of interpreting it, that agents and brokers should NOT offer specific advice about the implications of genetic testing. They must be able to offer generic advice about the implications for insurance of having, or not having, a genetic test and where to get further information about genetic testing such as through a medical practitioner.¹⁶⁶

24.192 IFSA's Genetic Testing Policy seeks to address this concern. Clause 10.3.3 provides a sample 'warning statement' that members should give to applicants who indicate that they are considering volunteering to take a genetic test for the purpose of obtaining insurance:

Insurance companies are always prepared to review any assessment for insurance, on the basis of the provision of new or additional information. However, you should be aware that having a genetic test is a serious decision, which has implications for you and your family. IFSA member companies encourage you to seek professional advice from your doctor or a qualified genetics counsellor to ensure you have a thorough understanding of the possible ramifications before you consider a test. IFSA member companies also encourage you to discuss this decision with your family.¹⁶⁷

Community education

24.193 IFSA and the Institute of Actuaries of Australia both agreed that there was a need to provide more community education about genetics and insurance. IFSA drew the following conclusions from a commissioned survey on consumer attitudes to genetic testing and life insurance:

Life insurance is a relatively low involvement product, even for those who have voluntary cover. It is not something that occupies consumers' minds at times other than the time of consideration / purchase. The result of this is a low level of awareness and understanding of life insurance products, and more generally, of the operation of life insurance companies ...

165 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

166 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

167 Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

The industry believes it is important to continue its efforts to provide better education on insurance matters to the community at large ...

The research indicates that community attitudes are malleable and that there is a need for communication and education not only by the insurers but also by the government and the wider medical community, and to be effective some of that communication should be done jointly.¹⁶⁸

24.194 The Institute of Actuaries of Australia noted the following paragraph in IP 26:

Community and professional education and the ready availability of information when needed can minimise misunderstanding of, over reaction to, and misuse of, genetic information.¹⁶⁹

and commented that:

IAAust's workgroup on genetics wrote its paper *Genetics in Society, 2001* partly as a community service to increase awareness of issues arising from genetics developments.¹⁷⁰

Improved education for industry and community

24.195 The majority of submissions dealing with this matter expressed general support for enhanced training and education, at both the industry and community levels. IFSA recommended that:

The industry and government encourage and enhance consumer education on insurance matters, particularly on current issues such as genetic testing, its benefits and its use by life insurance companies.¹⁷¹

24.196 The NSW Anti-Discrimination Board made the following recommendation in relation to industry education:

That the independent body (recommendation 15), in conjunction with the insurance industry, also undertake educational activities to ensure that agents, brokers and other significant participants in the insurance industry understand:

- that genetic information has been approved for use in underwriting;
- the different types and implications of genetic information generally; and
- the national genetic testing code of practice (recommendation 14).¹⁷²

168 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002, 43–44.

169 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 2.126.

170 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

171 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002.

172 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

24.197 The Institute of Actuaries of Australia expressed the view that:

there are adequate rules already in place to ensure that agents and brokers have the necessary knowledge on matters relating to the sales process. This includes knowledge on the correct completion of application forms to meet existing legal requirements for full disclosure of all information relevant to the risk the applicant is asking the insurance company to assume.¹⁷³

24.198 However, the Institute went on to note that it may be timely to consider the training and accreditation process provided by life insurance companies for their distribution networks, as ASIC is currently establishing training and accreditation rules under the *Financial Services Reform Act 2001* (Cth).

Inquiry's views

24.199 The Inquiry considers that education and training about the nature and use of genetic information are vital, both for the insurance industry and the broader community. The Inquiry recognises that the insurance industry is already active in this area, but there is still work to be done.

24.200 In Chapter 3, the Inquiry proposed the establishment of the HGCA. One of its suggested functions would be to assist with the development of community, school, university and professional education about human genetics. The establishment of the HGCA will provide an opportunity for a heightened focus on industry and community awareness of the wider issues associated with the use of human genetic information in insurance. The HGCA also should have a role in working with industry in relation to education and training.

24.201 However, responsibility for the training and education of industry representatives falls primarily on the industry itself. The Inquiry proposes an increased focus on training and education of industry members and authorised representatives in relation to the nature, collection and use of genetic information in insurance.

Proposal 24–9. The insurance industry, through its peak bodies, should review its policies and practices in relation to the training and education of industry members and their authorised representatives in relation to the nature, collection and use of genetic information in insurance.

¹⁷³ Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

25. Insurance and Genetic Privacy

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Introduction

25.1 The terms of reference require the Inquiry to report on whether, and to what extent, a regulatory framework is needed to protect the privacy of human genetic samples and information in a number of contexts, including insurance. Chapter 7 examined the legal framework for the protection of genetic privacy in Australia and made a number of proposals intended to promote greater harmony across Australian jurisdictions and to ensure that privacy laws apply to both genetic samples and information. This chapter considers whether the privacy laws provide sufficient protection for genetic information in the context of insurance.

25.2 Chapters 23 and 24 examined what genetic information is collected by insurers, the way in which it is used to underwrite insurance policies, and problems that can arise from that use, including possible unlawful discrimination. That discussion focussed on the underwriting of mutually rated insurance in which health information is collected and used, such as life insurance. Privacy issues can also arise, however, in relation to community rated insurance. Health insurers in both the public and private sectors also collect health information. For example, the Health Insurance Commission collects health data in the course of administering Medicare payments for medical services and private health insurers collect health information in relation to pre-existing conditions.

25.3 The privacy of health information held by health insurers is protected by a number of laws. Public sector organisations that administer programs at the federal level, such as the Health Insurance Commission, are bound by the Information Privacy Principles (IPPs) under the *Privacy Act 1988* (Cth), as well as

by guidelines issued by the Office of the Federal Privacy Commissioner (OFPC) pursuant to the *National Health Act 1953* (Cth).¹ Private health insurers are governed by the private sector provisions of the *Privacy Act* which are discussed below.

25.4 Submissions received by the Inquiry did not raise major concerns in relation to the privacy of genetic information collected in relation to health insurance. In conformity with the ambit of other chapters in Part G of this Discussion Paper, this chapter focuses on privacy concerns that arise in relation to genetic information collected in the context of mutually rated life and general insurance.

25.5 In addition, submissions received by the Inquiry did not indicate the existence of major inadequacies in the regulatory framework for protecting the privacy of genetic information in private sector insurance. This may be due to the information handling practices adopted by the industry over many years — predating regulation by the *Privacy Act*. It may also reflect the fact that legislation regulating private sector insurers has been in force only since 21 December 2001. It may be too early to expect comprehensive feedback on the practical application of the *Privacy Act* to the insurance industry.

Regulatory framework

25.6 As discussed in Chapter 22, a contract of insurance is said to be one of ‘utmost good faith’: an applicant for insurance has a duty at common law² and under legislation³ to disclose to the insurer all information that is known, or which reasonably ought to be known, to be relevant to the insurer. As a result, insurers can and do collect a great deal of health information, including some genetic information, from applicants. The privacy of that information was formerly regulated solely by industry standards; it is now regulated by statute and supplemented by industry standards.

Before 21 December 2001

25.7 Prior to 21 December 2001, when the *Privacy Amendment (Private Sector) Act 2000* (Cth) came into force in relation to the private sector, the insurance industry was essentially self-regulating in relation to the principles governing the collection, storage, use and disclosure of personal information. By many accounts, self-regulation was effective in protecting information privacy. In a 1996 Information Paper on the privacy implications of genetic testing, the then Federal Privacy Commissioner found that:

¹ Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

² *Carter v Boehm* (1766) 3 Burr 1905, 1909 (Mansfield LJ).

³ *Insurance Contracts Act 1984* (Cth) s 21. See also Australian Law Reform Commission, *Review of the Marine Insurance Act 1909*, Report 91 (2001), ALRC, Sydney, Ch 10.

life insurance companies put considerable emphasis on protecting the confidentiality of personal information and complaints about improper handling of information do not appear to be a major focus of dissatisfaction with industry practice.⁴

25.8 More recently, but prior to 21 December 2001, the Financial Industry Complaints Service (FICS) commented on the low number of complaints in the industry with respect to privacy. In a letter to the Investment and Financial Services Association (IFSA), FICS stated that:

Complaints about specific breaches of privacy by our life insurance company members are low. However, the Service has received a number of complaints related to disputed claims where the complainant has raised a privacy issue, such as an objection to the insurer seeking information from old medical records. It is not possible to determine the exact number of complaints the Service has received containing such an associated privacy issue. However, I have consulted our long standing staff members who have advised such complaints would only be in the vicinity of 2 to 3 per year.⁵

25.9 IFSA noted in its submission to the Inquiry that:

The life insurance industry has a long history of collecting medical and personal information for use in underwriting whilst at the same time safeguarding the individual's privacy. This has been demonstrated by the way in which the industry has managed the highly sensitive information associated with underwriting for HIV/AIDS.⁶

25.10 The Insurance Council of Australia notes on its website that:

[The general insurance industry] was first among private sector groups to adopt the National Principles for the Fair Handling of Personal Information, a voluntary set of information privacy principles for the private sector issued by the federal Privacy Commissioner in February 1998. At the same time the industry set up an independent complaints handling, monitoring and enforcement scheme to support the effective operation of the National Principles. The scheme (called the 'General Insurance Information Privacy Principles') was formally launched by the federal Attorney-General in August 1998.⁷

Since 21 December 2001

25.11 Since 21 December 2001, the collection, use, storage and disclosure of an applicant or insured's personal information by private sector insurers has been regulated by the *Privacy Act*. Under these provisions, the National Privacy Principles (NPPs) apply to insurers unless they choose to be bound by a privacy code approved by the Privacy Commissioner which provides an equivalent level of protection.

4 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), OFPC, Sydney, 40.

5 Investment and Financial Services Association Ltd, *Submission G049*, 14 January 2002, App F.

6 Ibid.

7 Insurance Council of Australia, *Submission G010*, 27 June 2001.

25.12 The Insurance Council of Australia was the first private sector organisation to develop a privacy code and to have it approved and listed on the Register of Approved Privacy Codes under s 18BG of the *Privacy Act*. The Code is based on the General Insurance Information Privacy Principles, with some additions and modifications to meet the new legislative requirements. The General Insurance Information Privacy Code was approved on 17 April 2002. It applies to general insurance business which, as discussed in Chapter 23, includes some insurance products in which an applicant's health information is collected and used for underwriting purposes.⁸

25.13 As discussed in Chapter 7, the NPPs do not apply to certain small business operators.⁹ Although insurance companies would not fall within this exemption, by reason of their annual turnover, the application of the NPPs to the businesses of insurance brokers and agents is a matter of concern. In its submission, the OFPC noted that:

Insurance is now covered by the private sector amendments to the Act, unless some entities within the industry can bring themselves within the small business exemption. For the most part, however, insurance agents and brokers will be either traders in personal information or related bodies in the terms of section 6D of the Act and hence will be subject to the Act.¹⁰

25.14 The Inquiry notes, however, that even traders in personal information are exempt from the *Privacy Act* in some circumstances, for example, if they only disclose personal information with the consent of the individual concerned or as required or authorised by legislation.¹¹

25.15 In Chapter 7 the Inquiry expressed the view that all small business operators who collect, use or disclose genetic information should be subject to the provisions of the *Privacy Act*. Proposal 7–4 was framed to address this gap in the coverage of federal privacy law, and would apply, if adopted, to small business operators in the field of insurance.

25.16 In addition to the role of federal legislation, the privacy of genetic information in underwriting is regulated by industry standards. For example, in 2001 IFSA issued a Genetic Testing Policy for its members which is described in more detail in Chapter 23. The Policy applies to genetic tests, as defined in the policy, and does not extend to genetic information in the form of family medical history. Several provisions in the Policy are directed to privacy issues regarding genetic test information, including the following:

⁸ See ICA website: Insurance Council of Australia, *Privacy Code*, <<http://www.ica.com.au/privacyprinciples/>>, 23 July 2002.

⁹ *Privacy Act 1988* (Cth) s 6C.

¹⁰ Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

¹¹ *Privacy Act 1988* (Cth) s 6D(7).

- 6 Insurers will ensure that results of existing genetic tests are only obtained with the written consent of the tested individual.
- 7 The results of genetic tests will only be used in the assessment of an insurance application in respect of the individual on whom the test was conducted. The result will not be used in the assessment of insurance applications of relatives of the tested individual.
- 8 Insurers will ensure that strict standards of confidentiality apply to the handling and storage of the results of genetic tests.
- 9 Access to the results of genetic tests in a form identifiable to particular individuals will be restricted to the insurer's underwriters and reinsurers. The results will be made available to other third parties only with the written authorisation of the applicant/insured or in the normal course of discovery during legal proceedings.¹²

Outstanding privacy issues

25.17 It would appear that there is a developed awareness of privacy principles and appropriate personal information handling practices across the insurance industry in Australia. Both the Insurance Council of Australia and IFSA have been active in promoting these principles to their members and in contributing to the development of sound practices in the insurance industry.

25.18 Submissions received by the Inquiry did not identify major problems in relation to the legal framework for protection of genetic information collected by the insurance industry. The OFPC expressed the view that:

As previously argued in this submission, the privacy protection framework for personal information across the private sector, including the insurance industry, is fundamentally sound.¹³

25.19 The Centre for Law and Genetics observed:

The new private sector privacy laws and arrangements, although as yet largely untested in view of their recent commencement, appear to provide quite a satisfactory framework for the protection of privacy interests in general. They are, of course, not specially geared to the protection of genetic information, although for most practical purposes, this category of information would be covered within the definition of health information which is recognized under the legislation as being a particularly sensitive form of information ...

Notably, although there have been ongoing concerns about the use by insurers of genetic test information, few, if any, complaints have been heard regarding insurers' failure to adequately protect the privacy of this information.¹⁴

12 Investment and Financial Services Association, *Genetics Testing Policy* (2002), Sydney.

13 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

14 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

25.20 The Inquiry considers that the basic framework for privacy protection in the insurance context is satisfactory. However, a number of specific issues were raised which require further consideration. These issues are discussed in the following sections and relate to:

- the quality of consent to collection and use of genetic information by insurers;
- the collection of family medical history by insurers; and
- the sharing of information between related insurance organisations.

Consent to collection and use of genetic information

25.21 Concern was expressed in some submissions about the quality of consent required to meet the standards set out in the NPPs. Consent may be required under the NPPs in a range of circumstances such as the collection of sensitive information (including most genetic information); use for any purpose other than the primary purpose of collection; and transfer of personal information out of Australia. The OFPC's *Guidelines to the National Privacy Principles* set out the requirements for valid consent under the *Privacy Act*:

Consent means voluntary agreement to some act, practice or purpose. It has two elements: knowledge of the matter agreed to, and voluntary agreement. Consent can be express or implied. Express consent is given explicitly, either orally or in writing. Implied consent arises where consent may reasonably be inferred in the circumstances from the conduct of the individual and the organisation. Consent is invalid if there is extreme pressure or coercion.¹⁵

25.22 The Guidelines identify two elements for valid consent — the informed nature of the consent and the voluntary nature of the consent. These issues are discussed separately below.

Informed consent

25.23 A number of submissions raised concerns about whether applicants for insurance are sufficiently well informed about the collection and use of genetic information by insurers to give valid consent. UnitingCare NSW & ACT stated in its submission:

One problem with privacy legislation is that a wide range of things can be done with information provided that the individual gives their consent to a company to disclose the information. This assumes that individuals are aware of the implications, for

¹⁵ Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), OFPC, Sydney.

themselves and others, of information being disclosed. This is likely to be untrue in many situations. People lack the information necessary to give informed consent. This makes legislative requirements hollow.¹⁶

25.24 The Centre for Law and Genetics was of the view that, in relation to genetic information in particular, there were grounds for ensuring that particular care is taken in collecting and using the information:

On balance, we are of the view that at this point in time, there are good grounds for suggesting that a heightened level of protection of this form of information is appropriate in some particular areas — not necessarily because genetic information should be regarded as ‘unique,’ but because there are a number of factors associated with it, the combined effect of which justifies taking particular care in the collection and use of this information. We would accordingly support an enhanced level of consent being required from the applicant in relation to genetic information to ensure that it is only collected when necessary, as one measure which would assist in the better protection of genetic information.¹⁷

25.25 Privacy NSW expressed a similar point in relation to medical authority forms used by insurers:

In the case of insurance contracts, it seems that no ‘standard’ medical authority is in use. If insurance companies are to collect genetic testing information, the consent form should be standardised and include a separate section on genetic testing with precise information as to the exact and specific nature of the test requested, why it is requested, and how it will be used and/or disclosed.¹⁸

25.26 In the Inquiry’s view, the collection and use of genetic information by insurers does give rise to the need to ensure that applicants are adequately informed. Genetic information has some special characteristics, such as its predictive and familial nature, which need to be raised with and considered by applicants at the time of disclosure.

25.27 There is a need to ensure that the public has confidence in the insurance industry’s underwriting practices in relation to genetic information. As part of this process, the Inquiry is of the view that insurers should review their consent forms, including medical authority forms, to ensure that they contain sufficient information to allow applicants to give informed consent to provide the genetic information in question.

16 UnitingCare NSW & ACT, *Submission G052*, 14 January 2002.

17 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

18 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

Proposal 25–1. Insurers should review their consent forms, including medical authority forms, to ensure that they contain sufficient information about the collection and use of genetic information to allow applicants to make an informed decision about whether to provide the information.

Voluntary consent

25.28 As noted above, legislation requires an applicant to disclose to the insurer all information that is relevant to underwriting the risk. A number of submissions expressed concern that this obligation may have implications for the voluntariness of an applicant's consent, which is the second element identified by the OFPC as necessary for valid consent under the *Privacy Act*.

25.29 Privacy NSW expressed the concern that, in the insurance context, the voluntariness of consent may be compromised:

In any event, even the full provision of accessible information will not support fully free consent in the insurance and employment context where penalties may apply if an applicant declines to provide information. Applicants may feel unable to refuse where there is a possibility of their application for employment or insurance being rejected if they do not agree to the disclosure of genetic testing information.

It is questionable as to whether this situation of *coerced consent* is adequately addressed in the existing privacy legislation. For instance, the guidelines to the *Privacy Act*, cite 'extreme pressure' as vitiating voluntary consent. This does not equate to the 'take it or leave it' option that is likely to arise when genetic testing information is solicited for insurance and employment purposes.¹⁹

25.30 UnitingCare NSW & ACT was also of the view that:

Reliance on individual consent also ignores the difference in power in the relationship of individuals with organizations. Employers and insurance companies have considerable power compared to individuals, based on their economic power, knowledge power, and coercive power. Individuals can feel powerless to say 'no' to insurance companies or employers. They need the law to protect them from unnecessary invasion of their privacy and erosion of their interests.²⁰

25.31 Associate Professor Margaret Otowski described the interaction between the disclosure obligations in the *Insurance Contracts Act 1984* (Cth) and the obligations in the *Privacy Act* in the following terms:

¹⁹ Ibid.

²⁰ UnitingCare NSW & ACT, *Submission G052*, 14 January 2002.

It should be noted that the new privacy laws, introduced last year by way of amendment to the Commonwealth *Privacy Act*, don't change [the obligation of disclosure] — although obviously this is a significant development ensuring the appropriate protection of privacy of personal information within the private sector (including information held by insurance companies). Information disclosed to the insurer pursuant to these disclosure obligations would be regarded as information provided with the consent of the individual even though individuals may feel they have no real choice about this and in that sense one might question the 'voluntary' nature of this disclosure.²¹

25.32 The Centre for Law and Genetics also addressed the tension between the need for voluntary consent under the *Privacy Act* and the requirement to disclose all relevant information to insurers:

The problem, is not so much one of controlling how information is collected, stored, and in what circumstances it may be disclosed. More fundamentally, the question is whether this should be information individuals are required to disclose to insurers in the first place pursuant to their obligation, under a contract of 'utmost good faith,' to disclose all information that is material to the insurers' assessment of risk.²²

25.33 Kathy Liddell also emphasised that privacy laws are directed toward how information is handled rather than what information is required in particular contexts:

Usually, privacy laws allow information to be used consistent with an individual's consent. The fundamental tenet of these statutory schemes is that an individual ought to have control over their personal information. The response by insurers is simply to refuse to enter into an insurance contract if the individual does not consent to the use of their information. In these circumstances there is no breach of information privacy law.²³

25.34 The Inquiry is of the view that in a properly regulated environment the duty of 'utmost good faith' of contracting parties is necessary and appropriate in relation to mutually rated insurance products in the private sector. While there may be a tension between an applicant's legal obligation to disclose all relevant information and the voluntariness of their consent to disclosure for the purposes of the *Privacy Act*, the tension is created by their desire to acquire the insurance product.

25.35 Some submissions identified the problem of coerced consent as arising in the contexts of both employment and insurance. The Inquiry considers that a relevant distinction can be drawn between these situations. The right to work has been recognised as a fundamental human right by many countries within the

21 M Otlowski, *Submission G159*, 24 April 2002.

22 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

23 K Liddell, *Submission G147*, 10 April 2002.

international community.²⁴ A person's ability to work is important to his or her financial security, self-esteem and community involvement. If access to employment were made conditional on the provision of genetic information to an employer, there may be a real sense in which consent to provide that information is coerced — the alternative to the offered employment may be unemployment.

25.36 The inability to access insurance products creates problems of a different order. While some insurance products provide financial support for the insured, or his or her family, on the occurrence of the insurance event, the consequences of being unable to purchase an insurance product are different in degree from the consequences of being unable to sell one's labour to earn a livelihood. In a practical sense, the voluntariness of consent may depend on the nature of the insurance and the circumstances of the insured. To a self-employed individual whose access to a mortgage depends on having income protection insurance, the disclosure of information may not seem entirely free. Yet, in general, consumers do voluntarily choose whether to apply for insurance, and thus enter into a commercial relationship with the insurer. One aspect of that commercial relationship is that the consumer gives up the right to decide what should be disclosed and what may be kept secret.

25.37 In the Inquiry's view, the essence of the problem does not appear to be that consent to providing the information is vitiated by coercion in purchasing the insurance product. The real problems appear to be whether genetic information is scientifically reliable and actuarially relevant to the application for insurance and the extent to which insurers' use of the information is fair and reasonable. The Inquiry considers that these problems are better addressed by examining industry practice and the operation of anti-discrimination laws (see Chapter 24), than by amending privacy laws.

25.38 A related issue, which also goes to the voluntariness of consent, is the question of 'bundled consents'. The OFPC set out the problem as follows:

An emerging and related problem is the operation of the new privacy law where a strong inducement that compromises privacy is offered through the 'bundling' of very broad consents to a number of uses and disclosures of an individual's information as a condition of purchase. In effect, a number of financial institutions are making it a condition of individuals' access to their services that the individuals agree to a very wide range of uses and disclosures, including marketing and no alternative course is offered ... Consideration should be given to whether privacy laws are strong enough to prevent this and, if not, then the law should be amended to ensure that real choice is available in the marketplace.²⁵

24 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 19 December 1966, 993 UNTS 3, (entered into force on 10 March 1976), art 6(1).

25 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

25.39 In the Inquiry's view, the question of 'bundled consents' is an issue that is appropriately addressed within the framework of privacy law. The Inquiry recognises that the bundling of consents has the potential to undermine the valid consent of an applicant for insurance and that this issue requires further consideration. The Inquiry invites further comment on this question.

Question 25–1. Does the practice of 'bundling consents' by insurers undermine the ability of an applicant to make an informed decision about whether to provide genetic information to an insurer? If so, what measures should be taken to address this problem?

Collection of family medical history

25.40 As discussed in Chapter 23, insurance companies routinely collect family medical history information and use it in underwriting. The collection and use is based on the long recognised fact that certain diseases have an hereditary component, and that information about the medical history of family members is relevant in assessing the applicant's risk. IFSA's current Genetic Testing Policy does not address the issue of family medical history in underwriting — it is solely focused on genetic test results, which are narrowly defined.²⁶

25.41 The collection and use of family medical history raises two distinct privacy issues. The first is whether it is permissible to use personal information that the insurer has already collected about an insured, X, in assessing the insurance application of a genetic relative, Y. This conduct would be in breach of the NPPs and the Inquiry has been informed that insurers do not engage in this practice. IFSA's Genetic Testing Policy, quoted above, provides that the results of a genetic test on X will not be used in the assessment of insurance applications of his or her relatives (ie Y). This does not cover the use of family medical history information collected from X in assessing Y's application, but it does address a similar concern.

25.42 The second issue is whether it is permissible for insurers, in assessing an insurance application from A, to collect personal information from A about that person's genetic relatives (B, C, D ...), without the knowledge or consent of those relatives. There are grounds for thinking that this widespread practice may not be consistent with NPP 1.5 and NPP 10.

26 Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999), para 9.1.

25.43 Similar issues have already been addressed by the OFPC in the context of the provision of medical services (see Chapter 18). Medical practitioners regularly take a medical history from patients, which may include the collection of personal information about genetic relatives of the patient. In its submission to the Inquiry, the OFPC identified some of the problems that arise in the application of the NPPs to this common situation.

Problems may arise, however, in circumstances where, in the course of a diagnosis, treatment or care of an individual, an organisation collects a medical history from an individual which also reveals health information about a genetic relative. NPP1.5 would require the organisation to inform the relative of the matters contained in NPP1.3, relating to the circumstances of the collection. NPP10 would also require the organisation to obtain the relative's consent to the collection of the health information about them, except in certain defined situations such as where the collection is required by law.²⁷

25.44 In order to overcome this difficulty, the Privacy Commissioner has made a temporary Public Interest Determination, the effect of which is to ensure that the relevant acts or practices engaged in by an organisation do not breach the *Privacy Act*.²⁸ In the words of the OFPC:

Since the collection of health information about relatives from an individual forms an integral part of a wide range of health services, the continuation of this practice by providers would have been in breach of NPP1 and NPP10. In order not to unduly impede the provision of health services, a Temporary Public Interest Determination under Section 80B(3) now allows the taking of family histories by health service providers without being in breach of the NPPs (OFPC, 2001e). This would include the collection by an organisation from an individual of genetic information about the individual's relative.²⁹

25.45 There is an analogy between a medical practitioner's collection of family medical history from a patient and an insurer's collection of family medical history from an applicant. The Inquiry is of the view that the collection of such information by insurers may not be consistent with the *Privacy Act* and that the lawfulness of existing industry practices should be clarified.

25.46 One means of doing so would be the issue of a Public Interest Determination under the *Privacy Act*. In considering whether to issue a Determination, the Privacy Commissioner is required to consider whether the public interest in allowing, for example, the collection of family medical history information outweighs, to a substantial degree, the public interest in adhering to the

27 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

28 *Privacy Act 1988* (Cth) s 80B.

29 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002. For further information on the Public Interest Determination process and, in particular, the Public Interest Determination in relation to the collection by health service providers of social and medical history information for the diagnosis, treatment or care of an individual, see Office of the Federal Privacy Commissioner, *The Australian Privacy Commissioner's Website*, <www.privacy.gov.au>, 27 September 2001.

NPPs or approved code. An application for a Public Interest Determination is a public process and would allow further consideration of the issues. In response to an application from a particular organisation, the Privacy Commissioner may make a determination that applies to all organisations engaging in that act or practice.³⁰

Proposal 25–2. Insurers should seek a Public Interest Determination under the *Privacy Act* in relation to the practice of collecting family medical history from applicants for use in underwriting insurance policies in relation to those applicants.

Sharing information between related organisations

25.47 A further issue raised in one submission to the Inquiry was the degree to which various arms of insurance organisations share genetic information. Privacy NSW stated in its submission that:

Existing privacy legislation does not specifically restrict information from being passed from one insurance arm (for example Life) to another (for example General) or to a re-insurer where it can be argued that the purpose is ‘directly related’ to the primary purpose of collection. General insurers also share details of refused applicants and claims through Insurance Reference Services P/L.

Privacy NSW recommends that the transfer of genetic information from life and associated product areas to general insurance areas should be prohibited or significantly restricted.³¹

25.48 The Inquiry has not received any other submissions indicating the extent to which information is currently shared between various arms of insurance organisations. Nor has the practice been identified by others as a matter of concern. The Inquiry would be interested in receiving further comment on this issue.

Question 25–2. Is there evidence that genetic information is shared between various arms of insurance organisations? If so, does this practice raise concerns about the protection of the privacy of genetic information? How might these concerns be addressed?

30 *Privacy Act 1988* (Cth) s 72(4).

31 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

Part H. Employment

26. The Use of Genetic Information in Employment

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Introduction

26.1 The right to work has been recognised as a fundamental human right by many countries within the international community.¹ A person's ability to work is important to his or her financial security, self-esteem and community involvement.

¹ *International Covenant on Economic, Social and Cultural Rights*, opened for signature 19 December 1966, 993 UNTS 3, (entered into force on 10 March 1976), art 6(1).

On a broader level, a person's ability to work allows him or her to contribute financially to the community through the income tax system, and to avoid dependence on state welfare. The possibility that a person might be excluded from employment as a result of his or her genetic status is therefore a serious concern.

26.2 Australian employers may currently request information about a job applicant's or employee's genetic information, subject to relevant anti-discrimination legislation. Employers may seek access to such information where it is relevant to a person's ability to perform the inherent requirements of the job, or where it is relevant to the employer's common law or statutory occupational health and safety obligations.

26.3 In light of the established use of pre-employment and other health assessments by Australian employers, there is reason to expect an increased use of genetic information in employment in the future, particularly if the cost of genetic testing falls and the number of available tests increases. The regulatory approaches taken in overseas jurisdictions may be instructive in determining the appropriate regulatory model for Australia.

Types of genetic information used in employment

Genetic test results

26.4 An employer might seek to obtain genetic test results from an employee or job applicant in several ways. An employer might include diagnostic or predictive genetic testing in a pre-employment medical examination, or as part of an ongoing health surveillance program. Alternatively, an employer might ask a job applicant to disclose the results of any diagnostic or predictive genetic tests previously conducted, for example through participation in a population screening or medical research program.

26.5 The Inquiry is not aware of any genetic testing currently conducted by Australian employers. United States employers have conducted genetic testing for various conditions in the past, for example in relation to the sickle cell trait.² Until recently, the United Kingdom's Ministry of Defence screened aircrew applicants for the sickle cell trait in the belief that carriers of the trait were vulnerable to health risks at high altitudes.³

2 See J Crespín, 'Genetic Screening in the Workplace for Sickle Cell Trait: A Dangerous Tool' (1992) 30 *Medical Trial Technique Quarterly* 91; J Seltzer, 'The Cassandra Complex: An Employer's Dilemma in the Genetic Workplace' (1998) 27 *Hofstra Law Review* 411, 418–420; K Brokaw, 'Genetic Screening in the Workplace and Employers' Liability' (1990) 23 *Columbia Journal of Law and Social Problems* 317, 322–326.

3 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 8.8.

26.6 The prospect of testing in employment has, however, been raised in Australia. In 2001 it was reported that the Professional Boxing and Martial Arts Board (Vic) had proposed the genetic testing of all professional boxers in Victoria as a condition of their licence to fight. The boxers would be tested for a genetic variation that might make them more susceptible to 'punch drunk syndrome'. The Board was reportedly concerned that it could be held liable for damages if it allowed boxers with a genetic predisposition to this condition to fight.⁴

Family medical history

26.7 In addition or as an alternative to requesting genetic test results, an employer might ask an employee or job applicant to disclose information about his or her family medical history. For example, an applicant might be asked to complete a pre-employment questionnaire outlining any family illnesses. Family medical history is a form of genetic information.

26.8 In one reported case, an 18-year-old male with a family history of Huntington's disease applied for acceptance into the public sector. His general practitioner noted the family history of the disease in his medical examination report. The man was told that he would only be employed if he undertook a genetic test which showed that he did not have the relevant genetic mutation.⁵

Genetic samples

26.9 In certain circumstances, employers might seek access to employees' DNA samples for use in identification. For example, in the United Kingdom police officers are requested to supply DNA samples for the Police Elimination Database so that they can be eliminated as a possible contaminant at crime scenes. By May 2002, over 56,000 DNA samples had been provided. Proposals have been made to make the supply of a sample a condition of entry to the police force.⁶

26.10 The Tasmanian Police Service also collects DNA samples from police recruits for the same purpose.⁷ The Tasmanian Police Commissioner has proposed to expand the program to all operational police and to establish a DNA database for police profiles. The Commissioner has indicated that if police do not provide samples voluntarily he will ask the Tasmanian government to implement

4 J Robotham, 'Pro Boxers Face Going Down for the Gene Count', *The Sydney Morning Herald*, 1 June 2001.

5 S Taylor, 'A Case Study of Genetic Discrimination: Social Work and Advocacy Within a New Context' (1998) 51(4) *Australian Social Work* 51, 53.

6 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 8.9.

7 In addition, s 22 of the *Criminal Investigation (Identifying People) Act 2002* (WA) permits the Western Australian Commissioner of Police to require police officers to undergo procedures to obtain the person's DNA profile.

legislation making it compulsory to provide them. The Police Association of Tasmania has opposed the plan, expressing the concern that, once obtained, the samples might be used in future for other purposes such as predictive health or other testing. The Police Federation of Australia has asked the Commissioner to reconsider the proposal.⁸

26.11 The United States Department of Defense collects DNA samples from every service member on active duty or in the reserve armed forces on a mandatory basis. The samples are collected for the purpose of identifying the remains of war casualties. The samples are stored in the Department's DNA Repository for a period of 50 years but may be destroyed at the request of the donor when he or she leaves the military.⁹

26.12 The Inquiry understands that the Australian Defence Force is currently considering whether to implement a policy of collecting genetic samples from members of the defence force for identification purposes.¹⁰

Categories of genetic testing in employment

Genetic screening

26.13 Genetic screening involves examining the genetic status of an employee or job applicant for certain inherited traits, disorders or susceptibilities, usually for the purpose of excluding high-risk persons from the workforce, or to provide an alternative form of work that may present fewer risks.¹¹

26.14 Genetic screening can take two forms. First, employers might screen employees or applicants for the presence of inherited traits that affect their susceptibility to workplace related diseases. An example is genetic testing for asthma susceptibility for workers in a dusty environment such as a bakery. Second, employers might screen employees or job applicants to detect inherited traits that predispose them to conditions that are unrelated to workplace hazards but which

8 G Warner, 'Greens Join Fight against Police DNA Testing Plan', *The Mercury* (Hobart), 13 February 2002. See also C Jackman, 'Police Fears on Push for DNA Bank', *The Sunday Herald Sun* (Melbourne), 24 February 2002, 30.

9 E Reiter, 'The Department of Defense DNA Repository: Practical Analysis of the Government's Interest and the Potential for Genetic Discrimination' (1999) 47(2) *Buffalo Law Review* 975, 983–984. For more information about the DNA Repository, see A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921.

10 Colonel G Wells (Australian Defence Force), *Telephone Communication*, 22 April 2002.

11 US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 5.

may impact on their ability to work in the future.¹² An example is genetic testing to identify workers who are presymptomatic of Huntington's disease.

Genetic monitoring

26.15 Genetic monitoring involves the periodic testing of employees exposed to industrial substances or hazards in the workplace to evaluate the genetic damage caused by exposure to the hazard. Genetic damage may take the form of chromosomal damage or genetic alterations or mutations.¹³

26.16 The purpose of genetic monitoring is to predict the risk of disease due to exposure to the hazardous substances, or identify early stages of genetic damage. An example is a health surveillance program involving genetic testing for workers exposed to asbestos or inorganic lead in the workplace. This form of testing could involve monitoring individual employees within the workplace, or groups of employees to identify risks to the entire exposed population.¹⁴

Current use of genetic information in employment

Regulation of genetic information in employment

26.17 As noted in IP 26, there is no *specific* regulation of the use of genetic information in the Australian employment context.¹⁵ There are no direct prohibitions on its use, nor any legal preconditions for the introduction of a screening program. In addition, there is no *specific* regulatory framework for the use or disclosure of information obtained.¹⁶ In the absence of specific legislation, employers' collection and use of genetic information is subject both to common law principles, and to Commonwealth, state and territory legislation dealing with privacy, unlawful discrimination and occupational health and safety.¹⁷ These are outlined in more detail below, and in Chapters 27-30.

12 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 8-9; see also US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 5.

13 US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 4.

14 Ibid.

15 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 10.4. See also M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 12.

16 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 12.

17 Ibid, 12.

Australian employers' use of genetic information

26.18 It is difficult to determine to what degree Australian employers are currently using genetic test or family medical history information in employment. The Inquiry has been unable to find statistical information about the current use of genetic information by Australian employers but is aware of anecdotal reports of alleged misuse of such information by employers.¹⁸ An interdisciplinary team of researchers is currently conducting an empirical study into the nature and extent of genetic discrimination in Australia, which is due to be completed in 2004.¹⁹

Employers' use of genetic information in other jurisdictions

26.19 The United States has a relatively long history of using medical and genetic testing in the workplace. One reason for the widespread use of testing by employers is that, in the absence of a universal health care system, the majority of Americans rely on employer-provided health insurance for their health care needs.

26.20 A recent survey by the American Management Association provides some guidance as to the current use of genetic information by United States employers. The Association conducts an annual survey of its 10,000 member companies, representing one quarter of the United States workforce. In its 1999 survey of 1,054 employers, less than 1% reported genetic testing for pregnancy and sickle cell anaemia; 4.3% reported genetic testing for breast or colon cancer; and 16.7% reported genetic testing for susceptibility to workplace hazards.²⁰ About 20% of employers surveyed obtained family medical history information from job applicants, and 12% obtained family medical history from employees. Five percent of employers surveyed admitted using this information in hiring decisions, and 2% in assigning or reassigning current employees.²¹

26.21 There is little information as to the use of genetic information by employers in other jurisdictions. The United Kingdom's Human Genetics Commission (HGC) has reported that there is currently no evidence of any

18 See K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250. These are outlined in Ch 27.

19 The research project has Australian Research Council funding and is being conducted by Associate Professor Margaret Otłowski (Faculty of Law, University of Tasmania), Dr Sandra Taylor (School of Social Work and Social Policy, University of Queensland) and Dr Kristine Barlow-Stewart (NSW Genetics Education Program).

20 R Jansson and others, *Genetic Testing in the Workplace: Implications for Public Policy* (2000), Institute for Public Health Genetics, Health Policy Analysis Program, Department of Health Services, School of Law, Department of Economics, University of Washington, Seattle, 19. However, misunderstanding of the definition of genetic testing appeared to skew the results. See also the surveys conducted by the US Office of Technology Assessment (OTA) in 1982 and 1989.

21 P Miller, 'Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace' (2000) 3(2) *Journal of Health Care Law & Policy* 225, 236.

systematic use of predictive personal genetic information in employment.²² The HGC's predecessor, the Human Genetics Advisory Committee (HGAC), reported in 1999 that it had not found any evidence of systematic use of genetic tests by European employers.²³ The HGAC did not comment on the use of family medical history by employers and it is difficult to determine the current use of such information in the employment context.

Other forms of health testing in Australian employment

26.22 Genetic screening and monitoring programs have a number of similarities with other forms of workplace screening programs including pre-employment testing, health surveillance, and drug and alcohol testing.

Pre-employment health screening

26.23 A large number of Australian employees are required to undergo pre-employment health screening as a pre-condition of employment.²⁴ This form of screening can involve a medical examination, a questionnaire, the taking of a medical and/or occupational history, or the use of medical tests or samples.²⁵

26.24 In certain industries, pre-employment or pre-placement medical examinations are *required* by occupational health and safety regulations. One example is where the employee will be working in activities that are hazardous to the public, such as some forms of transportation.²⁶

26.25 Associate Professor Richard Johnstone has commented that employers often see pre-employment screening as part of their 'managerial prerogative' to hire and fire as they choose.²⁷ In practice, however, employers' ability to conduct pre-employment health screening is limited by Commonwealth, state and territory anti-discrimination legislation.

22 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 8.9.

23 Human Genetics Advisory Committee, *The Implications of Genetic Testing for Employment* (1999), Human Genetics Advisory Committee, London, para 3.4.

24 R Johnstone, 'Pre-employment Health Screening: The Legal Framework' (1988) 1 *Australian Journal of Labour Law* 115.

25 Ibid, 115. The Australasian Faculty of Occupational Medicine of the Royal Australasian College of Physicians has issued guidelines for employment health assessments. See Australasian Faculty of Occupational Medicine, *Guidelines for Health Assessment for Work* (1998) Royal Australasian College of Physicians.

26 *Mines Inspection Act 1901* (NSW) s 18A. See generally, R Johnstone, 'Pre-employment Health Screening: The Legal Framework' (1988) 1 *Australian Journal of Labour Law* 115, 115–116.

27 R Johnstone, 'Pre-employment Health Screening: The Legal Framework' (1988) 1 *Australian Journal of Labour Law* 115, 117.

26.26 In some States and Territories, anti-discrimination legislation prohibits requests for information on which unlawful discrimination could be based, but contains an exception for information required for non-discriminatory purposes. This restricts the employer to asking questions or requiring tests that are directly relevant to the worker's capacity to perform the 'inherent requirements' or 'genuine occupational requirements' of the position.²⁸

26.27 By contrast, the *Disability Discrimination Act 1992* (Cth) (DDA) only prohibits requests that are themselves discriminatory, being requests that would not be made of a person who was not disabled.²⁹ As a result, general pre-employment inquiries appear to be permitted under the DDA, provided they do not constitute direct or indirect discrimination.³⁰

26.28 An employer may legitimately request information for the purpose of determining whether a person can perform inherent job requirements — including the ability to work safely; to identify any reasonable adjustments required in selection for employment or in the performance of work;³¹ or to establish rights and obligations regarding superannuation, workers' compensation and other insurance.³²

Other health assessments

26.29 Employees might be subjected to periodic health assessments before, during and after their employment. In addition to pre-employment health screening discussed above, these assessments include:

- Medical tests or examinations required under occupational health and safety regulations, or under specific legislation in industries involving exposure to dangerous hazards (see health surveillance below).
- Sickness examinations conducted to determine whether a person's illness or injury has resulted in a permanent or temporary impairment and/or disability, which may impact on work arrangements.

28 See *Anti-Discrimination Act 1991* (Qld) s 124; *Equal Opportunity Act 1995* (Vic) ss 100, 101; *Discrimination Act 1991* (ACT) s 23; *Anti-Discrimination Act 1992* (NT) s 26.

29 *Disability Discrimination Act 1992* (Cth) s 30. See M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 16.

30 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

31 *Disability Discrimination Act 1992* (Cth) s 15(4).

32 *Ibid.*, s 46.

- Workers' compensation examinations required by employers where an employee has claimed compensation, or in the course of resolving compensation disputes. (See Chapter 39 for more information).
- Executive health examinations of senior management to preserve their health by providing feedback on their current state of health, and information to enable lifestyle and health improvement.
- Retirement examinations, which may be carried out to advise retiring employees of any health problems or to discuss the need for ongoing medical surveillance.³³

26.30 Apart from health surveillance required in specific industries or workplaces, post-employment medical assessments are regulated in the same way as pre-employment assessments.

Health surveillance

26.31 Health surveillance is conducted in industries involving workplace exposure to hazardous substances or agents. The National Occupational Health and Safety Commission has prepared a package of regulations, standards and codes of practice, and each Australian jurisdiction has generally implemented the package in regulations under the principal occupational health and safety legislation.

26.32 Health surveillance involves monitoring a person's health to identify changes in health status as a result of workplace exposure to hazardous substances. Surveillance involves regular examining and testing of employees at risk, and may also include biological monitoring. Employers must conduct health surveillance in industries involving exposure to hazardous substances such as asbestos, carcinogenic substances or inorganic lead.³⁴ See Chapter 29 for more information.

Drug and alcohol testing

26.33 Drug and alcohol testing involves testing for alcohol, prescription and over-the-counter pharmacy drugs, as well as cannabis, cocaine, amphetamines and

33 See Australasian Faculty of Occupational Medicine, *Guidelines for Health Assessment for Work* (1998) Royal Australasian College of Physicians, 6–10.

34 See National Occupational Health and Safety Commission, *National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] (Updated for Amendments)*, Commonwealth of Australia; National Occupational Health and Safety Commission, *National Standard for the Control of Inorganic Lead at Work [NOHSC: 1012 (1994)]*, Commonwealth of Australia. These documents have generally been adopted by Commonwealth, state and territory governments into occupational health and safety regulations.

heroin. It is usually conducted by analysing a range of bodily samples including blood, urine, breath, hair and saliva.³⁵

26.34 Australian employers currently conduct alcohol and drug testing on job applicants and employees in a number of industries, including those involving risk to the health and safety of employees, their fellow workers and members of the general public. For example, workplace drug testing has been conducted on railway employees, prison officers, coal miners, airline workers, law enforcement officers and members of the Australian Defence Force. While the use of workplace drug and alcohol testing is generally acknowledged to be fairly widespread in Australia, the Inquiry is not aware of recent statistics regarding its use.³⁶

26.35 Employers justify drug and alcohol testing by reference to their duty to ensure the health and safety of their employees and third parties.³⁷ Some industry-specific legislation provides for drug and alcohol testing.³⁸ Otherwise, it is accepted that employers may use such testing to minimise exposure to hazards in the workplace caused by an employee under the influence of drugs or alcohol.

26.36 While workplace drug and alcohol testing has been introduced in a number of industries, concerns have been raised as to the accuracy of the results, the ability to measure whether an employee's work performance has been impaired by the drug, the real economic benefit resulting from the testing, and the potential invasion of privacy involved in such testing.³⁹

Future use of genetic information by Australian employers

26.37 It is difficult to predict to what extent Australian employers may seek to obtain and use genetic information about job applicants or employees in the future. Some employers already undertake a wide range of employee health, drug and alcohol assessments. Employers might in future wish to make use of genetic information as part of their pre-employment health assessments, or as part of ongoing health surveillance under occupational health and safety regulation.

26.38 The financial benefits for employers of screening out unhealthy employees from the workplace, and of limiting potential liability for workplace injuries or illnesses by screening susceptible employees out of employment, are

35 The Privacy Committee of New South Wales, *Drug Testing in the Workplace*, 64 (1992), Privacy Committee of New South Wales, Sydney, 5.

36 In 1991, nine of the top 600 Australian companies (being 1.5%) reported having drug testing procedures for employees. In 1992, a survey found that 11.5% of a range of private and public sector organisations had some form of drug and alcohol testing program: *Ibid*, 9–11.

37 *Ibid*, 7.

38 For example, see *Rail Safety Act 1993* (NSW) s 61; *Australian Federal Police Act 1979* (Cth) s 40M.

39 The Privacy Committee of New South Wales, *Drug Testing in the Workplace*, 64 (1992), Privacy Committee of New South Wales, Sydney, 19–25.

significant incentives for employers to seek to adopt more wide-ranging use of genetic information in the future.

26.39 As genetic technology advances, the range of genetic tests available is likely to expand. They are also likely to become cheaper and faster to perform. Associate Professor Margaret Otlowski has commented:

Concerns about genetic screening are magnified once account is taken of future gene chip analysis and the potential for testing for a range of non-medical traits, such as aggression, alcoholism or criminality; traits that an employer would undoubtedly be keen to screen for.⁴⁰

26.40 It has been suggested that employers may come under pressure to conduct genetic testing on their workforce from their insurers or from test manufacturers, who may seek to increase sales regardless of the social and ethical implications of testing.⁴¹

26.41 After reviewing recent case law, Joel Butler and Professor Ron McCallum commented that, in industries involving inherently dangerous work, the courts would generally permit employers to conduct mandatory drug testing on employees to determine any impact on the employee's performance. In relation to genetic testing, the authors suggested:

If a genetic test is able to demonstrate that an employee's performance is likely to be impaired because of a genetic condition, and that such an impairment is likely to negatively affect safety in the workplace – or the health of the employee, it seems likely that the courts would uphold an employer's policy requiring that such tests be taken.⁴²

Legal and ethical issues in workplace genetic testing

Employers' interests

Costs associated with unhealthy workers

26.42 One of the primary reasons employers might seek to use genetic information in the employment context is to reduce labour and other administrative costs. An employee with a susceptibility to a genetic disorder—whether workplace related or otherwise—might lead to productivity losses and costs associated with

40 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 9.

41 L Vogel, *The European Trade Union Confederation's View on Genetic Testing and the Workplace* (2000), European Trade Union Confederation, Brussels, 3.

42 J Butler and R McCallum, 'Genetic Testing and Employment Discrimination: A Working Paper' (Paper presented at University of Sydney, Faculty of Law, Continuing Legal Education Health Law Seminar Series 2001, 'Consent Law in an Age of High Technology: Some Current Problems and Legal Developments', Sydney, 11 April 2001), 9, 11.

sick leave, employing and training temporary or permanent replacements, potentially higher workers' compensation premiums, and potential legal liability for injuries to employees or the public.⁴³

26.43 However, these potential costs are tempered by some countervailing considerations. For example, a genetic test might disclose that a person has a susceptibility to a genetic condition, but there is no guarantee he or she will develop the condition. The predictive quality of the test might be low, or there might be little correlation between the occupational exposure to toxins and the onset of the disease. The employer might implement a costly genetic screening program without a clear view of the value of the information obtained.⁴⁴

26.44 In addition, if the use of genetic information in employment is contrary to prevailing community values, employers' attempts to collect or use this information might generate bad publicity and industrial tensions for the organisation. This might impact on its market performance and the employment preferences of job applicants.

26.45 Employers who request genetic information from job applicants might find that these applicants begin to seek employment with organisations that have not adopted these policies. However, this argument depends on the applicant's practical degree of choice in employment, which in turn depends on the applicant's qualifications and experience, and the nature of the industry and the economy.

Duty to protect employees' health and safety

26.46 Employers have a common law and statutory duty, under occupational health and safety legislation, to care for the health and safety of their employees and the general public.⁴⁵

26.47 Employers might seek to access the genetic information of their job applicants or employees for the purpose of complying with these duties. This might benefit an applicant or employee who is identified as having a genetic susceptibility to a workplace-related condition. The person could use this information to make career choices to avoid future exposure to hazardous workplaces, as well as for general health management.

43 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 9–10.

44 R Jansson and others, *Genetic Testing in the Workplace: Implications for Public Policy* (2000), Institute for Public Health Genetics, Health Policy Analysis Program, Department of Health Services, School of Law, Department of Economics, University of Washington, Seattle, 20–22.

45 See Ch 29 for more detail.

26.48 It is necessary to consider appropriate employer responses to information disclosing a genetic susceptibility in a job applicant or employee. An employer might seek to move a susceptible employee within the workplace to a position involving minimal exposure to relevant hazards; or it might seek to exclude the person from employment altogether. Alternatively, it has been argued that employers should prevent exposure to workplace hazards by seeking to minimise or eliminate the hazard itself, rather than excluding susceptible employees.⁴⁶

26.49 Employers might also seek access to an applicant's or employee's genetic information in relation to its duty to protect the health and safety of third parties, but it is generally questionable whether this could provide any greater indication of the onset of a condition than regular health monitoring.⁴⁷ This is discussed in more detail in Chapter 29.

Employees' interests

Privacy and bodily integrity

26.50 The use of genetic information by employers might pose a risk to the physical and informational privacy of job applicants and employees in several ways. The collection of a bodily sample may involve an invasive procedure, interfering with the person's bodily integrity. The collection of genetic information may also constitute an invasion of the informational privacy of the person involved, and his or her family.⁴⁸

26.51 While the collection of genetic information for medical or research purposes is generally based on the principle of informed decision-making, a number of commentators have criticised the appropriateness of this principle in the employment context. They argue that the validity of any informed consent given by a job applicant or employee is undermined by the unequal bargaining power in the workplace.⁴⁹ This might undermine a person's right 'not to know' whether he or she has a genetic susceptibility or predisposition.

46 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 35. See also Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

47 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 36–37. See also Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

48 See Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), OFPC, Sydney, 48.

49 For example, see E Draper, 'The Screening of America: The Social and Legal Framework of Employers' Use of Genetic Information' (1999) 20 *Berkeley Journal of Employment & Labour Law* 286, 294; M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 12–13, 39–40.

26.52 Another privacy concern relates to the confidentiality of genetic information collected by consent from job applicants and employees. Once an employer has collected the information, the person to whom it relates loses practical control over the information. Contractual and equitable principles offer some privacy protection,⁵⁰ as does the *Privacy Act 1988* (Cth) — subject to the exemption from the National Privacy Principles for personal information contained in ‘employee records’.⁵¹ See Chapter 30 for more detail.

Protection from unfair discrimination

26.53 The use of genetic information in employment has led to concerns that this information could be used to discriminate unfairly against job applicants and employees. For example, employers might seek to exclude ‘high risk’ persons because of their susceptibility to workplace related conditions, or because of risks unrelated to workplace exposure. Alternatively, job applicants or employees might fear subsequent discrimination by another employer, or insurers, if the genetic information is disclosed to them.

26.54 Cases of alleged discrimination by Australian employers on the basis of genetic information are outlined in Chapter 27. Existing laws provide some protection to job applicants and employees against employment discrimination on the basis of a current or future disability,⁵² or a person’s medical record.⁵³ The adequacy of these laws is also discussed in Chapter 27.

Employee autonomy

26.55 As noted above, employers might use genetic information to inform individual employees about their susceptibilities to workplace exposures, so that employees make more informed decisions about whether to take a particular position, and if so, about exposure risks, preventive measures, and early treatment of disease.⁵⁴ The value of this information will depend on the employee’s practical ability to refuse ‘high risk’ employment.

50 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 76–77.

51 *Privacy Act 1988* (Cth) s 7B(3).

52 *Disability Discrimination Act 1992* (Cth).

53 *Human Rights and Equal Opportunity Commission Act 1986* (Cth) s 3(1) (definition of ‘discrimination’); *Human Rights and Equal Opportunity Commission Regulations 1989* (Cth) r 4(a)(ii). See also *Disability Discrimination Act 1992* (Cth).

54 R Jansson and others, *Genetic Testing in the Workplace: Implications for Public Policy* (2000), Institute for Public Health Genetics, Health Policy Analysis Program, Department of Health Services, School of Law, Department of Economics, University of Washington, Seattle, 35–36.

26.56 A central tension is whether genetic tests should be used to ‘inform’ employees of risks, or to ‘protect’ them from risks in the workplace.⁵⁵ For example, if a susceptible employee chooses to accept an identified occupational health risk, should the employer be liable if the employee subsequently develops the condition about which he or she was warned? According to Roger Jansson and others:

Genetic testing may result in a Catch-22 for employers: greater liability for known harms of exposure to susceptible workers, but claims by workers of discrimination if employers try to protect them from exposures.⁵⁶

26.57 On the other hand, if employers are allowed to shift the responsibility for workplace hazards to employees, this might increase the incentive for employers to exclude susceptible employees from the workforce, rather than minimise environmental exposures for all employees.⁵⁷

Scientific basis of a genetic test

26.58 Employers sometimes initiate screening programs without determining whether they are justified by adequate scientific evidence.⁵⁸ Job applicants and employees might have legitimate concerns that employers will seek to rely on genetic information in making their employment decisions without fully comprehending the complex and predictive nature of the information.⁵⁹ This concern is discussed further in Chapter 28.

The public interest

26.59 There may be a public interest in reducing the incidence of occupational disease through early identification of employees’ susceptibilities to workplace related conditions. This might, in turn, lead to a reduction in the burden on the health care system and the social welfare system.⁶⁰ However, there is a risk that employers’ use of genetic information might undermine occupational health and safety standards by allowing employers to shift the focus of their efforts from the minimisation of exposure to harmful agents in the workplace to the exclusion of high risk individuals.⁶¹

55 Ibid, 37. This tension is also evident in the debate about the exclusion of pregnant women from positions involving exposure to lead substances.

56 Ibid, 36.

57 Ibid, 38.

58 E Draper, ‘The Screening of America: The Social and Legal Framework of Employers’ Use of Genetic Information’ (1999) 20 *Berkeley Journal of Employment & Labour Law* 286, 290.

59 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 42–43.

60 Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, para 6.8.

61 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 45.

26.60 The use of genetic information might lead to the creation of a 'genetic underclass' of persons who are currently asymptomatic and able to work, but are assigned to entrenched unemployment due to their genetic information. As noted above, the right to work is recognised as a fundamental human right by many countries, including Australia. A person's ability to work is important to his or her financial security, self-esteem, and ability to contribute financially to the community, through taxes and other means. There may be a public interest in protecting these persons from employment discrimination to protect the social welfare system, and other community interests.

26.61 Margaret Otłowski has suggested that there is also a public interest dimension to the protection of individual privacy: while privacy is usually defined in individual terms, the cumulative effect of the invasion of individual privacy has an impact on society as a whole.⁶²

Regulatory models for genetic information in employment

26.62 Overseas jurisdictions have taken different approaches in the regulation of genetic information in employment. A number of jurisdictions have implemented complete prohibitions on the use of genetic test information in employment. Others have implemented partial prohibitions, allowing specified exceptions for the protection of employee or third party safety.

Complete prohibition

26.63 The Inquiry understands that Austria, France and Norway have adopted absolute prohibitions on the use of certain types of genetic information in employment.⁶³ These prohibitions appear to focus on the use of genetic test results rather than family medical history. For example, in Norway it is prohibited to request, receive, possess or use information resulting from a genetic test on any person. It is also prohibited to ask whether a test has been carried out previously.⁶⁴

26.64 A number of United States jurisdictions have also prohibited the use of genetic information in employment. By February 2002, 24 states of the United States had enacted legislation on genetic information in employment.⁶⁵ Legislative prohibitions vary between jurisdictions. Some jurisdictions prohibit employers' collection and use of genetic information as well as discrimination on the basis of

⁶² Ibid.

⁶³ Ibid, 52.

⁶⁴ European Society of Human Genetics Public and Professional Policy Committee, *Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues* (2001) European Society of Human Genetics, 22.

⁶⁵ For a summary of the state legislation, see National Human Genome Research Institute, *Genetic Information and the Workplace: Enacted Legislation*, <http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/workplace.htm>, 4 April 2002.

that information; other jurisdictions prohibit discrimination only. In addition, a number of federal bills have been introduced into Congress.⁶⁶

26.65 Connecticut prohibits employers from requesting or requiring genetic information from an employee or job applicant, as well as from discriminating against any person on the basis of genetic information.⁶⁷ By contrast, California prohibits employers from discriminating against a person in various aspects of employment on the basis of genetic characteristics, but it does not regulate the collection of such information.⁶⁸

26.66 Jurisdictions also vary as to the scope of the information protected. Some older legislation focuses on particular genetic traits (eg sickle cell trait), while more recent legislation focuses on genetic test results, or test results and family medical history information more generally.

Partial prohibition

26.67 Another approach adopted by various jurisdictions is to prohibit the use of genetic information in employment, subject to specified exceptions. These exceptions generally involve screening for workplace related susceptibilities and/or for positions involving risks to the safety of third parties. Some United States jurisdictions also permit testing in the context of workers' compensation claims.⁶⁹

26.68 The Netherlands, Denmark, and several United States jurisdictions have adopted this approach, as has Israel.⁷⁰ While the United Kingdom is yet to implement legislation in this area, several advisory bodies have supported this approach.⁷¹ The models adopted by different jurisdictions vary in a number of respects, including the scope of the genetic information covered and the scope of the permitted exceptions.

66 For a summary of the bills, see National Human Genome Research Institute, *Issue Update: February 2002*, <http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/01UP_INSjan.html>, 23 July 2002.

67 See National Human Genome Research Institute, *Genetic Information and the Workplace: Enacted Legislation*, <http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/workplace.htm>, 4 April 2002, Connecticut (1998) S 80.

68 See *Ibid*, California (1998) S 654.

69 For example, see *Ibid*, New Hampshire (1995) NH ST 141-H: 1 & 3, Iowa (1992) IA ST: 729.6.

70 See M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 57; European Society of Human Genetics Public and Professional Policy Committee, *Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues* (2001) European Society of Human Genetics, 21–22; National Human Genome Research Institute, *Genetic Information and the Workplace: Enacted Legislation*, <http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/workplace.htm>, 4 April 2002.

71 For example, the Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, para 6.23; Human Genetics Advisory Committee, *The Implications of Genetic Testing for Employment* (1999), Human Genetics Advisory Committee, London, para 3.19.

26.69 Denmark generally prohibits employer access to predictive health data but allows an exception for the purpose of work-related susceptibility screening. An employer may collect health data to ascertain an employee's risk of developing or contracting diseases, provided this is instrumental to the prevention of a workplace related disease or the improvement of the working conditions, and it conforms with occupational health and safety legislative requirements.⁷²

26.70 In the United States, an Executive Order prohibits federal departments and agencies from using genetic information in hiring or promoting actions, subject to limited exceptions. 'Genetic information' is defined broadly, as information about a person's genetic tests or those of family members, and information about the occurrence of a disease or disorder in family members. The limited exceptions permit the collection of family medical history information to assess whether further medical evaluation is needed to diagnose a current disease, medical condition or disorder that could prevent the person from performing the essential functions of the position; and the conduct of genetic monitoring in certain cases.⁷³

26.71 The United Kingdom's House of Commons Science and Technology Committee has recommended another exception, allowing employers to conduct predictive screening for genetic traits that might put the public at direct and substantial risk. While the Committee stressed that it did not know of any genetic diagnosis that should be revealed to the employer when it released the report, it considered that provision should be made for future advancements in science.⁷⁴

26.72 By contrast, Israel has allowed an exception for work-related susceptibility screening, but decided against permitting an exception for the 'protection of the public' until such use is scientifically justified.⁷⁵

Retention of the status quo

26.73 A third option is to retain the status quo, allowing employers to seek and use job applicants' and employees' genetic information subject to existing privacy and anti-discrimination legislation. A number of jurisdictions appear to have taken this approach by default, in the sense that they have not yet implemented specific measures regulating the use of genetic information in the employment context.

72 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 60–61.

73 *Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information 2000* (United States). See also P Miller, 'Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace' (2000) 3(2) *Journal of Health Care Law & Policy* 225, 250.

74 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 63, citing House of Commons Science and Technology Committee, *Human Genetics: The Science and its Consequences* (1995), House of Commons, London.

75 European Society of Human Genetics Public and Professional Policy Committee, *Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues* (2001) European Society of Human Genetics, 21–22.

Overview of the Inquiry's draft proposals

26.74 In Chapter 8, the Inquiry proposed that the definition of 'disability' in the *Disability Discrimination Act 1992* (Cth) be amended to expressly bring genetic discrimination within the legislative framework of federal anti-discrimination law. In the following chapters the Inquiry discusses these issues in the context of employment, and examines a framework for regulating the collection and use of genetic information from employees and job applicants.

26.75 Chapter 27 discusses the legal framework for the regulation of discrimination in employment on the basis of genetic status. The chapter concludes that employers should be able to collect and use genetic information in relation to their employees where this is reasonable and relevant within the terms of anti-discrimination and occupational health and safety legislation, subject to two limitations.

26.76 The first limitation is discussed in Chapter 28. Employers should be able to collect and use genetic information where this is necessary to determine whether an employee is able to perform the 'inherent requirement of the job'. However, the 'inherent requirements' exception should be clarified so that it applies only to a person's current ability to perform the job. This would avoid the situation of employers making employment decisions on the basis of genetic information that may offer no more than probabilistic information about the future health of an employee. The Inquiry also proposes that an employer may request genetic information only if it can demonstrate that the information is necessary for a purpose that does not involve unlawful discrimination.

26.77 The second limitation is discussed in Chapter 29. The Inquiry proposes that employers should be able to collect and use genetic information in limited circumstances where this is relevant to the discharge of their obligations to protect and promote the health and safety of their workers and third parties. The Inquiry also proposes that the National Occupational Health and Safety Commission (NOHSC) develop model regulations regarding workplace genetic testing in consultation with the proposed national standing body on human genetics.

26.78 Finally, Chapter 30 discusses privacy issues involved in employers' collection and use of genetic information. In particular, the Inquiry considers the application of the *Privacy Act 1988* (Cth), and the specific exemption of 'employee records' from the National Privacy Principles.

27. Genetic Discrimination in Employment

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Introduction

Why should anybody invest all that money to train me, when there are a thousand other applicants with a far cleaner profile? Of course. It's illegal to discriminate — 'genoism' it's called — but no one takes the laws seriously.¹

27.1 The Inquiry's Terms of Reference require an examination of whether, and to what extent, a regulatory framework is needed to provide protection from inappropriate discriminatory use of human genetic information in a number of contexts, including employment. Chapter 26 outlined the various forms of genetic testing and information that are available to employers and the ways that these may be used in the employment context. It also canvassed some of the issues that arise from the use of this information including the interests that employers, employees and the community might seek to protect.

27.2 There is potential for discriminatory use of genetic information in the workplace. There are already documented cases of genetic testing and information allegedly being used inappropriately in Australia and overseas. This chapter examines in more detail the anti-discrimination regulatory framework currently in place in the employment context in Australia.

¹ From the screenplay of A Niccol, *GATTACA* (1997), Columbia Pictures.

Existing legal framework

27.3 As discussed in Chapter 8, Australia has anti-discrimination legislation at the federal level as well as legislation in all the States and Territories. This chapter, and those following, focuses on the federal legislation but reference will be made to the state and territory legislation in the context of discussing the need for greater harmonisation across Australian jurisdictions and where such legislation provides alternative models for consideration.

27.4 In relation to discrimination in employment on the basis of genetic status, the *Disability Discrimination Act 1992* (Cth) (DDA) and the *Human Rights and Equal Opportunity Commission Act 1984* (Cth) (HREOC Act) are the most relevant pieces of legislation. The *Sex Discrimination Act 1984* (Cth) (SDA) and the *Racial Discrimination Act 1975* (Cth) (RDA) may also have some application, depending on the nature of the genetic information under consideration. This is discussed above in Chapter 8. These Acts prohibit employers from discriminating against applicants for jobs or employees on the basis of the grounds set out in each Act. In general, an employer must not discriminate in:

- the selection process;
- the terms and conditions on which a job is offered;
- the terms and conditions offered during the course of employment;
- the training and promotion opportunities provided; or
- the termination of employment.

27.5 In addition, the *Workplace Relations Act 1996* (Cth) (WRA) contains provisions that prohibit discrimination on a range of grounds in terminating employment.

Human Rights and Equal Opportunity Commission Act

27.6 As noted in Chapter 8, the HREOC Act provides that the Human Rights and Equal Opportunity Commission (HREOC) may inquire into any act or practice, including any systemic practice, that has the effect of nullifying or impairing equality of opportunity or treatment in employment or occupation on a wide range of grounds. This is one mechanism which may be used to keep systemic discrimination on the basis of genetic status under review in the future.

Disability Discrimination Act

27.7 The DDA is the most relevant piece of federal anti-discrimination legislation in this area. The DDA prohibits an employer from discriminating against an applicant for a job or an employee based on his or her disability. There is some doubt about whether the definition of disability in the DDA is currently wide enough to include genetic status. This issue is addressed in detail in Chapter 8. In the Inquiry's view, discrimination on the basis of genetic status should be covered by the DDA, and other relevant legislation, and the proposals in Chapter 8 are intended to clarify the issue.

27.8 The employment provisions of the DDA attempt to balance the interests of employers, employees and the community. The legislation expressly acknowledges that in some circumstances a person's disability will impact on his or her ability to do a particular job. It is not unlawful to discriminate, therefore, if a person is unable to carry out the 'inherent requirements' of a job because of his or her disability and it would impose 'unjustifiable hardship' on the employer to provide services or facilities that would enable the person to do the job. The effect of these provisions is that employers are required to make reasonable accommodation for a person's disability.

27.9 It will often be the case that a person's genetic status will have no impact on his or her ability to carry out the inherent requirements of a job and will not require any accommodation on the part of the employer.

27.10 The DDA employment provisions do not apply to employment in the Australian Defence Forces in combat related positions or the Australian Federal Police as part of a peacekeeping force.² In other respects, the provisions are of wide application and will apply to most private and public sector employees.

27.11 As discussed in Chapter 8, under s 31 of the DDA, the Attorney-General may formulate Disability Standards which, once tabled before Parliament for a certain period, gain the force of law. Currently there are no standards in force in relation to employment. Draft standards have been prepared by HREOC in a process involving representatives of industry, people with disabilities and government. The process is not proceeding, however, as it has not been possible to reach a consensus on the adoption of the standards.³

² *Disability Discrimination Act 1992* (Cth) ss 53–54.

³ Disability Standards Sub-Committee of the National Committee on Discrimination in Employment and Occupation, *Disability Standards Under the Disability Discrimination Act Regarding Employment (Revised Draft)*, <http://www.hreoc.gov.au/disability_rights/standards/Employment_draft/employment_draft.html>, 29 July 2002.

Workplace Relations Act

27.12 The WRA makes it unlawful for an employer to terminate an individual's employment as a result of a range of factors including race, colour, sex, sexual preference, physical or mental disability, national extraction or social origin.⁴ The employer may do so, however, when this factor renders the employee unable to fulfil the 'inherent requirements' of a particular position.⁵

27.13 There are several differences between the protection offered by the DDA and that offered by the WRA. The WRA applies only in relation to termination of employment and excludes some employees, for example, those still in their probationary period, those employed on a casual basis for a short period or a specific task, and those employed under a traineeship agreement.⁶

27.14 In addition, the WRA does not include an 'unjustifiable hardship' provision and so does not appear to impose a requirement that the employer attempt to accommodate the employee's disability. The courts will, however, generally consider whether the employer has acted reasonably in the circumstances and any accommodation made by the employer, or failure to do so, may be considered in this context. Finally, the WRA does not contain a definition of 'physical and mental disability' and does not expressly extend to past, imputed or possible future disabilities.

27.15 In one respect the protection offered by the WRA is more robust than that offered by the DDA. Once discrimination is raised as an issue under the WRA, the onus is on the employer to establish that it had a valid reason for dismissal. By contrast, under the DDA the onus is on the complainant to establish discrimination and this can be difficult in some cases.⁷

Occupational health and safety legislation

27.16 The issue of the use of genetic information for the purposes of occupational health and safety is discussed in detail in Chapter 29. It is necessary at this point, however, to briefly consider the role of occupational health and safety legislation and how that legislation intersects with the anti-discrimination regime. Employers may wish to use genetic information to assist them in fulfilling their obligations under occupational health and safety legislation, for example, by monitoring the effect on the health of employees of hazardous substances in the workplace. Action taken as a consequence of genetic monitoring, such as moving

4 *Workplace Relations Act 1996* (Cth) s 170CK(2)(f). Under s 170CE(1)(a), an employee may also apply to the Commission for relief if his or her termination was harsh, unjust or unreasonable.

5 *Ibid*, s 170CK(3).

6 *Workplace Relations Regulations 1996* (Commonwealth) reg 30B(1).

7 See M Otowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, para 2.10.

an employee to a different position with a lower level of exposure, may amount to, or be perceived to be, unfair discrimination.

27.17 The Commonwealth and each State and Territory has occupational health and safety legislation which imposes requirements on employers to provide safe systems of work, prevent industrial injuries and diseases, protect public health and safety in relation to work activities and rehabilitate injured workers. Some state and territory anti-discrimination legislation provides that, if an employer does something that is necessary to comply with other legislation that act is not unlawful.⁸ However, the act must be 'necessary' and it is usually possible to meet occupational health and safety requirements without acting in a discriminatory way.

27.18 In addition, the Victorian legislation provides that an employer may discriminate against a person with an impairment if the discrimination is reasonably necessary to protect the health or safety of any person.⁹ The South Australian legislation provides that an employer may discriminate if the person suffering from the impairment would not be able to perform the work adequately without endangering him or herself, or other persons.¹⁰

27.19 The DDA, by contrast, no longer contains a general exemption for acts that are necessary to comply with other legislation. Section 47(3) did provide an exemption of this kind but the provision ceased to have effect on 1 March 1996. Instead, s 47(2) now provides:

This Part does not render unlawful anything done by a person in direct compliance with a prescribed law.

27.20 Some state laws have been prescribed under s 47(2), but not occupational health and safety legislation. It is possible, therefore, that some conduct that is required by occupational health and safety legislation may contravene the DDA.

27.21 The position of HREOC on the relationship between occupational health and safety laws and the DDA is that:

The DDA provides that a person who cannot perform the inherent requirements of the job need not be employed and may be dismissed without unlawful discrimination occurring. Meeting reasonable occupational health and safety standards must be accepted as being among the inherent requirements of any job ...¹¹

8 See *Anti-Discrimination Act 1977* (NSW) s 54; *Equal Opportunity Act 1995* (Vic) s 69; *Anti-Discrimination Act 1991* (Qld) s 106; *Equal Opportunity Act 1984* (WA) s 69(1)(a); *Discrimination Act 1991* (ACT) s 30; *Anti-Discrimination Act 1992* (NT) s 53.

9 *Equal Opportunity Act 1995* (Vic) s 80.

10 *Equal Opportunity Act 1984* (SA) s 71(2)(a).

11 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

27.22 In *X v Commonwealth*¹² the High Court was also of the opinion that the inherent requirements of a job include a duty not to expose others to real risks of injury. McHugh J commented:

Similarly, carrying out the employment without endangering the safety of other employees is an inherent requirement of any employment ... It would be extremely artificial to draw a distinction between a physical capability to perform a task and the safety factors relevant to that task in determining the inherent requirements of any particular employment. That is because employment is not a mere physical activity in which the employee participates as an automaton. It takes place in a social, legal and economic context.¹³

27.23 Gummow and Hayne JJ indicated that this principle also applies to the safety of the employee.

In particular, we consider that an employee must be able to perform the inherent requirements of a particular employment with reasonable safety to the individual concerned and to others with whom that individual will come in contact in the course of employment.¹⁴

27.24 McHugh J went on to state that the relevant provision of the DDA (s 15(4)) must be read as a whole. In considering whether a person can perform the inherent requirements of a job, it is also necessary to consider what services and facilities the employer might reasonably be expected to provide to assist the person.

If the employee can carry out those requirements with services or facilities which the employer can provide without undue hardship, s 15(4) does not render lawful an act of discrimination by the employer that falls within s 15. For discrimination falling within s 15 to be not unlawful, therefore, the employee must have been discriminated against because he or she was:

(a) not only unable to carry out the inherent requirements of the particular employment without assistance;

but was also

(b) able to do so only with assistance that it would be unjustifiably harsh to expect the employer to provide.¹⁵

27.25 HREOC has also stated in its guidelines for employers that:

12 *X v Commonwealth* (1999) 200 CLR 177.

13 *Ibid*, para 33.

14 *Ibid*, para 109.

15 *Ibid*, para 39.

The Federal Court is unlikely to accept that an exclusion or restriction on health and safety grounds is justified by the inherent requirements of the job where a non-discriminatory solution to the same issue is reasonably available.¹⁶

27.26 The effect of the DDA appears to be to impose an obligation on employers to make a reasonable effort to meet occupational health and safety obligations in ways that are not discriminatory. Section 15(4) of the DDA also requires employers to provide reasonable services and facilities to assist a person with a disability to do a particular job safely.

27.27 It will usually be possible for employers to comply with their obligations under occupational health and safety legislation without bringing them into conflict with the DDA. Where this is not possible, and it would impose unjustifiable hardship on the employer to provide services and facilities that would make it possible for the person to do the job without posing a risk to him or herself or others, the employer is likely to be protected by the 'inherent requirements' defence in s 15(4).

27.28 A further possibility is that an employer might seek a temporary exemption under s 55 of the DDA for acts done in compliance with occupational health and safety legislation, which are possibly inconsistent with the DDA. This would be appropriate where an employer requires a period of time to make adjustments to bring the workplace into line with the DDA.

Current employment practices in Australia

27.29 Discrimination in employment on the basis of genetic status does not appear to be widespread in Australia at present. Surveys to date have found only a small number of cases in which individuals believe they have been the subject of such discrimination. It is unclear whether, in all these cases, the acts in question would have amounted to unlawful discrimination. The submissions received by the Inquiry to date do not provide evidence of widespread misuse of this kind of information by employers.

27.30 HREOC has, to date, received only three complaints involving genetic status. Two were in the employment context and one of these did not proceed as it fell within one of the DDA exceptions. The one remaining employment case is described below. The Inquiry notes that it is possible that the number of complaints received by HREOC is not an accurate reflection of the actual size of the problem in the workplace. Other cases of discrimination on the basis of genetic status may not be brought to HREOC's attention because people are not aware of their rights or are fearful that lodging a complaint will lead to victimisation.

16 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

27.31 A recent study of genetic discrimination in Australia by Dr Kristine Barlow-Stewart and David Keays identified only two cases in which job applicants were required to undertake genetic testing as part of the employment selection process. They also identified three cases of alleged discrimination by employers against asymptomatic employees.¹⁷

27.32 A further nationwide study of discrimination on the basis of genetic status is currently being undertaken by an interdisciplinary team of researchers, including Dr Barlow-Stewart, funded by the Australian Research Council. The study is to run for three years, commencing January 2002, and may provide a more complete picture of the use of genetic information in the workplace.¹⁸

Job applicants

27.33 The one complaint raised with HREOC in the employment context, which did not fall within the DDA exceptions, involved an applicant for a position as a psychologist with a public employer. The interview process for the position included a series of aptitude tests, a medical examination and an interview with a psychologist. As part of the tests, the applicant told her employer that she had experienced enuresis (bed-wetting) until the age of fourteen, when the condition had entirely ceased. The employer refused to employ her on the basis that enuresis beyond ten years of age was indicative of psychological problems in adult life.

27.34 In response, the applicant produced evidence that there was a history of 'primary nocturnal enuresis' in her family. She claimed that she had inherited the disorder and that, since it was inherited, it was not indicative of any psychological disturbance. The complaint was terminated because there was no reasonable prospect of it being conciliated.¹⁹

27.35 The Barlow-Stewart and Keays' survey identified the following two cases involving the use of genetic information by employers in the selection process. In one case, a young woman reported that when she applied for a position with the public service, she was told that her successful application depended on a negative gene test for familial adenomatous polyposis (FAP). The employer knew she was at risk of the disease because she was undergoing regular colonoscopies for early signs of bowel cancer. When her gene test result was positive she did not continue with her job application.

17 K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250.

18 The research project is being conducted by Associate Professor Margaret Otlowski (Faculty of Law, University of Tasmania), Dr Sandra Taylor (School of Social Work and Social Policy, University of Queensland) and Dr Kristine Barlow-Stewart (NSW Genetics Education Program).

19 Human Rights and Equal Opportunity Commission, *Complaints of Genetic Discrimination under the Disability Discrimination Act: Case Studies*, 2002.

27.36 In the second case, a young man who applied for a position in the armed forces reported that he was required to provide evidence that he did not have the relevant genetic variation for a connective tissue disorder called Marfan syndrome, of which he had a family history. As he had participated in medical research overseas he was able to produce documentation indicating that he had not inherited the faulty gene. He was subsequently accepted for the position.²⁰

27.37 Another documented case of discrimination involved an individual with a family history of Huntington's disease who was initially rejected for a position with the public service. The man was informed that he would only be employed if he could provide evidence that he did not have the relevant genetic mutation. Following a written appeal to senior management this decision was reversed.²¹

Employees

27.38 The Barlow-Stewart and Keays' survey identified three cases of alleged discrimination on the basis of genetic status by employers against existing employees. These cases involved individuals with positive gene tests for either familial early-onset Alzheimer's disease or Huntington's disease. In one case, the person's employment was terminated. In the two other cases the employee was demoted after the employer became aware of the genetic test results.²²

Current employment practices overseas

27.39 It appears that, to date, very little use has been made of genetic information in employment in Europe.²³ The United Kingdom Human Genetics Commission report of May 2002 concluded that:

At present there is no evidence in this country of any systematic use of predictive personal genetic information in employment.²⁴

27.40 By contrast, and as noted in Chapter 26, the United States has a relatively long history of using genetic information in the workplace. In addition, there have been several well-publicised cases of covert genetic testing by American employers, which are discussed in more detail below. The difference in the

20 K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 254.

21 S Taylor, 'A Case Study of Genetic Discrimination: Social Work and Advocacy Within a New Context' (1998) 51(4) *Australian Social Work* 51.

22 K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 254, App 1.

23 European Society of Human Genetics Public and Professional Policy Committee, *Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues* (2001) European Society of Human Genetics, 36.

24 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 138.

comparative experience may be due to the fact that the overwhelming majority of Americans rely on employer-provided health insurance. As health insurance costs rise, employers are more likely to use health screening, including genetic screening, to reduce those costs.

27.41 Recently the United States Equal Employment Opportunity Commission (EEOC) reached a mediated settlement with Burlington Northern and Santa Fe Railway Company for US\$2.2 million. The EEOC alleged that the company violated the *Americans with Disabilities Act 1990* (US) by genetically testing, or seeking to test, 36 of its employees without their knowledge or consent. The genetic test was part of a comprehensive diagnostic medical examination that the company required of certain employees who had filed claims or internal reports of work-related carpal tunnel syndrome injuries. The case is the first EEOC litigation challenging genetic testing under that Act.²⁵

27.42 In another case, the Lawrence Berkeley Laboratory, a government-funded research institution, tested clerical and administrative employees for syphilis, pregnancy and the sickle cell trait during routine mandatory medical examinations. Certain employees brought an action against their employer alleging that the genetic testing was conducted without the employees' knowledge or consent and that the testing was not relevant to the jobs the employees had been hired to perform. The practices were successfully challenged under privacy legislation although the complaint under the *Americans with Disabilities Act 1990* (US) was dismissed on a range of grounds, including that no job-related action was taken against the plaintiffs as a result of the test.²⁶

Consultations and submissions

27.43 IP 26 sought feedback on whether federal anti-discrimination legislation and workplace relations laws adequately protect a person with a predisposition to a genetic disorder, but no present symptoms, from unfair discrimination in the employment context.²⁷ There was overwhelming support in the submissions received for the position that employees should be protected from this and all unfair discrimination on the basis of genetic status, but there was a range of views expressed on what level of protection would be adequate.

27.44 The Androgen Insensitivity Syndrome Support Group made the following general points:

25 Equal Employment Opportunity Commission (US), *EEOC and BNSF Settle Genetic Testing Case under Americans with Disabilities Act*, Press Release, <<http://www.eeoc.gov/press>>, 29 July 2002.

26 P Miller, 'Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace' (2000) 3(2) *Journal of Health Care Law & Policy* 225, 252–253.

27 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, 281.

Discrimination hurts everybody. Apart from the personal and social cost, recent damages payments awarded for discrimination cases, have sent a clear signal that discriminatory practices are neither socially acceptable nor responsible ...

As access to improved testing and analysis techniques becomes a reality, both practically and financially, more information about familial and personal medical histories is potentially available. Whereas other attributes in anti-discrimination legislation are matters of fact that relate to one person and are able to be established at a given date and time, genetic information is able to be applied to individuals and familial groups and gives the impression of establishing future fact. Both of these features unique to genetic information give it a potential for discriminatory application not possible with other forms of information.²⁸

27.45 The National Council of Women provided the following example:

[A] woman with a predisposition to breast cancer, may work quite satisfactorily for 20 years in a job and then be killed in a road-traffic accident before ever developing breast cancer. She should not be denied the job.²⁹

27.46 In its submission to the Inquiry, Privacy NSW set out some of the arguments used in support of increased use of genetic testing and information in insurance and employment. They included the following:

Within a free market economy it is an article of faith that both firms and individuals should be able to seek and use information that (they believe) will make them economically better off. It follows then that firms should be entitled to use personal information to minimise projected risk and maximise expected profits, and should be entitled to demand this information as one condition of a consensual transaction.³⁰

27.47 In an environment in which there is likely to be pressure to increase the use of genetic information in the workplace there is clearly broad support for the proposition that employers should not be able to use that information to discriminate unfairly. A preliminary question is, however, should employers be able to request or use genetic information at all.

27.48 Several submissions expressed the view that employers should not be able to request or use genetic information for any purpose.³¹ This was generally put on the basis that the information is rarely sufficiently relevant, that it is complex and subject to misinterpretation, and that it is subject to misuse by employers seeking to advance their commercial interests.

28 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

29 National Council of Women Australia, *Submission G095*, 31 January 2002.

30 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

31 Australian Council of Trade Unions, *Submission G037*, 14 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; P Henman, *Submission G055*, 15 January 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

27.49 Others expressed the view that an employer should be able to ask for and use genetic information in very limited circumstances, for example, where the information is reasonably required to:

- determine whether a person is able to perform the inherent requirements of a job;
- decide what reasonable accommodation might be necessary to enable a person to perform the inherent requirements of a job; or
- promote occupational health and safety.³²

27.50 However, the point was made in many submissions that genetic tests that indicate that a person may have a predisposition to a particular disorder will only rarely, if ever, be sufficiently reliable or relevant to be reasonably required for these purposes.

27.51 Concern was also expressed about employers' ability to accurately and objectively interpret test results given the considerable uncertainty about the quantification of such risks and how that information should be evaluated.³³ It was suggested in a number of submissions that, if employers are able to request or require genetic tests or information, these requests and the interpretation of the results should be subject to some level of independent scrutiny or oversight and that authoritative guidelines should be developed around this process.³⁴ The difficulties associated with the interpretation of genetic tests are considered in more detail in Chapter 6 above.

Inquiry's views

27.52 Discrimination on the basis of genetic status in the Australian workplace does not appear to be widespread. The situation in the United States demonstrates, however, that where there is a shift in economic incentives the collection of genetic test information and family medical history may become more widespread. It is probable that, as tests become cheaper and more reliable, Australian employers will seek to make more extensive use of them to attempt to ensure a healthier workforce, lower risk and higher productivity. These changes may occur very quickly. The Androgen Insensitivity Syndrome Support Group made the following point in its submission to the Inquiry:

32 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002; Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

33 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 4.

34 Centre for Law and Genetics, *Submission G048*, 14 January 2002; National Council of Women Australia, *Submission G095*, 31 January 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

Without doubt, the underlying principle of equal opportunity and anti-discrimination legislation is the Australian ideal of a fair go for all. In practice, it is most often the case that equal opportunity legislation is one step behind rapid societal attitude changes. An inevitable by product of this 'legislation lag' is that some person often has to suffer damage before the law recognises the need for change.³⁵

27.53 For this reason it is important to ensure that the regulatory structures and, in particular, the anti-discrimination framework is adequate to protect people from inappropriate use of genetic information in employment. If discrimination on the basis of an existing disability is inappropriate in certain circumstances, then discrimination on the basis of genetic status, which may indicate only the possibility of a future disability, is just as inappropriate. In these circumstances, individuals should not have to suffer harm before the law recognises the need for change.

27.54 While submissions were divided on the issue, the Inquiry does not propose a complete prohibition on the use of genetic information by employers. As knowledge and understanding of genetic information increases, it is possible that there will be scope for applying genetic information in the employment context in ways that draw an appropriate balance between the interests of employers, employees and the public at large. In the Inquiry's view, a more productive approach is to examine carefully the legal framework within which such information may be collected and used and to ensure that the appropriate limits and safeguards are in place to guide collection and use.

27.55 In response to the significant concerns identified in submissions, however, the Inquiry is of the view that the existing anti-discrimination and occupational health and safety laws should be clarified, and that certain safeguards should be put in place in relation to the collection and use of genetic information in the workplace. The Inquiry's specific proposals in this regard are set out in Chapters 28, 29 and 30.

Proposal 27-1. Employers should be able to collect and use genetic information in relation to their employees only where this is reasonable and relevant within the terms of anti-discrimination and occupational health and safety legislation, and subject to the limitations set out in the proposals in Chapters 28-30.

35 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

28. Inherent Requirements of the Job and Related Issues

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Introduction

28.1 In Chapter 27 the Inquiry expressed the view that, in the employment context, the use of genetic information should continue to be regulated within the existing framework of anti-discrimination and occupational health and safety legislation. In relation to the anti-discrimination regime, the following issues were identified as significant concerns in submissions received by the Inquiry:

- the meaning and scope of the term ‘inherent requirements’;
- requests for genetic testing or information; and
- independent oversight of testing and use of information.

28.2 This chapter examines each of these issues and puts forward a range of proposals intended to address the deficiencies identified in submissions.

The meaning and scope of ‘inherent requirements’

28.3 Currently, under the *Disability Discrimination Act 1992* (Cth) (DDA) it is not unlawful for an employer to discriminate against a person on the ground of the person’s disability if, because of his or her disability, the person is unable to carry out the ‘inherent requirements’ of the particular job or would, in order to do so, require services or facilities that would impose an unjustifiable hardship on the employer. This defence is only available to an employer in relation to ‘hire and fire’ decisions, namely determining who should be offered employment or dismissed as an employee.¹

28.4 One question posed in IP 26 was how a genetic predisposition should be considered in relation to an individual’s ability to fulfil the inherent requirements of a particular position.² This raises two questions as to the scope of the inherent requirements exception. First, what are the inherent requirements of a particular employment position, and should an employer be able to determine these requirements in line with its own business interests? Second, should an employer have the right to discriminate against an employee or job applicant on the basis that, while he or she is currently fit for work, this may not be the case in the future?

Current law

28.5 The term ‘inherent requirements’ is currently used at the federal level in the DDA, the *Human Rights and Equal Opportunity Commission Act 1984* (Cth) (the HREOC Act), and the *Workplace Relations Act 1996* (Cth) (WRA). The term is also used in New South Wales, Tasmanian and Northern Territory anti-discrimination legislation, while other jurisdictions use terms such as ‘work genuinely and reasonably required’.³ The term ‘inherent requirements’ is not defined in the DDA, the HREOC Act or in the WRA. In HREOC’s view, inherent requirements must be determined in the circumstances of each job and may include:

- the ability to perform the functions that are a necessary part of the job;
- productivity and quality requirements;
- the ability to work effectively in the team or other type of work organisation concerned; and

¹ *Disability Discrimination Act 1992* (Cth) s 15(4).

² Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 10–2.

³ *Anti-Discrimination Act 1991* (Qld) s 35(1); *Equal Opportunity Act 1984* (SA) s 71(2).

- the ability to work safely.⁴

28.6 There has been some judicial consideration of the term ‘inherent requirements’ as it appears in the WRA and other industrial relations legislation. In *Cramer v Smithkline Beecham*,⁵ two employees of a pharmaceutical plant were dismissed because of their ongoing sensitivity to penicillin, to which they were exposed at work. The Federal Court decided that penicillin tolerance was an inherent requirement of working in the pharmaceutical plant and therefore the dismissal of the two employees was not unlawful.

28.7 In *Qantas Airways Ltd v Christie*,⁶ Qantas had dismissed a 60 year old international airline pilot on the basis of his age. In deciding whether the pilot could fulfil the inherent requirements of his position, the High Court considered it relevant to look at the surrounding context of his employment, as well as his physical ability to perform the task. As most countries prohibit pilots over 60 years of age from flying in their airspace, the Court decided that, although the pilot might be physically capable of flying, the surrounding context meant that he was not able to fulfil the inherent requirements of the job.

28.8 In *X v Commonwealth*,⁷ as discussed in Chapter 27, the High Court considered the dismissal of a soldier from the Australian Defence Force (ADF) because he had tested positive to HIV. The soldier was discharged from the ADF despite being asymptomatic and in excellent physical health at the time. Once again, the High Court interpreted the inherent requirements exemption broadly, finding that these are not restricted to the performance of physical tasks involved in the job. Inherent requirements are the essential elements of the employment, including those required by the surrounding context. These might include the ability to work in a manner that does not pose a risk to the health or safety of the individual or other employees.⁸ In this case, it was argued that the soldier was unable to bleed safely in the field without risking the infection of his fellow soldiers. The Court indicated, however, that this approach would not allow an employer to frame the terms of the contract, or the nature of its business, to allow unlawful discrimination.

4 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

5 *Cramer v Smithkline Beecham* (1997) 73 IR 470.

6 *Qantas Airways Limited v Christie* (1998) 193 CLR 280.

7 *X v Commonwealth* (1999) 200 CLR 177.

8 Ibid, 200 (McHugh J). See also M Hirst, ‘X v Commonwealth: Inherent Requirements and the HIV Soldier: Casualties of the Anti-discrimination Battlefield’ (2000) 21(1) *University of Queensland Law Journal* 102, 105–109.

28.9 In the above cases, the disability or other basis of alleged discrimination was a current or existing one. The cases did not consider a disability that might arise in the future. In *X v Commonwealth* it was argued that, although the soldier in question was asymptomatic, he was not able to fulfil the inherent requirements of the job because of the current risk of transmitting the virus.

Consultations and submissions

28.10 Most submissions indicated that it was essential to differentiate between individuals who actually had the symptoms of a genetic disorder and individuals with a predisposition to a genetic disorder but who were asymptomatic. It was generally acknowledged that existing symptoms may have some impact on a person's ability to perform the inherent requirements of a job and that this impact should be assessed, along with any necessary accommodation by the employer, in order to determine whether a person is able to do a particular job. In this respect, a genetic condition was seen to be no different to any other medical condition or existing disability. Difficulties arise, however, in relation to genetic information that indicates that a disability may or will arise in the future.

28.11 In relation to asymptomatic individuals, the Victorian Disability Discrimination Legal Service made the following comment:

Life is complex and changing and an individual's predisposition to certain conditions cannot be said to be sufficiently scientifically and/or medically determinative to exclude that individual on any grounds other than their current capacity to perform the position.⁹

28.12 The NSW Anti-Discrimination Board also commented:

There has been a considerable increase in job mobility in recent decades, therefore it is an increasingly unrealistic [expectation] that people will remain with the same employer for any extended periods of time. Accordingly, it is unfair for employers to be able to discriminate on the basis of a person's capacity to do the job which may not arise for many years, and indeed which may not arise at all. However, it is possible that an employer may argue that a person's capacity to do the job in future forms part of the inherent requirements of a particular position.¹⁰

28.13 The Advisory Committee on Health Research to the World Health Organisation has summarised the issue as follows:

Similar ethical concerns apply to the use of genetic testing by employers or potential employers. Current health problems that would prevent a person from carrying out the duties of employment, even when employers have made reasonable accommodations for illness or disabilities, can justifiably be used in employment decisions. But genetic conditions that constitute risks for future health problems should not be used to bar

⁹ Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

¹⁰ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

otherwise qualified people from employment. If and when they prevent the individual from continuing in employment, they can be dealt with appropriately.¹¹

28.14 While these comments reflect the position adopted in most submissions, the Australian Institute of Actuaries expressed the view that:

If an employer is recruiting for the long term, then a person who is currently fit for work, but who is known to be unlikely to remain fit in the future, would be a materially different prospect from persons who are likely to remain fit throughout their working lives.¹²

28.15 An analogy can be drawn to sex discrimination on the basis of potential pregnancy. In the SDA, a reference to potential pregnancy includes a reference to:

- the fact that the woman is or may be capable of bearing children; or
- the fact that the woman has expressed a desire to become pregnant; or
- the fact that the woman is likely, or is perceived as being likely, to become pregnant.¹³

28.16 Discrimination on the basis of pregnancy or potential pregnancy is unlawful. The fact that a woman might have a child in the future, or is perceived as likely to have a child in the future, is not considered a relevant or reasonable basis for discrimination in employment.¹⁴ The arguments in support of such an approach appear even stronger in relation to a genetic condition over which the individual has no control and which might manifest in the future, or is perceived as likely to manifest in the future.

28.17 The Inquiry notes that the definition of disability in the DDA includes a disability that 'may exist in the future'.¹⁵ The NSW Anti-Discrimination Board pointed out in its submission that:

A reading of these provisions which would allow an employer to assess an individual's ability to comply with the inherent requirements of a particular position in the future, would be incongruous with this prohibition.¹⁶

28.18 One of the objectives of the DDA, and of anti-discrimination legislation more generally, is to prohibit discrimination on the basis of some factors that may arise in the future. Such factors are not considered a relevant or reasonable basis

11 Advisory Committee on Health Research, *Genomics and World Health* (2002), World Health Organization, Geneva, 159.

12 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

13 *Sex Discrimination Act 1984* (Cth) s 4B.

14 *Wardley v Ansett Transport Industries (Operations) Pty Ltd* (1984) EOC 92-002.

15 *Disability Discrimination Act 1992* (Cth) s 4(1).

16 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

for discrimination in the employment context. The United States Equal Employment Opportunity Commission (EEOC) has echoed these concerns in the following statement:

[E]mployers may only require employees to submit to any medical examination if those examinations are job related and consistent with business necessity. Any test which purports to predict future disabilities, whether or not it is accurate, is unlikely to be relevant to the employee's present ability to perform his or her job.¹⁷

Inquiry's views

28.19 The position of the EEOC is consistent with the majority of submissions received on this issue and with the Inquiry's analysis of the objectives of the DDA and other anti-discrimination legislation. It is the Inquiry's view that employers should not deny a person employment on the basis of tests or information indicating that an individual has a genetic predisposition to a particular disorder that may give rise to a future inability to perform the inherent requirements of a job. Information about genetic predisposition can usually reveal only risks and probabilities. It is simplistic to suggest that a person's future health can be accurately assessed on the basis of that information. Other factors such as environment, lifestyle and chance also have a major impact on a person's health.

28.20 It remains to consider whether there are any circumstances in which a potential inability to perform in the future might legitimately relate to the inherent requirements of the job. No examples were included in submissions received by the Inquiry. However, an argument might be developed where the job involves essential elements running some period into the future. An example might be astronauts training for a mission some years in the future, or scientists being stationed in Antarctica for a long period. In cases such as these it might be argued that an employee's capacity at some time in the future is an inherent requirement of the job. Even in these circumstances, however, while some predictive medical assessment might be justified, genetic information indicating that an individual might suffer from some genetic disorder at some indeterminate point in the future is likely to be of marginal relevance.

28.21 It was also suggested in a number of submissions that genetic information that indicates a genetic predisposition or susceptibility might be relevant in the workplace in relation to occupational health and safety issues. The relationship between the anti-discrimination regime and the occupational health and safety regime was discussed in Chapter 27. The use of genetic information in the occupational health and safety context is examined in detail in Chapter 29.

¹⁷ Equal Employment Opportunity Commission (US), *EEOC and BNSF Settle Genetic Testing Case under Americans with Disabilities Act*, Press Release, <<http://www.eeoc.gov/press>>, 29 July 2002.

28.22 In general it is the Inquiry's view that it is not reasonable to rely on genetic information to attempt to predict a person's future capacity to perform the inherent requirements of a job. In addition, it is generally not consistent with disability discrimination policy to include future performance as one of the inherent requirements.

28.23 A similar policy has been articulated in the Victorian Equal Opportunity Commission Employer Guidelines on Pre-Employment Medical Testing:

The main features of a non discriminatory pre-employment medical test are:

- it relates specifically to the genuine and reasonable requirements of the job;
- the specific physical capacities required for the job are accurately identified and are reasonable in all the circumstances;
- reasonable ways of accommodating people with disabilities/impairments have been considered;
- any facilities or services reasonably required by applicants with disabilities/ impairments are provided if reasonable;
- any assessment of a person's ability to perform the inherent requirements of the job is made in conjunction with these facilities or services;
- the test only assesses current health status and does not attempt to predict any future deterioration unless the employer can demonstrate that it is reasonable to do so.¹⁸

28.24 The Inquiry acknowledges that there may be rare circumstances in which an assessment of an applicant or employee's future health may be justified, such as the case of the astronaut or Antarctic scientist described above. However, such cases are likely to be so exceptional that the Inquiry considers it unnecessary to make specific legislative exception to accommodate them. If an employer were faced with such a case, there are adequate mechanisms to deal with it, including the possibility of obtaining an exemption by the administering agency from the application of the anti-discrimination legislation. These exemptions are discussed more fully in Chapter 27.

28.25 In the Inquiry's view, it would be valuable to clarify this issue in the DDA, the HREOC Act and the WRA. It would also be possible to clarify the matter in Disability Standards issued under s 31 of the DDA. As an interim measure, guidelines should be issued to employers under the DDA. The States and

18 Equal Opportunity Commission Victoria, *Employer Guidelines: Pre-Employment Medical Testing*, <http://www.eoc.vic.gov.au/rescentre/publications/emp_guidelines.html>, 23 May 2002.

Territories should consider amending their legislation, where necessary, to implement this underlying policy.

28.26 The Inquiry is also of the view that the production of clearly defined job descriptions by employers, which set out the inherent requirements of each position, would assist in ensuring better employment practices.

Proposal 28–1. In assessing whether an applicant or employee is able to perform the inherent requirements of a job, only current ability to perform the inherent requirements should be relevant. The term ‘inherent requirements’ in the DDA, the HREOC Act and the *Workplace Relations Act 1996* (Cth) should be clarified accordingly. The States and Territories also should consider amending their legislation to similar effect.

Proposal 28–2. Peak employer associations should encourage members to produce clearly defined job descriptions that set out the inherent requirements of every position in the workplace.

Requests for genetic testing or information

28.27 Requests for, or requirements to produce, genetic information lie at the heart of concerns about genetic discrimination. Such requests could include a request for information about family medical history, the results of a past genetic test or a request to undertake a new genetic test. Several submissions expressed the view that the circumstances in which employers are able to request or require such information should be very limited. Irrelevant questions about genetic status are unlikely to contribute to fair recruitment and employment processes. This is particularly so in relation to genetic information in view of its sometimes predictive nature and the possibility that the information may be misinterpreted or misapplied.

28.28 The DDA and other anti-discrimination laws are, in general, aimed at acts of discrimination such as refusing to employ a person because of that person’s disability or perceived disability. However, in order to create an environment in which acts of unlawful discrimination are less likely to occur, some anti-discrimination legislation also prohibits the collection of information upon which those acts might be based. This is particularly important because individuals are often hesitant to bring complaints of discrimination, for a range of reasons — including fear of further reprimand, and difficulties with satisfying the onus of proof imposed on complainants. In relation to discrimination on the basis of genetic status, it may also be that individuals are not willing to allow sensitive health information to become more widely known through bringing a complaint.

Against this background, it is important to ensure that genetic information is only requested or required by employers in appropriate circumstances.

Current law

28.29 The collection of personal information is regulated by privacy laws, as discussed in Chapter 7. However, the DDA, the SDA, and the anti-discrimination legislation in Queensland, Victoria, the ACT and the Northern Territory also contain express provisions regulating requests for information in connection with, or for the purposes of, an act of discrimination.¹⁹

28.30 Section 30 of the DDA currently provides:

If, because of another provision of this Part (other than section 32), it would be unlawful, in particular circumstances, for a person to discriminate against another person on the ground of the other person's disability, in doing a particular act, it is unlawful for the first-mentioned person to request or require the other person to provide, in connection with or for the purposes of the doing of the act, information (whether by completing a form or otherwise) that persons who do not have a disability would not, in circumstances that are the same or are not materially different, be requested or required to provide.

28.31 Section 27(1) of the SDA is in similar terms. In its report, *Pregnant and Productive: It's a Right not a Privilege to Work while Pregnant*,²⁰ HREOC noted that the meaning of the SDA provision was unclear and recommended that it be amended to simplify and confirm the intent of the section. The Sex Discrimination Amendment (Pregnancy and Work) Bill 2002 (Cth), currently before the Commonwealth Parliament, forms part of the government's response to the HREOC report and is intended to clarify the meaning of s 27(1).

Consultations and submissions

28.32 The NSW Anti-Discrimination Board, in its submission to the Inquiry, expressed similar doubts in relation to s 30 of the DDA. It is not clear, for example, whether the provision prohibits questions asked of all applicants or employees or only questions asked specifically of individuals with a disability. The HREOC guidelines on disability discrimination in employment state that a question asked of

19 *Disability Discrimination Act 1992* (Cth) s 30; *Sex Discrimination Act 1984* (Cth) s 27; *Anti-Discrimination Act 1991* (Qld) s 124; *Equal Opportunity Act 1995* (Vic) ss 100, 101; *Discrimination Act 1991* (ACT) s 23; *Anti-Discrimination Act 1992* (NT) s 26.

20 Human Rights and Equal Opportunity Commission, *Pregnant and Productive: It's a Right Not a Privilege to Work While Pregnant* (1999), HREOC, Sydney.

all applicants may amount to unlawful indirect discrimination²¹ but it remains unclear whether this sort of question would be unlawful under s 30.

28.33 In looking at alternative models for a provision of this kind, it is important to consider whether an employer should be able to seek any information about genetic status or to request that a person undergo any genetic testing. The Australian Council of Trade Unions (ACTU) made the following recommendation in its submission:

The ACTU recommends that employers be prohibited from requiring, requesting, collecting or disclosing information derived from genetic testing of current or potential employees.²²

28.34 HREOC's policy, however, in relation to requests for information about disability is as follows:

The Commission considers that discouraging, or unnecessarily restricting, discussion or inquiries regarding a person's disability in ... legitimate work related respects would be damaging to effective equality of opportunity and thus would be contrary to the objects of the DDA as well as presenting difficulties for employers. The Commission does not interpret the DDA as having this effect.²³

28.35 While this policy makes clear that employers should be able to seek some information about disability, those inquiries are limited to 'legitimate work related' issues. The NSW Anti-Discrimination Board expressed the following view in its submission:

There are insufficient safeguards in place to ensure that the information sought by employers relates to the inherent requirements of the particular position in issue ... In order to comply with anti discrimination legislation, pre-employment medicals *should* only be used to assess a person's capacity to carry out the inherent or essential requirements of a position, once the employer has identified the preferred candidate.²⁴

28.36 The Genetic Support Council of Western Australia expressed the view that employers should only be able to collect genetic information where it is relevant for occupational health and safety purposes.²⁵

28.37 The United States EEOC made the following statement in relation to the *Americans with Disabilities Act 1990* (US) in a Media Release of 9 February 2001:

21 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

22 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

23 Human Rights and Equal Opportunity Commission, *Frequently Asked Questions: Employment*, <http://www.hreoc.gov.au/disability_rights/faq/Employment/employment_faq_1.html#questions>, 22 April 2002.

24 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

25 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

The Commission takes the position that basing employment decisions on genetic testing violates the ADA. In particular, employers may only require employees to submit to any medical examination if those examinations are job related and consistent with business necessity. Any test which purports to predict future disabilities, whether or not it is accurate, is unlikely to be relevant to the employee's present ability to perform his or her job.²⁶

Options for reform

28.38 As noted in Chapter 26, the US Executive Order of 8 February 2000, which provides guidance on employment with federal departments and agencies, entirely prohibits requests for genetic tests or test results and allows only limited use of family medical history. Genetic monitoring of biological effects of toxic substances in the workplace is permitted, however, subject to certain safeguards. The US Executive Order, although not legally binding, is one model for reform.

28.39 The Genetic Information Nondiscrimination Bill 2002 (US), currently before the United States Congress, seeks to extend the policy set out in the Executive Order to the private sector and provides another model. The Bill makes it unlawful for an employer to request, require or purchase genetic information about an employee.²⁷ It is not unlawful, however, where the employer is imposing a 'qualification standard, test or other selection criterion' which is shown to be job related and consistent with business necessity. A qualification standard may include a requirement that a person not pose a direct threat to the health or safety of other individuals in the workplace.²⁸ Collection of information is allowed for genetic monitoring of biological effects of toxic substances in the workplace.²⁹ Unlike the Executive Order, the Bill does not impose a strict prohibition on requests for genetic tests or test results. Instead, it requires that any test be shown to be job-related and consistent with business necessity.

28.40 In Europe, Article 12 of the *Convention on Human Rights and Biomedicine 1996* states that:

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

26 Equal Employment Opportunity Commission (US), *EEOC and BNSF Settle Genetic Testing Case under Americans with Disabilities Act*, Press Release, <<http://www.eeoc.gov/press>>, 29 July 2002.

27 Genetic Information Nondiscrimination Bill 2002 (USA), para 202(b).

28 Ibid, para 202(d).

29 Ibid, para 202(b)(1).

28.41 As discussed in Chapter 26, a number of European countries have legislation in place that strictly limits employers' rights to request genetic test information. The Biomedicine Convention provides the framework for further legislative change. The Explanatory Report on the Convention notes the difficulties and uncertainties surrounding predictive genetic tests and makes clear that any testing must benefit the health of the individual employee, not further the commercial interests of the employer. The Report goes on to state:

Article 12 prohibits the carrying out of predictive tests for reasons other than health or health-related research, even with the assent of the person concerned. Therefore, it is forbidden to do predictive genetic testing as part of pre-employment medical examinations, whenever it does not serve a health purpose of the individual. This means that in particular circumstances, when the working environment could have prejudicial consequences on the health of an individual because of a genetic predisposition, predictive genetic testing may be offered without prejudice to the aim of improving working conditions. The test should be clearly used in the interest of the individual's health. The right not to know should also be respected.³⁰

28.42 In the United Kingdom, the Human Genetics Commission (HGC) in its recent report stated:

We generally believe that – in accordance with the principle of respect for persons — employers must not demand that an individual take a genetic test as a condition of employment ... We believe that there must be compelling medical or safety grounds before an employer could offer a genetic test, and in some cases therefore refuse to employ someone who declined to take such a test.³¹

28.43 Another possible model, currently under consideration in Australia, is the Sex Discrimination Amendment (Pregnancy and Work) Bill 2002 (Cth) which proposes to replace existing s 27(1) of the SDA with the following provision:

It is unlawful for a person (the *first person*) to request or require another person (the *other person*) to provide information (whether by way of completing a form or otherwise) if:

(a) the information is requested or required in connection with, or for the purposes of, the first person doing a particular act; and

(b) under Division 1 or this Division, it would be unlawful in particular circumstances for the first person, in doing that act, to discriminate against the other person on the ground of the other person's sex, marital status, pregnancy or potential pregnancy; and

(c) persons:

30 Steering Committee on Bioethics, *Explanatory Report to the Convention on Human Rights and Biomedicine* (1996), Council of Europe.

31 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 140, 144.

- (i) of the opposite sex; or
- (ii) of a different marital status; or
- (iii) who are not pregnant or potentially pregnant;

as the case requires, would not be requested or required to provide the information in circumstances that are the same or not materially different.

28.44 The language is somewhat clearer than the existing provision and it would be possible to redraft s 30 of the DDA along similar lines. However, the proposed amendment is still unclear in relation to the lawfulness of questions asked of all applicants.

28.45 The NSW Anti-Discrimination Board has suggested that s 26 of the *Anti-Discrimination Act 1992* (NT) provides a clearer and more appropriate model. Section 26 provides:

- (1) A person shall not ask another person, whether orally or in writing, to supply information on which unlawful discrimination might be based.
- (2) Subsection (1) does not apply to a request that is necessary to comply with, or is specifically authorised by –
 - (a) a law of the Territory or the Commonwealth;
 - (b) an order of a court;
 - (c) a provision of an order or award of a court or tribunal having power to fix minimum wages and other terms of employment;
 - (d) a provision of an industrial agreement; or
 - (e) an order of the Commissioner.
- (3) Subsection (1) does not apply if the person proves, on the balance of probabilities, that the information was reasonably required for a purpose that did not involve discrimination.

28.46 This provision does not specifically address genetic information. If a provision modelled on this section were included in the DDA, employers would be prohibited from asking questions about any disability, including genetic status, unless they could prove that the information was reasonably required for a purpose that did not involve discrimination. An employer would have to be able to demonstrate, for example, that the information was necessary to ensure that the person was able to perform the inherent requirements of the job, including the ability to work safely.

28.47 Section 26 also includes a range of exceptions where a request for information is necessary to comply with, or specifically authorised by, a law, an order of a court, an award and so on. These exceptions would need careful consideration if the model were adopted at the federal level.

28.48 There is an important difference between s 26 of the Northern Territory Act, extracted above, and s 30 of the DDA. Under provisions such as s 30 of the DDA, and s 27(1) of the SDA, the onus falls on the employee to show that information was requested in connection with or for the purposes of discrimination. Under s 26 of the Northern Territory Act, however, the onus falls on the employer to prove that information was reasonably required for a non-discriminatory purpose. The onus of proof under the unlawful termination provisions of the WRA also falls on the employer once disability has been raised as an issue.³² A reversal of the onus of proof under s 30 of the DDA would provide a higher level of protection for employees than currently exists.

28.49 In this context, Associate Professor Margaret Otowski has noted:

In contrast, under anti-discrimination legislation, the onus rests on the complainant to establish that he or she has been discriminated against on the grounds of disability. Needless to say, this is, in practice, very difficult to prove since employers are unlikely to admit being prejudiced against a person on the basis of disability ... it may ... be very onerous to substantiate that an employer, faced with several qualified applicants, was influenced by the disability, especially where the employer is able to put forward other sufficient grounds for his or her decision.³³

28.50 In summary, there is a range of possible reform options for consideration:

- A prohibition on requests for genetic testing and information in the work environment except where this is necessary for health monitoring in hazardous work environments (US Executive Order);
- A prohibition on requests for genetic testing and information except where this is relevant to the health (European Biomedicine Convention) or health and safety (UK Human Genetics Commission) of an applicant or employee;
- A prohibition on requests for genetic testing and information, except where the employer can demonstrate that the information is reasonably required for a purpose that does not involve discrimination. A provision of this kind might also include an exception for requests that are necessary to comply with other legislation, for example, occupational health and safety legislation (s 26 *Anti-Discrimination Act 1992* (NT)).

³² *Workplace Relations Act 1996* (Cth) s 170CQ.

³³ M Otowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 32.

Inquiry's views

28.51 In submissions that dealt with this issue, there was some recognition that genetic information may be legitimately required in some circumstances, but that these will be very limited. The Inquiry is of the view that in relation to genetic information, including test results and family medical history, the DDA should prohibit an employer from requesting or requiring such information unless the employer can demonstrate that the information is necessary for a purpose that does not involve discrimination. An example would be information that is used to ensure that a person is able to perform the inherent requirements of a job, including occupational health and safety considerations.

28.52 In the Inquiry's view, s 30 of the DDA does not make a clear statement of this kind and an amendment along these lines would be desirable. Although the Inquiry is particularly concerned about requests for genetic information, it recognises that the effect of a general amendment would have a wider application.

28.53 Although the proposed amendment to s 27(1) of the SDA goes some way towards clarifying that section, in the Inquiry's view a similar amendment to s 30 of the DDA would not resolve all the difficulties in the interpretation of the latter provision. It may still leave open the possibility that employers may request information upon which unlawful discrimination might be based if the information is requested from all applicants or employees.

28.54 Section 26 of the *Anti-Discrimination Act 1992* (NT), with its reversal of the onus of proof, reflects a sounder policy. In drafting an amendment along these lines it is important to consider what exceptions might be desirable, such as for conduct that is necessary to comply with, or specifically authorised by, occupational health and safety legislation. It may not be necessary to adopt all the exceptions listed in s 26, or to adopt them in their current form.

28.55 Not all States and Territories expressly prohibit requests for information that might be used for the purposes of unlawful discrimination. In these jurisdictions it is necessary to look at the decision-making process, or the decision itself, to determine whether there has been unlawful discrimination. Although the legislation in these jurisdictions might be interpreted to include an implied prohibition on the asking of such questions, the position is unclear. The Inquiry considers that the States and Territories should consider adopting a similar provision to that proposed for the DDA in their anti-discrimination legislation, to the extent that such a provision does not currently exist.

Proposal 28–3. The DDA should be amended to prohibit an employer from requesting or requiring genetic information from a job applicant or employee unless the employer can demonstrate that the information is necessary for a purpose that does not involve unlawful discrimination, such as ensuring that a person is able to perform the inherent requirements of the job. The States and Territories should consider adopting a similar provision in their anti-discrimination legislation, where one does not already exist.

Independent oversight of requests for genetic testing or information

28.56 The discussion above highlights that requests for genetic tests or genetic information should be confined to situations in which this information is required for a non-discriminatory purpose. Even in these circumstances, submissions raised concerns about processes for testing in the workplace and employers' ability to interpret and use the results of such tests in a reasonable manner. IP 26 asked what measures should be put in place to establish the reliability, accuracy and proper interpretation of any genetic testing before employers make decisions based on that information.³⁴

Consultations and submissions

28.57 The Human Genetics Society of Australasia suggested that there might be considerable opportunity for employers to misinterpret genetic test results to fulfil particular agendas, such as excluding high-risk employees as a means of minimising administrative costs.³⁵

28.58 The Institute of Actuaries of Australia submitted that an employer should be able to rely on the interpretation of genetic tests results by competent medical practitioners without further question. However, any decisions an employer makes should be justified within the framework of anti-discrimination legislation.³⁶ The National Council of Women Australia also suggested that a qualified medical practitioner should be used to assess the reliability, accuracy and interpretation of any particular genetic test before an employer makes decisions regarding offering or refusing an applicant a job.³⁷

34 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 10–3.

35 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

36 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

37 National Council of Women Australia, *Submission G095*, 31 January 2002.

28.59 The Disability Discrimination Legal Service gave examples of situations in which employers have displayed a general ignorance of disability-related issues, and have misused sensitive information in the past. It submitted:

In circumstances where [genetic] testing is permitted, a regime needs to be developed to facilitate the rigorous assessment of the reliability, accuracy and proper interpretation of genetic testing results. The uncertainty of such information is such that any definitive decision-making based on such information is currently doubtful and education and awareness addressing these issues needs to occur in the context of a broader community awareness campaign.³⁸

28.60 The author of a confidential submission suggested that a genetic scientist or counsellor should interpret genetic test results for a client. The author suggested that doctors ordering genetic tests have a duty of care to inform the prospective employees of their right of refusal and of possible discrimination and other implications of the test results.³⁹

Inquiry's views

28.61 In the Inquiry's view some level of independent oversight of the use of genetic tests and information by employers is justified to ensure that test results are interpreted accurately and that genetic information is not used inappropriately. It is important to ensure that persons are not excluded from employment on the basis of unnecessary or irrelevant tests or on the basis of misinterpretation of test results.

28.62 In Chapter 29 the Inquiry proposes that the National Occupational Health and Safety Commission (NOHSC), in consultation with the proposed national standing body on human genetics, should prepare model regulations dealing with the collection and use of genetic information for occupational health and safety purposes. The Inquiry is of the view that a parallel process should be established in the anti-discrimination context whereby HREOC, in consultation with the proposed national standing body and other relevant stakeholders, develop Disability Standards dealing with the collection and use of genetic information in employment. It will be important to ensure that, in developing such Standards, the principles and procedures adopted are, as far as possible, consistent with the model regulations to be developed in the occupational health and safety context. As an interim measure, HREOC should issue guidelines on the collection and use of genetic information in employment.

38 Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

39 *Confidential Submission G051CON*, 14 January 2002.

Proposal 28—4. HREOC should, in consultation with the proposed HGCA and other relevant stakeholders, develop Disability Standards dealing with the collection and use of genetic information in employment. As an interim measure, HREOC should issue guidelines in this area.

29. Occupational Health and Safety

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Introduction

29.1 In Chapter 27, the Inquiry proposed that the collection and use of human genetic information by Australian employers should be subject to the broad framework of existing anti-discrimination and occupational health and safety laws. In Chapter 28 the Inquiry made a range of proposals designed to clarify, and in some cases provide extra safeguards within, anti-discrimination laws. This chapter proposes changes to occupational health and safety regimes in so far as they relate to the use of human genetic information.

29.2 There are several contexts in which employers might seek access to genetic information for occupational health and safety reasons. These are genetic screening for work-related susceptibilities; genetic monitoring for workplace-induced disease; and genetic screening for the protection of third party safety.

Regulatory framework for occupational health and safety

29.3 The extent of occupational illness and injury in Australia is difficult to estimate, largely because until recently there were no national statistics in relation to these occurrences. In a 1995 report, the Industry Commission estimated that every year in Australia there are over 500 fatalities as a result of traumatic injury at work; between 650 and 2,200 workers die of occupational cancers (with the majority of cancers resulting from exposure to hazardous substances); and up to 650,000 workers (that is, one in 12 workers) suffer illness or injury at work. A 1993 study found a strong relationship between workplace exposure to toxic vapours, dyes, asbestos, pesticides, metals, dusts, petrochemicals, solvents and allergens and workplace fatalities.¹

Occupational health and safety legislation

29.4 The Australian occupational health and safety framework seeks to prevent workplace injury, disease and death; compensate workers who suffer work related injury (or their dependents in the case of death); and rehabilitate workers suffering occupational injuries or disease.²

29.5 The Commonwealth and each State and Territory has implemented occupational health and safety legislation which sets out requirements for ensuring health and safety in the workplace.³ In addition, industry-specific legislation also applies in some jurisdictions. This legislation makes provision for the protection of workplace health and safety in a particular industry.

Employer's duty of care to employees

29.6 Each occupational health and safety statute imposes a duty on employers to take reasonable care for the health, safety and welfare at work of all employees. Despite differences in wording, the employer's duty is similar in all Australian jurisdictions except New South Wales and Queensland. The employer must take all

1 See R Johnstone, *Occupational Health and Safety Law and Policy: Text and Materials* (1997) LBC Information Services, Sydney, 11, 13, 15. See also National Occupational Health and Safety Commission, *Data on OHS in Australia: The Overall Scene* (2000), Commonwealth of Australia, Sydney.

2 R Johnstone, *Occupational Health and Safety Law and Policy: Text and Materials* (1997) LBC Information Services, Sydney, 36.

3 *Occupational Health and Safety (Commonwealth Employment) Act 1991* (Cth); *Occupational Health and Safety Act 2000* (NSW); *Occupational Health and Safety Act 1989* (ACT); *Occupational Health and Safety Act 1985* (Vic); *Occupational Health, Safety and Welfare Act 1986* (SA); *Occupational Safety and Health Act 1984* (WA); *Work Health Act 1986* (NT); *Workplace Health and Safety Act 1995* (Qld); *Workplace Health and Safety Act 1995* (Tas).

reasonably practicable steps to protect the health and safety at work of all employees.⁴

29.7 In New South Wales, the employer's duty is not qualified by the 'practicability' of complying with the duty. However, the employer may rely on a defence that it was not reasonably practicable to comply, or that the breach was due to causes over which it had no control, and it was impracticable to make provision for such a happening.⁵ In Queensland, the employer must ensure the health and safety of its employees at work, subject to a number of qualifications provided in the statute.⁶

29.8 Most legislation gives examples of the content of the employer's duty of care, for example requirements for promoting occupational health and safety in the workplace; providing systems of work that are safe and without risk to health; preventing industrial injuries and diseases; protecting the health and safety of the public in relation to work activities; and rehabilitation of injured workers.⁷

Employer's duty of care to third persons

29.9 In most jurisdictions, occupational health and safety legislation also imposes duties of care on employers to persons other than employees, including persons not working for the employer but present at the workplace — for example, police, fire fighters, inspectors, clients, visitors and trespassers; and persons outside the workplace affected by the conduct of operations at the workplace.⁸

Employee's duties

29.10 In most jurisdictions, an employee has a duty to take care for his or her own health and safety while at work. All jurisdictions impose a general duty on employees to take care for the health and safety of others at the workplace. Some jurisdictions impose a duty on an employee to co-operate with the employer in the interests of workplace health and safety. Also, some jurisdictions impose a duty on

4 *Occupational Health and Safety (Commonwealth Employment) Act 1991* (Cth) s 16; *Occupational Health and Safety Act 1989* (ACT) s 27; *Occupational Health, Safety and Welfare Act 1986* (SA) s 19(1); *Workplace Health and Safety Act 1995* (Tas) s 9(1); *Work Health Act 1986* (NT) s 29; *Occupational Health and Safety Act 1985* (Vic) s 21(1). See generally, A Brooks, 'Occupational Health and Safety' in J Golden and D Grozier (eds), *The Laws of Australia: Labour Law* (1998) The Law Book Company Limited, Sydney, [73]–[74].

5 *Occupational Health and Safety Act 2000* (NSW) ss 8(1), 28.

6 *Workplace Health and Safety Act 1995* (Qld) s 28.

7 National Occupational Health and Safety Commission (Worksafe Australia) and Australian Chamber of Commerce and Industry, *The National Standards Guide (Final Draft)* (1997), Commonwealth of Australia.

8 See generally, A Brooks, 'Occupational Health and Safety' in J Golden and D Grozier (eds), *The Laws of Australia: Labour Law* (1998) The Law Book Company Limited, Sydney, [81]. However, compare New South Wales: *Occupational Health and Safety Act 2000* (NSW) s 8(2).

persons within workplaces not to wilfully or recklessly place at risk the health or safety of another at the workplace.⁹

Regulations, standards and codes of practice

29.11 While occupational health and safety legislation imposes general duties regarding workplace health and safety, regulations provide more detailed requirements for specific hazards. Commonwealth, state and territory governments issue codes of practice to advise on acceptable ways of complying with their occupational health and safety legislation.¹⁰

29.12 The National Occupational Health and Safety Commission (NOHSC) develops and declares national standards dealing with specific workplace hazards or hazardous environments.¹¹ These standards set out essential requirements for inclusion in the occupational health and safety legislation or regulations of each jurisdiction. NOHSC also declares national codes of practice to advise employers and workers on acceptable ways of meeting the national standards.¹²

29.13 Under all NOHSC standards and codes, employers have a duty to impose a systematic process of hazard identification, risk assessment, risk control and review in the workplace; make sure employees receive appropriate training, instruction and supervision; obtain and provide appropriate information; consult with employees likely to be exposed to risks, and with their health and safety representatives; and keep appropriate records.¹³ Additional or more specific requirements apply in some areas, for example in relation to hazardous substances.

Workers' compensation legislation

29.14 Each Australian jurisdiction has enacted workers' compensation legislation. These statutes require most employers to insure against their statutory and common law liability to compensate workers for work-related injury and disease that results in incapacity or death.¹⁴ Workers' compensation schemes provide workers with a no-fault statutory entitlement to specified benefits as

9 See generally, A Brooks, 'Occupational Health and Safety' in J Golden and D Grozier (eds), *The Laws of Australia: Labour Law* (1998) The Law Book Company Limited, Sydney, [90]–[92], [95].

10 National Occupational Health and Safety Commission (Worksafe Australia) and Australian Chamber of Commerce and Industry, *The National Standards Guide (Final Draft)* (1997), Commonwealth of Australia.

11 NOHSC is a tripartite body representing the Commonwealth, state and territory governments, employer organisations, and trade unions. It drafts model regulations, national standards and codes of practice for implementation by the Commonwealth, and state and territory governments.

12 National Occupational Health and Safety Commission (Worksafe Australia) and Australian Chamber of Commerce and Industry, *The National Standards Guide (Final Draft)* (1997), Commonwealth of Australia.

13 Ibid.

14 R Johnstone, *Occupational Health and Safety Law and Policy: Text and Materials* (1997) LBC Information Services, Sydney, 549.

compensation for losses suffered as a result of a work-related injury or disease. Depending on the legislation, the worker might also be able to bring a common law action against the employer for damages.¹⁵ Chapter 39 discusses workers' compensation in more detail.

Common law principles

29.15 While occupational health and safety and workers' compensation are primarily regulated by legislation, common law principles continue to have some application in certain jurisdictions. For example, employers have a common law duty to take reasonable care for the safety of their employees, breach of which may amount to breach of contract, and give rise to an action for damages for negligence.¹⁶

Genetic screening for work-related susceptibilities

29.16 The first area in which employers might seek to use genetic information in the occupational health and safety context is for screening for a genetic susceptibility (or predisposition) to a work-related condition. Family medical history information, or genetic test results, may disclose that a person has an inherited predisposition to a condition that may be triggered by exposure to certain workplace hazards. If a predisposition is identified, the person is considered 'hyper susceptible' to that condition.

29.17 In 1990, the United States Office of Technology Assessment reported that about 50 genetic traits had been identified as affecting susceptibility to specific environmental agents.¹⁷ For example, individuals with a genetic deficiency in the production of a particular protein — alpha-1 antitrypsin — are more susceptible to lung disease if exposed to dusty work environments.¹⁸ In addition, the Inquiry understands that a genetic trait may have been identified affecting susceptibility to a form of occupational overuse syndrome known as 'carpal tunnel syndrome'.¹⁹

15 Ibid, 575.

16 J Macken and others, *The Law of Employment* (5th ed, 2002) Lawbook Company, Sydney, 118.

17 T Lemmens, "'What About Your Genes?'" Ethical, Legal and Policy Dimensions of Genetics in the Workplace' (1997) 16(1) *Politics and Life Sciences* 57, 60; US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 83.

18 See National Institutes of Health, *Understanding Alpha-1 Antitrypsin Deficiency*, <www.nhlbi.nih.gov/health/public/lung/other/antitryp.htm>, 23 July 2002.

19 The US Equal Employment Opportunity Commission brought proceedings against the Burlington Northern Santa Fe Railroad in 2001 in relation to the company's policy of requiring employees who submitted claims for work-related carpal tunnel syndrome to provide blood samples. It was alleged that these samples were used for a genetic test that is claimed to predict some forms of carpal tunnel syndrome: US Equal Employment Opportunity Commission, *Press Release: EEOC Petitions Court to Ban Genetic Testing of Railroad Workers in First EEOC Case Challenging Genetic Testing under Americans with Disabilities Act*, 9 February 2001.

Current law and practice

29.18 Currently, an employer can ask an applicant or employee to provide family medical history or genetic test information to identify whether the person has a susceptibility to a particular work-related condition pursuant to the employer's occupational health and safety obligations. If a relevant susceptibility is identified, the employer might seek to exclude the job applicant or employee from employment, or the employer might use the information as a baseline assessment for further health surveillance (see below for more detail).

29.19 In some industries, employers are required to conduct pre-placement health assessments to identify an employee's individual risk status. For example, the National Standard for the Control of Inorganic Lead at Work (Lead Standard) provides that employers must provide health surveillance for employees commencing work or working in lead-risk jobs.²⁰

Issues and problems***Relevance of genetic information***

29.20 The Inquiry has heard a number of concerns regarding the use of genetic screening for work-related susceptibilities. One concern relates to the accuracy and reliability of predictive genetic tests and family medical history in identifying real risks to an applicant or employee's future health and safety. As most genetic conditions are multifactorial in nature, a genetic test may indicate only a probability that the person will suffer the disease or condition in future; the person may never develop the disease or condition. Alternative forms of assessment, such as regular medical examinations, may be a more useful indicator of risk. See Chapter 26 for more detail.

29.21 A second concern is that employers might misuse genetic screening programs to test for traits unrelated to workplace exposures, but which might affect the person's future health and ability to work, potentially impacting on the employer's administrative costs through sick leave or replacement costs.²¹

Scope of the employer's duty of care

29.22 As more accurate and reliable genetic tests become available for identifying susceptibilities to work-related diseases or conditions, it will become necessary to ask whether the employer's occupational health and safety duties include a duty to conduct genetic screening.

20 National Occupational Health and Safety Commission, *National Standard for the Control of Inorganic Lead at Work [NOHSC: 1012 (1994)]*, Commonwealth of Australia, cl 15.

21 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

29.23 The Institute of Actuaries of Australia submitted that if genetic tests become available that measure some aspect of an employee's ability to perform their duties, and there is an issue of safety to the employee or third persons, the employer would be likely to have a duty of care to use the test.²²

29.24 Associate Professor Margaret Otłowski has suggested that the extent of the employer's duty to employees with regard to genetic testing is unclear. She notes that the scope of the duty of care may be that the employer must simply inform applicants or employees of known potential hazards in the workplace, and offer them screening where it is available, or at least advise them of its benefits. If the employer meets its required safety standards, and the applicant chooses to take the risk by declining testing, or pursuing employment despite an identified susceptibility, the employer would not be in breach of its duty of care.²³

29.25 The Inquiry has heard concerns that employers might seek to comply with their occupational health and safety duties by excluding susceptible employees from the workforce, rather than by eliminating exposure to workplace hazards.²⁴ Otłowski has commented:

While employers' use of genetic screening may be advocated on the basis of enabling job applicants to make 'informed choices' about whether to take up a particular position, the reality is that the job is unlikely to be offered to a person who is identified as at risk. Further, allowing employers to use genetic testing for the purpose of selecting their employees would deflect attention away from their obligation as employers to endeavour to provide a workplace which is safe and without risk to health for all employees.²⁵

29.26 Trudo Lemmens has also expressed concerns regarding the potential exclusion of susceptible persons from employment.

Considering the importance of individual decision-making in the area of health, the specificity of genetic information, the importance of work, and the danger of systematic discrimination against 'high risk' populations, exclusion on the basis of susceptibility is acceptable only in exceptional cases. People are permitted to take some risks, particularly if necessary to participate in labor.²⁶

29.27 The Australian Council of Trade Unions (ACTU) submitted that the most effective way for employers to protect the safety of susceptible employees would be to provide a safe workplace, free from potential exposure to hazards.

22 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

23 M Otłowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 26–27.

24 Eg Australian Council of Trade Unions, *Submission G037*, 14 January 2002; Australian Nursing Federation, *Submission G080*, 10 January 2002.

25 M Otłowski, 'Employers' Use of Genetic Test Information: Is There a Need for Regulation?' (2002) 15 *Australian Journal of Labour Law* 1, 21.

26 T Lemmens, "'What About Your Genes?'" Ethical, Legal and Policy Dimensions of Genetics in the Workplace' (1997) 16(1) *Politics and Life Sciences* 57, 70.

[E]mployers are responsible for providing employees with a safe and healthy workplace, while work-related illnesses and injuries are caused by hazards in the workplace, not by employees' genetic make-up ... removing workers with a genetic predisposition to some cancers from work environments where they may be exposed to conditions putting them at additional risk is an unacceptable solution to chemical hazards in the workplace ... While there might be some statistical validity to such an approach, the fact is that many workers not showing some genetic predisposition, either because they don't have one or because of inadequacies in the testing process, will be exposed and will develop cancer. Removal of hazards for *all* workers cannot be substituted by removal of some workers.²⁷

29.28 The Anti-Discrimination Board of NSW submitted that where a person has a predisposition that may expose employees to safety risks, the employer should take all steps necessary to reduce the occupational health and safety risks, without requiring testing of employees.²⁸

Nature of participation

29.29 If employers are permitted to collect genetic information for the purpose of susceptibility screening, it is necessary to consider whether screening should be conducted on a mandatory or voluntary basis. Generally, mandatory testing would involve the employer advising employees or applicants that if they do not consent to testing, they may suffer some form of penalty that might include termination of employment.

29.30 Several international instruments emphasise the need for free and informed consent to medical and other procedures.²⁹ Although some Australian jurisdictions impose a duty on an employee to co-operate with his or her employer in the interests of workplace health and safety, it is unlikely the courts would interpret this to include a duty to comply with a mandatory genetic testing program, especially where an alternative form of screening exists.

29.31 In practice, employees may consent to susceptibility testing as a means of avoiding potentially serious health problems arising out of workplace exposures. However, the power imbalance in the employment relationship suggests that it is important to ensure consent is informed and freely given, rather than given through fear of reprisals if the employee withholds consent to screening.

29.32 Several submissions suggested the need to protect employee autonomy over their health and employment by providing for voluntary participation in screening programs. Some submissions suggested that employers should warn

²⁷ Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

²⁸ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

²⁹ See *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*, Council of Europe, (entered into force on 1 December 1999), Art 5; *Universal Declaration of the Human Genome and Human Rights*, UNESCO, <<http://www.unesco.org/ibc/en/genome/projet/>>, 29 July 2002, Art 5.

employees about potential workplace risks, and allow them to seek private medical advice about the risks involved.³⁰ The Australian Nursing Federation submitted:

If employers provide all relevant information about the work to be undertaken and its possible effect on the health of all current and potential employees then the employee can, in consultation with their own medical officer, make an informed decision about the suitability of the employment or the need for genetic testing.³¹

29.33 Dr Paul Henman emphasised the need to protect employee autonomy:

If such a link can be made between genetics and the workplace environment, then the appropriate action is for employers to advise employees that X in the workplace environment may bring about Y in people with a genetic predisposition. This allows employees control over their own genetic information and to decide whether to take steps based on the implications of their workplace environment and what steps they may choose to take. Anything else takes control away from the individual.³²

29.34 Finally, the Anti-Discrimination Board of NSW suggested that where an employee has been given adequate information about the risks but elects not to be tested and to continue to work in the environment in question, this will significantly reduce the likelihood that the employer would be liable in such circumstances.³³

Options for reform

Prohibition on genetic susceptibility screening

29.35 One option that was favoured by the ACTU and several other submissions was to completely prohibit employers from collecting or using genetic information to identify an applicant or employee's susceptibilities.³⁴ This approach emphasises the employer's responsibility for providing a safe workplace, and protects the privacy of employees' genetic information. However, the Inquiry does not consider this approach realistic in light of the nature of many potential workplace hazards.

29.36 The Inquiry recognises that eliminating hazardous substances and tasks from the workplace is the most effective means of protecting employees from safety risks. If exposure to these risks were eliminated individual susceptibilities would become irrelevant. However, in practice complete elimination of workplace

30 Australian Nursing Federation, *Submission G080*, 10 January 2002; National Council of Women Australia, *Submission G095*, 31 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

31 Australian Nursing Federation, *Submission G080*, 10 January 2002.

32 P Henman, *Submission G055*, 15 January 2002.

33 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

34 For example, Australian Council of Trade Unions, *Submission G037*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002.

hazards may not be possible. For example, if a typist were identified with a genetic susceptibility to a form of occupational overuse syndrome, it might be possible to make accommodation in his or her work tasks. However, because the very nature of the position involves exposure to repetitive typing activities, it might not be possible to eliminate exposure to this hazard altogether.

29.37 In addition, some genetic testing, particularly in the future, may be of benefit to employees by permitting the early avoidance of potentially harmful exposure.

Permit access to family medical history only

29.38 A second option is to permit the collection and use of family medical history only, for the purpose of susceptibility screening. The United States' Executive Order is an example of this model.³⁵ A federal department or agency may request family medical history information, but not genetic test results, from an applicant or employee. This information may be used to determine whether to conduct further medical evaluation to diagnose a current disease, medical condition or disorder that could prevent that person from performing essential job functions. In relation to an employee, the information may also be requested if the department or agency reasonably believes the employee will pose a direct threat due to a medical condition.³⁶

29.39 The model does not appear appropriate in the context of employment involving exposure to hazardous substances. In these circumstances, family medical history information may be insufficient to identify relevant susceptibilities unless other family members have been exposed to similar work environments.

Permit access to genetic information

29.40 A third option is to permit the collection and use of both genetic test results and family medical history for the purpose of susceptibility screening, subject to strict limitations. A number of overseas jurisdictions have taken this approach.

29.41 For example, Denmark permits employers to collect health data where it is relevant for the employee's ability to perform the specific work; and to determine the employee's risk of developing or contracting illnesses if the

35 *Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information 2000* (United States). President Bill Clinton signed the Executive Order in February 2000.

36 Equal Employment Opportunity Commission, *Policy Guidance on Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information* (2000) EEOC, 10–13.

conditions of the working environment make it reasonable and appropriate to do so in relation to the individual, or other employees.³⁷

29.42 The collection of information must be instrumental in the prevention of a work-related disease, or the improvement of working conditions, and must conform to occupational health and safety requirements. The employee must be informed about any consequences that the results may have for him or her, as well as any possible adverse effects of a refusal to undergo an examination. In certain circumstances, an employer may use the results of a health examination to exclude a person from employment. The local and national working environment service must be notified before any examinations are undertaken.

29.43 The Inquiry has received several submissions supporting this option, provided strict safeguards are implemented in relation to the collection, use and disclosure of genetic information.³⁸ The Centre for Law and Genetics emphasised that the employer's primary focus should be on elimination of hazards in the workplace, but gave limited support to the use of susceptibility screening.

[I]n some limited circumstances, employers would be justified in having access to an employee or job applicant's genetic information for occupational health and safety reasons such as determination of whether an employee has a genetic susceptibility to a disease that may [be] triggered by substances present in the workplace and there would be general support for such use in the interests of employees/applicants for employment.³⁹

29.44 They cited the United Kingdom's Nuffield Council on Bioethics' guidelines as a starting point for this consideration. The Nuffield Council recommended that genetic screening for increased occupational risks should only be considered where:

- there is strong evidence of a clear connection between the working environment and the development of the condition for which the screening is conducted;
- the condition in question is one which seriously endangers the health of the employee or is one in which an affected employee is likely to present a serious danger to third parties; and

37 *Act On the Use of Health Data etc on the Labour Market*, Act No 286 of 24 April 1996, cited in M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, 60–61.

38 For example, see Centre for Law and Genetics, *Submission G048*, 14 January 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

39 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

- the condition is one for which the dangers cannot be eliminated or significantly reduced by reasonable measures taken by the employer to modify or respond to the environmental risks.⁴⁰

29.45 The Centre for Law and Genetics stressed that susceptibility testing should be based on the principle of informed consent. Where an employee withholds consent to susceptibility testing, or is identified as susceptible but desires to continue working, they did not recommend excluding the person from employment, but suggested:

[T]he best way to ensure that the voluntariness of consent is not undermined, is to avoid impediments to such a person being engaged, but then to give some defence against liability to employers who have fully complied with occupational health and safety best practice.⁴¹

29.46 They suggested that an independent review process should objectively determine whether the grounds for the exemption have been satisfied before genetic testing is undertaken. An independent body should also oversee testing, and the use of genetic information obtained by employers, to ensure it is used only for the limited purpose for which it was obtained.⁴²

29.47 The Anti-Discrimination Board of NSW emphasised the need for clear guidelines in relation to genetic testing in employment, and proposed a comprehensive genetic testing code of practice providing a general prohibition on requesting genetic information and testing in employment with specific exceptions. The code would include guidelines on employment testing, informed consent, counselling, and rights and obligations under relevant legislation. Sections of the code could be incorporated into industry codes of practice under relevant occupational health and safety legislation.⁴³

29.48 Finally, Lemmens has suggested that specially appointed committees consisting of employer, employee and government representatives, geneticists and specialists in ethics and law, should decide on the value, validity and ethical use of genetic testing in employment. He suggested that regulatory agencies should consider four minimum requirements before approving a new genetic test in the workplace. Proposed genetic tests should have a sound scientific base; there should be no other way to gather the desired information; tests should relate directly to

40 Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, para 6.23, 6.28.

41 Centre for Law and Genetics, *Submission G048*, 14 January 2002. See also House of Commons Science and Technology Committee, *Human Genetics: The Science and its Consequences* (1995), House of Commons, London, para 233.

42 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

43 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

identified and accepted outcomes; and health information should remain confidential.⁴⁴

Inquiry's views

29.49 Chapter 26 outlines the interests of employers, employees and the public in relation to the use of genetic information in the employment context. Arguments in favour of genetic screening for work-related susceptibilities include its potential to protect susceptible employees from avoidable risk to their health and safety, and to protect employers from potential legal liability and financial costs for illness suffered by susceptible employees. Arguments against this form of screening include the potential for unfair discrimination, invasion of a person's information privacy, misinterpretation of test results, and concerns for the creation of a genetic underclass of persons rendered unemployable by their genetic makeup.

29.50 The Inquiry considers that in certain circumstances genetic screening may be appropriate to protect the health and safety of persons with susceptibilities relevant to their particular workplace. While there are currently few genetic tests that may accurately indicate a predisposition to work-related conditions, it is reasonable to assume the number of tests will expand with technological advances.

29.51 In the Inquiry's view, however, genetic screening for work-related susceptibilities should be regulated to protect job applicants and employees from unreasonable privacy invasions and unfair discrimination. The Nuffield Council's three preconditions for the use of genetic screening for increased occupational risks provide an appropriate model. The Inquiry considers a number of further safeguards are necessary for the conduct of this form of screening. In particular, screening should be subject to independent oversight to be provided by NOHSC, in consultation with the proposed national genetics standing body (see Chapter 3).

29.52 The Inquiry proposes that NOHSC draft model regulations for the use of genetic information to identify susceptibilities to work-related conditions. The model regulations should address the genetic tests that have been approved for use; the form of family medical history information that may be collected; the provision of genetic counselling for those undergoing screening; guidelines for the interpretation of screening results; confidentiality of results; and the appropriate response by employers to persons identified with relevant susceptibilities.

29.53 In addition, screening should be conducted only on a voluntary basis. It is arguable that an employer would satisfy its duty of care to employees and others by eliminating or minimising employee exposure to workplace hazards, and offering voluntary genetic testing programs to those employees who might be exposed.

44 T Lemmens, "What About Your Genes?" Ethical, Legal and Policy Dimensions of Genetics in the Workplace' (1997) 16(1) *Politics and Life Sciences* 57, 69.

Once approved by the proposed national standing body, NOHSC could declare the model regulations for implementation by each Australian jurisdiction under its occupational health and safety legislation.

Proposal 29–1. Genetic screening of applicants or employees for susceptibility to work-related conditions should be conducted only where:

- there is strong evidence of a clear connection between the working environment and the development of the condition;
- the condition may seriously endanger the health or safety of the applicant or employee; and
- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

Proposal 29–2. The National Occupational Health and Safety Commission (NOHSC), in consultation with the proposed HGCA, should develop model regulations regarding genetic screening for susceptibility to work-related conditions. The model regulations should:

- specify the genetic tests that have been approved for use;
- provide guidelines for interpreting test results;
- indicate the circumstances in which family medical history may be collected and used;
- make provision for genetic counselling for those undergoing screening;
- provide for the confidentiality of test results; and
- indicate appropriate responses by employers where genetic screening reveals relevant susceptibilities.

Genetic monitoring for workplace-induced conditions

29.54 Genetic monitoring involves the periodic testing of employees exposed to workplace hazards such as toxic chemicals or radiation to assess whether there has been any genetic modification as a result of workplace exposure.⁴⁵

29.55 Conventional biological monitoring (such as testing for lead concentration in the blood) is intended to provide early indicators of dose or adverse health effects. Genetic biomonitoring is a new form of monitoring. It assesses the risk associated with exposure to genotoxic compounds by measuring biomarkers of 'biologically effective dose' (for example, DNA adducts) and 'early biological effects' (for example, chromosomal changes) within an exposed person.⁴⁶ The Inquiry understands that the technology associated with genetic monitoring is not currently sophisticated enough for precise and uniformly dependable test results.⁴⁷

Current law and practice

29.56 Health surveillance involves the conduct of ongoing health assessments to identify whether an employee's health is being affected by exposure to a hazardous substance in the workplace. This can assist in minimising health risks from hazardous substances by confirming that the absorbed dose is below the acceptable level; by indicating biological effects requiring cessation or reduction of exposure; and by collecting data to evaluate the effects of exposure.⁴⁸

29.57 Health surveillance in industries involving workplace exposure to hazardous substances is regulated under a package of regulations, standards and codes of practice prepared by NOHSC. The National Model Regulations for the Control of Workplace Hazardous Substances (Model Regulations) apply to workplaces in which hazardous substances are used or produced, and to persons with potential exposure to hazardous substances in those workplaces.⁴⁹ Each

45 US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 55–56.

46 K van Damme, 'Genetic Testing in the Workplace: The Scientific Aspects' (Paper presented at Round Table: Genetic Testing in the Workplace, Brussels, 6 March 2000), 8. See also US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, Ch 4.

47 L Trettin, C Musham and R Jablonski, 'Genetic Monitoring in the Workplace: A Tool Not a Solution' (1999) 10(1) *Risk: Health, Safety & Environment* 31. See also J Ford and others, 'Genetic Tests in the Workplace: Detecting Past or Current Chemical Toxicity' (1999) 15(2) *Journal of Occupational Health and Safety* 155.

48 National Occupational Health and Safety Commission, *National Codes of Practice for the Control of Workplace Hazardous Substances [NOHSC: 2007 (1994)]*, Commonwealth of Australia, cl 14.1.

49 National Occupational Health and Safety Commission, *National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] (Updated for Amendments)*, Commonwealth of Australia.

Australian jurisdiction has implemented the package (with some variations) in regulations under its occupational health and safety legislation.

29.58 The Model Regulations and the Lead Standard (discussed above) both provide for health surveillance of employees to identify changes in health status due to workplace exposure to hazardous substances. These regulations outline the circumstances in which health surveillance should be conducted, the form of surveillance, the retention and confidentiality of surveillance records, and in some circumstances, the appropriate remedial response to identified exposure.⁵⁰

Issues and problems

Scope of the employer's duty of care

29.59 The employer's duty to provide a safe workplace is of particular importance in industries involving workplace exposure to hazardous substances. Health surveillance programs have been developed for these industries as one means for an employer to comply with its statutory duty to safeguard employees' health and safety; and to allow for early intervention to prevent onset of a disease in employees exposed to workplace hazards.

29.60 The Model Regulations and Lead Standard currently provide for 'biological monitoring' as a component of health surveillance. The Model Regulations define 'biological monitoring' as the measurement and evaluation of hazardous substances or their metabolites in the body tissues, fluids or exhaled air of an exposed person.⁵¹ The Lead Standard defines biological monitoring in terms of determining the amount of lead in capillary or venous blood and related measurements.⁵² It is unclear whether the term 'biological monitoring' as it is currently defined would include genetic testing.

29.61 As more accurate and reliable genetic tests become available for monitoring exposure and response to hazardous substances, it will be necessary to consider whether employers have a duty to conduct genetic testing as part of a health surveillance program.

50 Eg, the Lead Standard provides for removal of an employee from a lead risk job, to a job without lead risks, on the basis of his or her personal medical condition, or if she is pregnant or breast feeding: National Occupational Health and Safety Commission, *National Standard for the Control of Inorganic Lead at Work [NOHSC: 1012 (1994)]*, Commonwealth of Australia, cl 14.

51 National Occupational Health and Safety Commission, *National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] (Updated for Amendments)*, Commonwealth of Australia, reg 4.

52 National Occupational Health and Safety Commission, *National Standard for the Control of Inorganic Lead at Work [NOHSC: 1012 (1994)]*, Commonwealth of Australia, cl 7.

Nature of participation

29.62 In addition, as with genetic susceptibility screening, it is necessary to consider whether employee participation in genetic monitoring programs should be mandatory or voluntary. As noted above, in some jurisdictions employees have a duty to co-operate with employers in the interests of workplace health and safety.⁵³ This duty has been incorporated into the Model Regulations and Lead Standard in the requirement that employees must comply, to the extent they are capable, with all activities carried out under those regulations.⁵⁴ However, mandatory programs undermine employee autonomy in the workplace context, as well as their information privacy.

Options for reform

29.63 The Inquiry received few submissions addressing the use of genetic monitoring in employment. The Anti-Discrimination Board of NSW emphasised that employers should make every effort to reduce workplace risks without the need for testing employees, but gave qualified support for the provisions of the United States' Executive Order in relation to genetic monitoring.⁵⁵

29.64 Under the Executive Order, a federal department or agency may conduct genetic monitoring of the biological effects of toxic substances in the workplace if the following conditions are met:

- the department or agency has received the employee's prior knowing, voluntary and written authorisation;
- the department or agency notifies the employee when the results are available, makes any protected genetic information that may have been acquired available to the employee, and tells him or her how to obtain such information;
- the monitoring conforms to any genetic monitoring regulations promulgated by the Department of Labor; and

53 See generally, A Brooks, 'Occupational Health and Safety' in J Golden and D Grozier (eds), *The Laws of Australia: Labour Law* (1998) The Law Book Company Limited, Sydney, [92].

54 National Occupational Health and Safety Commission, *National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] (Updated for Amendments)*, Commonwealth of Australia, reg 16; National Occupational Health and Safety Commission, *National Standard for the Control of Inorganic Lead at Work [NOHSC: 1012 (1994)]*, Commonwealth of Australia, cl 17.

55 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

- the department or agency officials receive results only in aggregate terms that do not disclose the identity of specific employees.⁵⁶

29.65 Otowski has also suggested that in appropriate circumstances, genetic monitoring might be conducted anonymously on groups of workers, rather than individually. The test results would be disclosed to the individual employees, but the employers would receive only aggregate results. This would focus employer attention on improving workplace safety, rather than identifying and eliminating ‘at risk’ employees from the workplace.⁵⁷

Inquiry’s views

29.66 Genetic information may be useful in health surveillance programs for employees exposed to hazardous agents or substances in the workplace. Genetic test information that discloses an unacceptable level of exposure to harmful agents, or indicates a genetic response to exposure, could allow for early intervention to avoid the onset of a work-related disease in a particular employee. In addition, the genetic monitoring of groups of employees may provide employers with useful information regarding workplace exposure.

29.67 The Inquiry supports the use of genetic information as part of a health surveillance program provided the use of that information is strictly regulated to protect employees from unfair discrimination or breach of their information privacy. It is unclear whether the Model Regulations and Lead Standard currently provide for genetic testing as a component of biological monitoring. In any case these regulations do not specify which genetic tests may be conducted, who should be responsible for the interpretation of test results, or the appropriate response to results indicating employee exposure to workplace hazards.

29.68 In keeping with its proposals on susceptibility screening, the Inquiry proposes that genetic monitoring should be included in the proposed model regulations to be drafted by NOHSC, in consultation with the proposed national genetics standing body (see Chapter 3). These model regulations should specify the genetic tests that have been approved for use; provisions for genetic counselling for those undergoing monitoring; guidelines for the interpretation of monitoring results; the confidentiality of results; and the appropriate response by employers to persons identified as having been exposed to hazards in the workplace. The model regulations should also specify whether genetic monitoring may be conducted on an individual basis, or on an aggregate basis in relation to groups of employees.

⁵⁶ Equal Employment Opportunity Commission, *Policy Guidance on Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information* (2000) EEOC, 17.

⁵⁷ M Otowski, ‘Employers’ Use of Genetic Test Information: Is There a Need for Regulation?’ (2002) 15 *Australian Journal of Labour Law* 1, 34.

29.69 Once approved by the proposed national standing body, NOHSC could declare the model regulations for implementation by each Australian jurisdiction under its occupational health and safety legislation.

Proposal 29–3. Genetic monitoring of employees should be conducted only where:

- there is strong evidence of a clear connection between the working environment and the development of the condition;
- the condition may seriously endanger the health or safety of the employee; and
- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

Proposal 29–4. NOHSC, in consultation with the proposed HGCA, should develop model regulations for the conduct of genetic monitoring of employees exposed to hazardous substances in the workplace.

Genetic screening for the protection of third party safety

29.70 The third context in which employers might seek access to an applicant or employee's genetic information is to identify whether he or she has a genetic predisposition to a condition that, if it becomes manifest while the person is at work, could pose a significant risk to the health and safety of other employees or the public.

29.71 This application of genetic screening is more likely to occur in 'safety critical' positions. There are a vast number of positions involving potential responsibility for the safety of fellow employees or the public. Examples include public transport (for example, airline and ship pilots; train or bus drivers), certain emergency services (for example, fire fighters, police officers), and positions involving the storage or transport of dangerous chemicals or products.⁵⁸

⁵⁸ See generally Australasian Faculty of Occupational Medicine, *Guidelines for Health Assessment for Work* (1998) Royal Australasian College of Physicians, 22–23.

Current law and practice

29.72 As discussed above, employers generally have a statutory duty to protect the health and safety of third persons present at the workplace or otherwise affected by the conduct of operations at the workplace.

29.73 In some industries, specific legislation requires employers to ensure the health and safety of their employees so that they may perform their work without safety risks to other workers or the public. For example, the *Rail Safety Act 1993* (NSW) provides that all railway employees performing railway safety work must be of sufficient good health and fitness to perform the functions for which they are certified.⁵⁹

29.74 Some industries have developed industry-based policies for meeting occupational health and safety requirements. For example, the Civil Aviation Safety Authority Australia (CASA) has the statutory power to regulate the safety of civil aviation operations in Australia.⁶⁰ Pilots must undergo regular medical assessments as a condition of their licence, rather than as a condition of employment. If a health risk is identified, the medical examiner must notify CASA and the employee, but not the employer.⁶¹

29.75 Some employers implement their own workplace policies for the purpose of satisfying their occupational health and safety duties. For example, a number of Australian employers conduct drug and alcohol testing on employees engaged in inherently dangerous work activities to determine whether they are under the influence of a drug likely to affect their performance and place the safety of others at risk.

Issues and problems

Relevance of genetic information

29.76 In some countries, there have been reported cases of employers collecting genetic information from employees to identify potential safety risks for a number of years. For example, in the 1970s, the United States armed forces and airline industry screened pilots and aircrew applicants for the sickle cell trait in the apparent belief that carriers might suffer adverse health risks in certain atmospheric conditions. These policies were subsequently discontinued due to insufficient

59 *Rail Safety Act 1993* (NSW) s 61.

60 See *Civil Aviation Act 1988* (Cth) s 9.

61 See generally Civil Aviation Safety Authority, *Designated Aviation Medical Examiner's Handbook* (2001) CASA.

evidence that carriers posed such a risk.⁶² The United Kingdom Ministry of Defence also conducted sickle cell screening on aircrew applicants until recently.⁶³

29.77 A number of submissions argued that predictive genetic testing is an inaccurate indicator of a person's future performance. These tests are not yet sufficiently reliable to accurately determine the degree of risk posed by an employee identified with a certain predisposition.⁶⁴ The Disability Discrimination Legal Service submitted:

Until such time as scientific reliability and certainty of genetic test results can be determined and verified, such risk to the public let alone the individual themselves, is unable to be assessed. Given this uncertainty, such testing would constitute a breach of the human rights of individuals and groups within the community with no appreciable benefit to public or individual safety.⁶⁵

29.78 Several submissions suggested that instead of collecting genetic information, employers could avoid potential safety risks through alternative measures such as regular medical examinations to identify the onset of symptoms, or by providing technological or other measures to assist employees if safety risks arise.⁶⁶ Dr Paul Henman submitted:

We have not had aircraft and bus crashes or nuclear generator collapses that have resulted from a person's sudden manifestation of an undiagnosed genetic condition ... In terms of safety critical employment, the key issue pertains to the existence of a genetic condition that has a sudden, unexpected onset. In contrast, most (all?) genetic conditions that impair a person's capabilities are gradual ... Safety critical jobs normally have a range of procedures to ensure safety ... These checks all make genetic information unnecessary and irrelevant to the operation of safety critical functions. In particular, if a genetic condition may lead to a deterioration of a person's capacity to work, such deterioration is likely to be identified at a regular medical examination. It is only at such time that it is appropriate for the condition to affect one's employment.⁶⁷

29.79 The Australian Nursing Federation recommended a 'universal precautions' approach, noting that risk identification, reduction and management processes are routinely undertaken in relation to employees. As examples, it cited

62 J Crespin, 'Genetic Screening in the Workplace for Sickle Cell Trait: A Dangerous Tool' (1992) 30 *Medical Trial Technique Quarterly* 91, 95-96.

63 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 8.8.

64 Disability Discrimination Legal Service, *Submission G146*, 28 March 2002; Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002.

65 Disability Discrimination Legal Service, *Submission G146*, 28 March 2002.

66 See Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; Australian Huntington's Disease Association (NSW) Inc, *Submission G054*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002; Australian Nursing Federation, *Submission G080*, 10 January 2002; Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

67 P Henman, *Submission G055*, 15 January 2002.

the current practice of having more than one pilot in most aeroplanes, and the requirement that professional drivers take regular rest breaks.⁶⁸

29.80 By contrast, the Centre for Law and Genetics submitted that there might be limited circumstances in which genetic screening for the protection of third party safety might be justified:

[T]here would need to [be] some quantification of the risk such that it is reasonable to be taking precautions against it ... Amongst other things, there would need to be consideration of the prevalence of the condition and the likelihood of the person actually developing it. The probability of the person developing the condition also has to be weighed against the seriousness of the hazard that this person represents to others should he or she develop the condition: the more serious the consequences for third parties, the more justifiable testing would be.⁶⁹

29.81 The Anti-Discrimination Board of NSW considered that employers should be permitted to monitor employees' health in cases where public safety is at issue and there is no way of eliminating the risk without knowledge of a person's health.⁷⁰

Scope of the employer's duty of care

29.82 The scope of the employer's duty of care for the health and safety of its employees or third parties may be unclear in relation to predictive genetic information. The Institute of Actuaries of Australia suggested that the duty might include a duty to screen employees on recruitment, and to test them regularly during their service, to ensure they do not pose a preventable safety hazard. The Institute suggested that if a genetic test becomes available that is deemed sufficiently reliable for measuring a person's fitness to do a specific job, the employer is likely to be obliged to introduce the test in order to comply with its duty of care.⁷¹

Options for reform

Prohibit access to genetic information

29.83 One option is to prohibit genetic screening for the protection of third party safety completely, on the basis that its need is not yet scientifically demonstrated. As most predictive genetic tests cannot yet accurately predict the time of onset of a disease, or in most cases, whether the disease will manifest at all, this information is of little use to employers seeking to protect third party safety. A

68 Australian Nursing Federation, *Submission G080*, 10 January 2002. See also P Henman, *Submission G055*, 15 January 2002.

69 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

70 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

71 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

notable exception is the single gene disorder, Huntington's disease, in which case the age of onset of the condition depends on the number of repetitions of the DNA sequence 'CAG' in one portion of one gene.⁷²

29.84 While this approach seems reasonable in the short term, the Inquiry considers that due to the likelihood that more accurate and reliable genetic tests will become available in future, some legislative framework should be established for this application of genetic screening.

Permit access to family medical history

29.85 A second option is to allow employers access to family medical history information to identify whether employees in safety critical positions have a family medical history of certain 'high risk' conditions. If so, the employer could implement a program of health surveillance to ensure the employee undergoes regular medical examinations to identify the potential onset of symptoms. For example, if a pilot has a family history of neurological or cardiac conditions known to have strong genetic traits, this would indicate a need for ongoing medical review. Again, this form of screening may not be sufficient to identify all relevant susceptibilities.

Permit access to genetic information generally

29.86 Several overseas jurisdictions have permitted the use of genetic information in employment for the purpose of genetic screening for the protection of third party safety. A number of submissions supported the use of genetic screening for this purpose.

29.87 The Centre for Law and Genetics submitted that this form of testing should only be permitted in exceptional circumstances where a case can objectively be made that testing is necessary for the protection of other employees or the public generally. They recommended a number of procedural safeguards, including the need to demonstrate clear scientific evidence of the risk to third parties, and that the danger could not be guarded against by less invasive means such as regular performance monitoring; quantification of the risk so that it is reasonable to take precautions against it; evidence as to the probability of the person developing the condition; and oversight by an independent body.⁷³

29.88 The Anti-Discrimination Board of NSW also recognised that there may be limited circumstances in which genetic testing may be appropriate where particular positions involve significant safety risks to the public, the employee

72 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 55–56.

73 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

concerned, or other employees. The Anti-Discrimination Board of NSW submitted that genetic testing of applicants or employees should be limited to:

[P]ositions where the risk to public safety could not be eliminated other than by being aware of a person's condition or predisposition; and conditions which would [affect] a person's capacity to carry out the inherent requirements of the particular job.⁷⁴

29.89 The Haemophilia Foundation Victoria submitted that the only circumstance in which tests should be available in employment is where there is a proven link between the particular genetic condition and the ability to conduct the job safely.

For example, if a person's genetic information shows that they are likely to have a heart attack, and they are at a high-risk age, that person should not fly planes, drive buses or undertake any job in which a sudden heart attack would put the public, or fellow workers, at risk.⁷⁵

29.90 The Foundation considered that genetic testing should be voluntary, on the basis of informed consent, and must 'carry no fear of reward nor reprisal'. The Foundation emphasised the need for strict guidelines to protect employees from inappropriate use of testing.

Inquiry's views

29.91 The Inquiry recognises the desirability of protecting employees and the general public from unreasonable risks to their health and safety. In very limited circumstances, it may be reasonable for employers to obtain and use genetic information from persons working in safety-critical positions to identify relevant risks to third parties. An example might be a genetic predisposition to a condition with a sudden and unpredictable onset that would pose a direct and significant threat to the safety of third persons.

29.92 At present, it is difficult to find examples of conditions with a genetic component involving the sudden and unpredictable onset of symptoms that could not have been identified through regular medical examinations. A possible example is the testing of airline pilots or bus drivers for Huntington's disease due to the risk of the sudden onset of irrational behaviour, which is one of the first symptoms of the condition;⁷⁶ or for Marfan syndrome, which is difficult to diagnose but may lead to heart failure or irregularities of the heart's rhythm.

74 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

75 Haemophilia Foundation Victoria, *Submission G145*, 25 March 2002.

76 M Otlowski, 'Employers' Use of Genetic Test Information: Is There a Need for Regulation?' (2002) 15 *Australian Journal of Labour Law* 1, 21–22.

29.93 Such circumstances will be rare. In most cases, regular performance monitoring and/or medical examinations would offer an effective and reliable means of identifying ‘high risk’ employees. This could identify any deterioration of performance, or development of symptoms, whether resulting from genetic or other causes.⁷⁷ The Inquiry considers that performance monitoring and medical examinations are generally preferable to genetic testing for reasons of reliability of prediction.

29.94 However, the Inquiry recognises that more accurate and extensive predictive testing may become available in future. Therefore, as with susceptibility screening and genetic monitoring, the Inquiry proposes that NOHSC develop model regulations for the use of genetic information for the protection of third party safety, in consultation with the proposed national genetics standing body (see Chapter 3). The model regulations should specify the genetic tests that have been approved for use; the form of family medical history information that may be collected; provisions for genetic counselling for those undergoing screening; guidelines for the interpretation of screening results; the confidentiality of results; and the appropriate response by employers to persons identified with relevant susceptibilities.

29.95 Once approved by the proposed national standing body, NOHSC could declare the model regulations for implementation by each Australian jurisdiction under its occupational health and safety legislation.

Proposal 29–5. Genetic information should be collected from an applicant or employee and used for the protection of third party safety only where:

- the applicant or employee’s condition poses a real risk of serious danger to the health or safety of third parties; and
- the danger cannot be eliminated or significantly reduced by other reasonable measures taken by the employer to eliminate or reduce the risks.

Proposal 29–6. NOHSC, in consultation with the proposed HGCA, should develop model regulations with respect to the collection and use of genetic information from applicants and employees for the protection of third party safety. (See also Proposal 29–2).

77 Ibid, 22.

Occupational health and safety and discrimination

29.96 As discussed in Chapter 26, one of the central tensions regarding the use of genetic information in relation to occupational health and safety is the scope of the employer's power to lawfully exclude 'high risk' employees from the workplace. Roger Jansson and others have commented:

Perhaps the over-arching ethical question involves whether the responsibility for the safety and health of workers should be assigned to employees or employers. The answer to this question determines whether genetic testing will be used merely to inform susceptible workers of risks or will allow employers and governments to exclude susceptible workers from risks.⁷⁸

29.97 As discussed in Chapter 27, in some circumstances the *Disability Discrimination Act 1992* (Cth) (DDA) and occupational health and safety legislation do not sit well together. For example, an employer who seeks to comply with occupational health and safety legislation might nevertheless be acting unlawfully under the DDA by excluding applicants or employees from employment because they pose an unacceptable risk to their own safety, or that of third parties.

29.98 In some circumstances, this may not be the case. If an employee's genetic status renders him or her unable to work without posing a significant risk to his or her own safety, or that of third parties, that person may be unable to fulfil the 'inherent requirements' of the job. An employer can then remove the employee from the workplace without breaching anti-discrimination laws. This exemption is discussed further in Chapter 28.

29.99 A more difficult situation arises where a person is currently asymptomatic of a condition to which he or she is genetically predisposed. Genetic screening may disclose a potential future risk to health and safety, but would not indicate if or when the condition will be manifested. In most cases, an employer would not be justified in excluding these persons from employment. The Centre for Law and Genetics submitted that in exceptional circumstances it might be appropriate to exclude persons for the protection of third party health and safety. After outlining very strict preconditions for such testing, the Centre submitted that an employer might be justified in excluding an employee for the protection of third party safety where the employee is identified as at risk, or where he or she refuses to undergo testing for a condition that has been determined to warrant predictive testing on health and safety grounds.⁷⁹

78 R Jansson and others, *Genetic Testing in the Workplace: Implications for Public Policy* (2000), Institute for Public Health Genetics, Health Policy Analysis Program, Department of Health Services, School of Law, Department of Economics, University of Washington, Seattle, 31.

79 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

29.100 The DDA does not make specific provision for compliance with occupational health and safety requirements, but provides four primary forms of exemption from its operation. First, s 15(4) provides an ‘inherent requirements’ exception from the operation of the DDA. However, the Inquiry considers that an employer who discriminates against a person on the basis of a potential future risk to health and safety should not generally be able to rely on this exception.

29.101 Second, s 31 allows the federal Attorney-General to make disability standards that may explain respective rights and responsibilities in relation to employment, and explain how the DDA relates to other laws regulating employment. Third, s 47(2) provides that anything done in direct compliance with a prescribed law is not unlawful under the DDA.⁸⁰ Fourth, s 55 provides that employers may apply to HREOC for a temporary exemption from the operation of the DDA.

29.102 Any of these exceptions might be appropriate in the circumstances of an employer who seeks to exclude a person from employment based on his or her potential future risk to health and safety. For example, the Attorney-General could declare disability standards providing guidelines as to when an employer might appropriately exclude ‘high risk’ persons from employment; alternatively, the proposed model regulations for the collection and use of genetic information in the context of occupational health and safety could, once implemented under occupational health and safety regulations, be prescribed for the purpose of s 47(2) of the DDA. Employers would then be exempt from the DDA to the extent that they acted in direct compliance with these prescribed regulations.

29.103 The Inquiry considers that employers could apply to the Human Rights and Equal Opportunity Commission (HREOC) for a temporary exemption from the operation of the DDA. Temporary exemptions are granted for up to five years at a time, and in assessing applications for exemptions, HREOC could provide independent supervision of employers’ exclusion policies. By way of example, temporary exemptions from the operation of the *Sex Discrimination Act 1984* (Cth) have been granted to employers in the lead industry to allow them to lawfully exclude pregnant and breastfeeding women from lead risk jobs.⁸¹

⁸⁰ Occupational health and safety legislation is not currently prescribed under the DDA.

⁸¹ Human Rights and Equal Opportunity Commission, *Pregnant and Productive: It's a Right Not a Privilege to Work While Pregnant* (1999), Human Rights and Equal Opportunity Commission, Sydney, para 9.51.

30. Employment and Genetic Privacy

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Introduction

30.1 The terms of reference require the Inquiry to report on whether, and to what extent, a regulatory framework is needed to protect the privacy of human genetic samples and information in a number of contexts, including employment. Previous chapters in Part H have examined the various forms of genetic testing and information that are available to employers, the way in which these may be used in employment, and some of the issues that arise from these uses. The Inquiry is presently of the view that there are circumstances in which the use of genetic information in employment is justified. The proposals in Chapters 28 and 29 seek to ensure that this use is appropriately regulated by anti-discrimination laws and occupational health and safety laws.

30.2 In Chapter 7 the Inquiry examined the legal framework for the protection of genetic privacy in Australia and made a number of proposals to promote greater harmony across Australian jurisdictions and to ensure that privacy laws apply to both genetic samples and information. It remains to consider whether those privacy laws, if amended as proposed, would provide sufficient protection for genetic information in employment. The issue of harmonisation of state and territory privacy laws has been dealt with in Chapter 7. Against that background, this chapter focuses on privacy protection at the federal level.

Current law and practice

Current employment practice

30.3 Chapter 26 discussed the kinds of genetic testing and information available to, and in use by, employers both in Australia and overseas. While anti-discrimination legislation generally targets the unlawful use of information, it is

also important to ensure that the information itself is protected, that is, that personal information is collected, used, stored and disclosed by employers in appropriate ways.

30.4 In an Information Paper prepared in 1996, the then federal Privacy Commissioner expressed the concern that:

While there is no evidence that trade in such information is being conducted to an appreciable extent in Australia, there may be economic incentives for firms to disclose personal genetic information (with or without the consent of the individual concerned).

Industry associations (or wider employer bodies) could wish to maintain shared lists of employees judged to be genetically unsuitable for employment. Especially if the genetic tests to determine health risk were expensive, this would allow a reduction in the cost per employer.¹

30.5 The Australian Council of Trade Unions (ACTU) stated in its submission that:

It appears that there is potentially some trade in such information, as was seen last year when a small company established an internet site and invited employers to submit names and details of employees who took, in their view, excessive sick leave. The plan was to charge potential employers a fee for access to the database so obtained. While this project does seem to involve some breaches of the *Privacy Act* (although there is also an exemption for small business), it does indicate the level of interest in the subject of employee absenteeism. ... There can be little doubt that genetic information, if obtainable by employers, would be circulated to potential employers and others, particularly in the private sector.²

30.6 One current use of genetic information by employers, which highlights the need for appropriate privacy protection, is the collection of genetic samples from classes of employees for the purposes of identification. For example, Tasmanian police recruits are asked to supply genetic samples so that a recruit's DNA can be eliminated as a possible contaminant at crime scenes. The Tasmanian Police Commissioner has expressed the view that this program should be made mandatory and that legislation may be required. In Western Australia, the *Criminal Investigation (Identifying People) Act 2002* (WA) empowers the Commissioner of Police to require police officers to provide a genetic sample for the purposes of identification.³

30.7 In the United States, the Department of Defense collects genetic samples from every service member on active duty or in the reserve armed forces on a mandatory basis for storage in a DNA Repository. The samples are collected for

1 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), OFPC, Sydney.

2 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

3 *Criminal Investigation (Identifying People) Act 2002* (WA) s 22.

the purpose of identifying the remains of service members. The policy was unsuccessfully challenged in 1995 by two marines who objected to providing a sample on the basis that it was an unreasonable intrusion on their privacy.⁴

30.8 Chapter 26 notes that the Australian Defence Force is considering implementing a similar policy. There are approximately 50,000 permanent defence force personnel in Australia and almost 20,000 reserves who could potentially be required to provide a genetic sample if this policy were implemented in Australia.⁵ With such developments on the horizon it is important to ensure that privacy in employment is given adequate consideration and protection.

30.9 These examples also highlight the importance of the proposals in Chapter 7, namely, that the definitions of ‘personal information’ and ‘health information’ in the *Privacy Act* be amended to include genetic samples and ensure comprehensive coverage for genetic information. In the absence of such amendments, genetic samples and information collected from police officers and, potentially, members of the Australian Defence Force may not be adequately protected.

30.10 This kind of systematic collection of genetic information from employees is not currently a widespread practice in Australia. However, employers do commonly collect a wide range of health information, including some genetic information, from employees for the purposes of pre-employment health screening, occupational health and safety assessment and monitoring, and so on. Dr Roger Magnusson noted in his submission to the Inquiry that:

[T]here is nothing discrete or self-contained about genetic information as a form of health information. As clinical genetics continues to develop, any attempt to compartmentalise genetic health data from other forms of health information will likely become unworkable. This is because — as the clinical implications of the genetic determinants of disease come to be better understood — genetic testing, and the volume of clinical genetic information, will both increase.⁶

30.11 On this basis, and as noted in a range of other contexts in this Discussion Paper, the use of genetic information by employers and others is likely to increase in the future and become simply one element of general health information. The use of genetic information by employers is, therefore, likely to impact on an expanding section of the community.

4 E Reiter, ‘The Department of Defense DNA Repository: Practical Analysis of the Government’s Interest and the Potential for Genetic Discrimination’ (1999) 47(2) *Buffalo Law Review* 975.

5 Department of Defence, *Defence Annual Report 2000–01* (2001), Commonwealth of Australia.

6 R Magnusson, *Submission G039*, 10 January 2002.

Existing regulatory framework

30.12 Existing contractual and equitable principles may offer some level of privacy protection to individuals in a contract of employment. Employers have an implied duty of confidence and trust toward their employees.⁷ This may include a duty to respect the confidentiality of genetic information obtained about an employee. It may preclude the employer from disclosing that information to third parties, such as insurance companies. While contractual duties will not apply to job applicants who do not enter into an employment relationship with the employer, the employer may still have an equitable duty to maintain the confidentiality of genetic information provided by them.⁸ At the federal level, and as discussed in Chapter 7, the collection, use, storage and disclosure of employees' personal information is also regulated by the *Privacy Act 1988* (Cth).

30.13 As noted in IP 26⁹ and in Chapter 7, different privacy regimes apply to employment in the Commonwealth public sector, state and territory public sectors, and the private sector. The handling of employees' personal information in the Commonwealth and ACT public sectors is regulated by the Information Privacy Principles (IPPs) set out in the *Privacy Act*. The Act does not apply to other state and territory government bodies but employees in these organisations will be covered by state or territory privacy legislation where such legislation exists.

30.14 The handling of employees' personal information in the private sector is now regulated under amendments to the *Privacy Act*, which came into force on 21 December 2001. Under the new legislation, private sector employers may choose to be bound by a privacy code approved by the Privacy Commissioner. In the absence of such a code, the National Privacy Principles (NPPs) in the legislation will apply. As discussed in Chapter 7, most small business operators are exempt from the operation of the Act under s 6C, but this does not include small business operators who provide health services and hold health information that is not contained in an employee record.

30.15 In relation to private sector employers who do not fall into the small business exemption and are therefore covered by the *Privacy Act*, s 7B(3) states:

An act done, or practice engaged in, by an organisation that is or was an employer of an individual, is **exempt** for the purposes of paragraph 7(1)(ee) if the act or practice is directly related to:

7 For example, see *Blaikie v SA Superannuation Board* (1995) 65 SASR 85.

8 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, para 4.4.1.

9 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 10.90–10.105.

- (a) a current or former employment relationship between the employer and the individual; and
- (b) an employee record held by the organisation and relating to the individual.

30.16 An 'employee record' is defined in s 6(1) of the *Privacy Act* as:

A record of personal information relating to the employment of the employee. Examples of personal information relating to the employment of the employee are health information about the employee and personal information about all or any of the following:

- (a) the engagement, training, disciplining or resignation of the employee;
- (b) the termination of the employment of the employee;
- (c) the terms and conditions of employment of the employee;
- (d) the employee's personal and emergency contact details;
- (e) the employee's performance or conduct;
- (f) the employee's hours of employment;
- (g) the employee's salary or wages;
- (h) the employee's membership of a professional or trade association;
- (i) the employee's trade union membership;
- (j) the employee's recreation, long service, sick, personal, maternity, paternity or other leave;
- (k) the employee's taxation, banking or superannuation affairs.

30.17 The House of Representatives Standing Committee on Legal and Constitutional Affairs delivered an Advisory Report on the Privacy Amendment (Private Sector) Bill 2000, which included the following examples of how the exemption might operate in practice.

As a result of the exemption, an employer would be able to obtain information about sensitive issues such as health, criminal convictions or trade union membership from a previous employer or some other person without the employee being informed. This could also include information about disciplinary matters, financial records or health records ... In the Committee's view it is also important to note that, while the terms of the exemption offer some protection against disclosure by employers of employee information for commercial purposes, employee information may be disclosed to organisations for other reasons. An employer could, for example, provide personal information on all its employees to a superannuation fund for the purposes of securing superannuation benefits for its employees.¹⁰

30.18 The employee records exemption is limited in several ways. For example, it only applies to information held by an employer about its current and former employees, where that information is held in employee records, and its use or disclosure relates to the employment relationship with that employer. The exemption does not cover information held about applicants for employment who

¹⁰ Standing Committee on Legal and Constitutional Affairs, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000* (2000), House of Representatives, Parliament of the Commonwealth of Australia, Canberra, para 319.

were unsuccessful and who, therefore, did not enter into an employment relationship. In addition, there is no exemption for employee records held in the public sector.

30.19 The Attorney-General's Second Reading Speech on the Privacy Amendment (Private Sector) Bill 2000 included the following statement about the employee records exemption:

The bill also includes an exemption for employee records. An 'employee record' is defined to capture the types of personal information about employees typically held by employers on personnel and other similar files.

While this type of personal information is deserving of privacy protection, it is the government's view that such protection is more properly a matter for workplace relations legislation.

It should be noted, however, that the exemption is limited to collection, use or disclosure of employee records where this directly relates to the employment relationship. This is designed to preclude an employer selling personal information contained in an employee record to a direct marketer, for example.¹¹

30.20 As discussed in IP 26, however, it appears that the current provisions of the *Workplace Relations Act 1996* (Cth) (WRA) have limited scope to protect the privacy of employee records.¹² While regs 131K and 131L, made under s 353A of the WRA, permit employees to access, copy and correct employee records, the ACTU has expressed concern that the provisions in the regulations are intended to cover 'time and wages' information and are not wide enough to cover the broad range of information, including health information, that may be collected as an 'employee record' under the *Privacy Act*.¹³

Parliamentary committee consideration

30.21 Both the House of Representatives Standing Committee on Legal and Constitutional Affairs and the Senate Legal and Constitutional Legislation Committee expressed concern about the employee records exemption in their reports on the Privacy Amendment (Private Sector) Bill 2000.¹⁴ The House of Representatives Committee concluded that:

11 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 12 April 2000, 15749 (The Hon Daryl Williams QC AC MP (Attorney-General)).

12 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 10.93–10.105.

13 Standing Committee on Legal and Constitutional Affairs, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000* (2000), House of Representatives, Parliament of the Commonwealth of Australia, Canberra, 27.

14 Ibid; Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), The Parliament of Australia.

In the light of the evidence it has received, the Committee is not satisfied that existing workplace relations legislation provides enough protection for the privacy of private sector employee records and has grave concerns about the inclusion of the employee records exemption in the Bill. It has not been persuaded that there is any clear need for employees to be without privacy protection in relation to their workplace records.

The need for protection is particularly evident when the kind of information held by employers is considered. Employers frequently hold more information in relation to their employees than almost anyone else those employees will come into contact with. Further, this information can be extremely sensitive, even intimate. It may include sensitive health information ranging from genetic test results to medical records.¹⁵

30.22 The Committee drew a distinction between information relating to disciplinary matters or career progression, in which a future employer may have a legitimate interest, and other personal information such as health, family or financial information. The Committee was of the view that this latter information should not be provided to anyone without the employee's consent. The Committee recommended that the definition of an employee record be amended to include only those matters covered by paragraphs (a), (b) and (e) of the definition, that is, information about the engagement, training, disciplining or resignation of the employee; information about the termination of the employment of the employee; and information about the employee's performance or conduct.

30.23 The Senate Committee also expressed concern about the exemption and recommended a sunset clause, which would allow the exemption to operate for two years while the relevant agencies examined whether existing workplace relations and state and territory legislation were adequate to protect the privacy of employee records.

30.24 In a joint press release of 29 November 2000, issued during passage of the Privacy Amendment (Private Sector) Bill 2000, the Attorney-General and the then Minister for Employment, Workplace Relations and Small Business announced that:

The Government will review existing Commonwealth, State and Territory laws to consider the extent of privacy protection for employee records and whether there is a need for further measures ...

The review will be carried out by officers of the Attorney-General's Department and the Department of Employment, Workplace Relations and Small Business and will involve consultation with State and Territory Governments, the Privacy Commissioner and other key stakeholders.

15 Standing Committee on Legal and Constitutional Affairs, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000* (2000), House of Representatives, Parliament of the Commonwealth of Australia, Canberra, para 3.29–3.30.

The Government will await the outcome of the review before considering what, if any, action should be taken in relation to privacy and employee records. The review will be completed in time to assist the Privacy Commissioner when he conducts the more general review of the legislation two years after it commences operation.¹⁶

30.25 The Attorney-General's Department provided the following update on the review in its submission to the Inquiry:

The review of current privacy protection for employee records by this Department and the Department of Employment and Workplace Relations is under way and is due to be completed before the Privacy Commissioner's review of the operation of the private sector amendments to the Privacy Act (ie, end of 2003).¹⁷

Consultations and submissions

30.26 The Australian Chamber of Commerce and Industry expressed support for the employee records exemption, both before the House of Representatives and Senate Committees, and in consultations with this Inquiry. The Institute of Actuaries of Australia advised a cautious approach stating that:

The 'employee records' exemption was deemed appropriate by Parliament. The *Privacy Act* only commenced to apply from December 21, 2001 and it should be given a fair trial, say three years, before any amendments to it are considered. No other forms of privacy legislation that may clash with that Act should be contemplated in its initial period of operation.¹⁸

30.27 However, the majority of the submissions to the Inquiry that addressed the exemption expressed concern or opposition. The Department of Health and Ageing stated:

The Department agrees with the concerns raised ... relating to the exemption of personal health information, including genetic information, that may be held in employee records. This is an issue that also arose in the context of the Privacy Act amendments — and it should be revisited following the current Commonwealth Department of Employment and Workplace Relations (DEWR) inquiry. Given the potential for discrimination in the workplace arising from inappropriate handling and interpretation of genetic information, this is an issue on which the Inquiry could provide valuable advice in the context of the DEWR review.¹⁹

30.28 The ACTU stated:

16 The Hon Daryl Williams QC AC MP (Commonwealth Attorney-General) and The Hon Peter Reith (Commonwealth Minister for Employment Workplace Relations and Small Business), *Joint News Release* (2000).

17 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

18 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

19 Commonwealth Department of Health and Ageing, *Submission G150*, 15 April 2002.

The ACTU strongly opposed the exemption for employment records in the amendments to the Privacy Act extending it to the private sector. ... Many employers hold a great deal of sensitive information on their employees, including health information. There is nothing in the Privacy Act to prevent an employer passing on this information to a potential employer of a past or current employee.²⁰

30.29 The Genetic Support Council of Western Australia stated:

The genetic support groups felt that the Privacy Act (1988) was inadequate in covering genetic information in terms of its application to workforce issues. The groups felt that the Privacy Act should be modified to include current and past employee records.²¹

30.30 The Office of the Federal Privacy Commissioner also expressed concern about the exemption and reiterated some of the points made before the Senate Committee:

The proposed exemption, as set out in the Bill, is also not consistent with the proposed treatment of sensitive information, including health information, proposed elsewhere in the Bill. This follows from the definition of 'employee record' as including, for example, trade union membership, membership of professional or trade associations and aspects of employee health information.

Sensitive information, and more particularly, health information are given more specific levels of protection in the Bill. I strongly support this approach. I do not support proposals that might then weaken that protection for the many Australians who are employees.²²

30.31 The Centre for Law and Genetics made the following comment in relation to the protection provided in the context of employment:

Inclusion of the 'employee records' exemption within the privacy scheme applying to the private sector has been justified on the basis that whilst this type of personal information deserves privacy protection, such protection is more properly a matter for workplace relations legislation. The reality is, however, that workplace relations legislation does not provide such protection, leaving workers in the private sector in a precarious situation.²³

30.32 Privacy NSW was also of the view that

the current industrial relations framework has a limited capacity to deal with privacy issues and offers no adequate appeals mechanisms. The Australian Industrial Relations Commission does not have the power to establish provisions for workplace privacy through the award system. Given the inequality of bargaining power between employers and employees, it is unlikely that there would be a genuine capacity to negotiate.

20 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

21 Genetic Support Council Western Australia (Inc), *Submission G112*, 13 March 2002.

22 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

23 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

30.33 Margaret Otlowski summarised the arguments as follows:

the current coverage of employee privacy in the workplace relations context is patently inadequate. While there are some statutory protections applying to the public sector, for the majority of workers in Australia there is little tangible protection of the privacy of their employment records ... The protection available through the ordinary courts is also far from satisfactory. Whilst there are some contractual and equitable principles for maintaining confidentiality that offer some protection, these are, in practice, costly to pursue (involving private litigation in the civil courts) and not easy to establish. In short, neither existing legislation in the workplace context nor common law or equitable principles provide adequate protection of the privacy interests of employees.²⁴

Inquiry's views

30.34 The employee records exemption, in conjunction with the lack of comprehensive privacy protection under workplace relations legislation, has been the focus of sustained criticism since the introduction of the Privacy Amendment (Private Sector) Bill into Parliament in 2000. The criticism has highlighted that sensitive information, which is given a high level of privacy protection in other contexts, is virtually without protection in the private sector employment context. This is of particular concern because employees may be placed under considerable pressure to provide sensitive information to employers, including health information.

30.35 In his Second Reading Speech in Parliament, the Attorney-General acknowledged that the personal information of private sector employees requires privacy protection²⁵ but the Government has not, to date, moved to ensure that adequate protection is provided by workplace relations legislation.

30.36 The importance of protecting health information was acknowledged in the development of the small business exemption in the *Privacy Act*, which is examined in Chapter 7. The exemption does not apply to small businesses that provide health services and hold health information except in an employee record.²⁶

30.37 There appears to be no reasonable justification for the fact that the health information of public sector employees is protected but the health information of private sector employees is not.

24 M Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (2001) Centre for Law and Genetics, Hobart, para 4.4.3.

25 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 12 April 2000, 15749 (The Hon Daryl Williams QC AC MP (Attorney-General)).

26 *Privacy Act 1988* (Cth) s 6D(4)(b).

30.38 Against this background, the Inquiry is currently of the view that the employee records exemption in the *Privacy Act* is too broad and should be amended. Genetic information held by private sector employers about their employees should be given a high level of privacy protection, as it is in other contexts, for example, where such information is held by health service providers and insurance companies.

30.39 In this context there is a fine line between genetic information and health information. In light of the Inquiry's terms of reference, the proposal below is limited to the protection of human genetic information. However, in the Inquiry's view it is important that the Attorney-General's Department and the Department of Employment and Workplace Relations, in reviewing the employee records exemption, consider carefully the implications of the exemption more generally, particularly in relation to health information that is not genetic information.

Proposal 30-1. The definition of 'employee record' in the *Privacy Act* should be amended to exclude genetic information held by an employer in relation to a current or former employee.

Proposal 30-2. The pending inter-departmental review of the employee records exemption to the *Privacy Act* should consider whether health information generally should be excluded from the ambit of the exemption.

Part I. Other Contexts

31. DNA Parentage Testing

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Introduction

31.1 Parentage testing refers to testing conducted to confirm or deny the biological parentage of a particular child or individual. Testing may be conducted by blood group or DNA analysis. DNA parentage testing is one form of kinship testing; other forms include twin testing, sibship testing and grandparent testing.

31.2 DNA parentage testing may exclude a person as the biological parent of a child with certainty, but it cannot prove absolutely that a person is the child's biological parent.¹ The test result can, however, provide a probability that a person is the biological parent of a child and, if that probability is sufficiently high, an inference of parentage may be confidently drawn.

31.3 As a child's maternity is usually not in question, most parentage testing relates to paternity. However, there are circumstances in which maternity may be misattributed or otherwise unclear; for example, where a child has been separated from its mother soon after birth, or where maternity is at issue in the context of an immigration application. Accordingly, the generic term 'parentage testing' is used in this chapter, unless the context indicates otherwise.

31.4 There are many reasons why a person may seek parentage testing. A man may seek parentage testing to confirm or deny suspicions that he may not be the biological father of a child who is said to be his own offspring. A woman may seek parentage testing to confirm or deny her suspicions that her child is not the biological child of her husband or partner. A child may seek parentage testing to establish a biological link with a parent for the purposes of identity, child support, family provision or succession to property. A person may seek parentage testing to provide evidence of a family relationship in the context of an Australian visa application.

31.5 IP 26 briefly discussed the use of DNA testing in establishing parentage. The paper asked whether such testing should be conducted only by accredited laboratories or under court supervision, in order to meet concerns regarding informed consent, counselling and quality control.² Since IP 26 was released in November 2001, the media have shown considerable public interests in the subject. This has been spurred in part by a few well-publicised cases, and in part by controversial comments by public figures, such as the Chief Justice of the Family Court of Australia (Family Court).³

1 C Pearman, 'Parentage Testing' in I Freckelton and H Selby (eds), *Expert Evidence in Family Law* (1999) LBC Information Services, 745.

2 Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, 14.59–14.65.

3 L Schwartz, 'Paternity: Stop DNA by "Stealth"', *The Sunday Age* (Melbourne), 26 May 2002, 1.

31.6 In response to the growing interest in parentage testing, the Inquiry has given the topic greater prominence in this Discussion Paper. The recent media interest has sparked a small number of submissions to the Inquiry but, in light of the public interest, the Inquiry anticipates conducting further consultations on this matter before delivering its final recommendations to the Attorney-General and the Minister for Health and Ageing in March 2003. As explained further in Chapter 1, the proposals in this Discussion Paper are amenable to change in response to additional evidence and reasoned argument. To this end, the Inquiry welcomes further submissions addressing the proposals and questions identified in this chapter.

Considerations applying to the regulation of genetic testing generally

31.7 Chapter 5 provides important background to the parentage testing issues raised in the present chapter. Chapter 5 seeks to address a number of general concerns in regulating access to genetic testing, whether for identification purposes or for health or medical purposes. Key outcomes of that chapter were to:

- ask whether legislation should require accreditation by the National Association of Testing Authorities, Australia (NATA) for all laboratories conducting genetic testing — to enhance the technical and scientific reliability of genetic tests;
- ask whether genetic test results should be admissible in court proceedings only if conducted by NATA accredited laboratories — to encourage use of accredited testing facilities;
- propose that the relevant bodies formally consider extending NATA accreditation standards to address issues such as consent to testing and procedures for protecting the integrity of the sample;
- propose that the availability of home use genetic testing kits be regulated either through the federal Therapeutic Goods Administration (TGA) or through codes of practice developed by the proposed Human Genetics Commission of Australia;
- ask whether the advertising of home use genetic testing kits on the Internet should be prohibited where the test in question has not been approved by the TGA; and
- propose that the Commonwealth, States and Territories develop a new criminal offence of knowingly submitting another person's genetic sample for testing without their consent or other lawful authority.

Considerations specific to the regulation of parentage testing

31.8 When one applies these general considerations to the specific context of parentage testing, there may be reasons to take a different approach on some or all issues. There are several factors that call for special consideration in relation to parentage testing.

31.9 First, parentage testing does not take place in a legal vacuum. Existing laws already set out a regulatory framework for testing, at least where the testing is conducted for the purpose of family law proceedings. Those laws provide a benchmark against which ‘unregulated testing’ may be measured.

31.10 Second, the information that is revealed by DNA parentage testing is particularly sensitive. Of course, the sensitivity of genetic information is an important theme throughout this Discussion Paper, both for what the information may reveal about the person tested and for what it may reveal about that person’s family members. However, DNA parentage testing goes beyond the common notion of ‘familial information’— it not only provides information about related persons, but goes to the very nature and identity of the family itself.

31.11 Third, the context in which parentage information is revealed is often highly emotionally charged. Where parentage has been misattributed, perhaps for many years, there may be issues of ‘betrayal, revenge, truth and the search for resolution’.⁴ Parentage testing is not alone in this respect, but it is a prime example of the need for affected parties to have access to counselling before and after testing.

31.12 Fourth, DNA parentage testing differs from many other kinds of genetic testing. For many medical purposes, useful information can be obtained by testing the genetic material of a single individual, who may be shown to have (or not to have) a particular genetic mutation with potential clinical consequences. Parentage testing, by contrast, is relationship testing and requires the participation of two, sometimes three, individuals in order to reveal useful information about the biological relationship between those persons. As a result, parentage testing necessarily involves more than one individual, both in the sampling and in the information derived from analysing the sample.

31.13 Fifth, in most cases (although not invariably) one of the individuals whose genetic sample is required for testing will be a child. In such cases, who should make an informed decision on behalf of the child about whether the child should submit a genetic sample for testing? This question is particularly difficult when those who have parental responsibility for the child (who in other

4 A Stanley, ‘In DNA Tests, TV Finds Elixir to Raise Ratings’, *New York Times*, 19 March 2002.

circumstances would make important decisions affecting the child's welfare) are directly affected by the outcome of the testing procedure.

31.14 Sixth, the accessibility of DNA parentage testing currently surpasses that of many other forms of genetic testing, and this has highlighted practical problems that are yet to be confronted in other fields of genetic testing. Parentage testing does not require the referral of a medical practitioner, as does genetic testing for most medical purposes, and it is often consumer-initiated. Moreover, home use genetic testing kits (or, more accurately, genetic sampling kits) are readily available, and there is widespread advertising of local and offshore testing facilities via the Internet and other media. For these reasons, some of the detriments associated with widespread and unregulated access to genetic testing have become apparent in the particular context of parentage testing. These may provide valuable lessons for other kinds of testing in the future.

31.15 Finally, under existing Australian law, the outcome of parentage testing may have important consequences for the financial obligations of a father or mother to support and maintain a child. It has been suggested that the economic consequences of DNA parentage testing may enhance the possibility of fraud (particularly in an unregulated testing environment) in a way that is largely absent in the context of genetic testing for medical purposes. In response to financial incentives, fraudulent practices might arise both in seeking to attribute parentage where none exists and in seeking to deny parentage where it does.

31.16 The complexity of these considerations suggests that difficult policy choices necessarily will be involved in deciding whether and how to regulate access to DNA parentage testing. Underlying these choices is a broad policy issue of the extent to which parent-child relationships should be seen as socially or biologically constructed. These are matters on which reasonable minds may differ. The remainder of this chapter gives further consideration of a number of specific issues that arise in respect of parentage testing and puts forward some proposals for reform for community consideration.

Methods of parentage testing

Blood group testing

31.17 Traditionally, parentage testing was conducted by blood group (serological) analysis. Blood group analysis involves the use of scientific principles regarding the inheritance of blood types to establish whether a person is excluded as the parent of a child, or whether a person may be the parent of a child — it cannot establish with certainty that a person is the parent of the child.

31.18 The analyst determines what the blood group of a putative parent can or cannot be, given the blood group of the other parent and the child. For example, if a child's blood group is AB and its mother's blood group is also AB, according to principles of blood group inheritance the biological father's blood group can be A, B or AB, but it cannot be O. If, according to these principles, the blood group of the putative father is inconsistent with that of the child, the putative father can be conclusively excluded as its biological parent.⁵ The value of blood group evidence in parentage testing has increased markedly in recent times, with 18 different blood groups now commonly tested in Australia.⁶

DNA testing

31.19 DNA parentage testing has developed since the mid-1980s and is generally considered to be a more reliable form of testing than blood group testing. As with serological testing, it cannot definitively prove that a man is the biological father of a child but instead produces a probability of paternity.⁷ DNA parentage testing is usually conducted using the Polymerase Chain Reaction (PCR) method (see Chapter 4).

31.20 DNA parentage testing usually involves determining whether the putative parent has a series of DNA markers identified as having been inherited by the child. For example, in paternity testing, it is assumed that the mother is the biological mother of the child, and that half of the child's DNA has been inherited from her. The analyst then identifies a series of DNA markers that must have been inherited from the biological father. If the putative father does not carry all of the required DNA markers, he can be definitively excluded as the biological father of the child.⁸ If the putative father does carry all of these paternal markers, either:

- he is the biological father of the child; or
- he is not the biological father but carries the genes by co-incidence.⁹

31.21 As it is not possible to prove paternity absolutely, the analyst then estimates the probability that the putative father is the biological father of the child.

5 A Dickey, *Family Law* (1997) LBC Information Services, Sydney, 296.

6 Ibid, 297.

7 B Atchison, A Georgalis and O Drummer, 'Disputed Paternity Testing' (1994) October *Law Institute Journal* 947.

8 C Pearman, 'Parentage Testing' in I Freckelton and H Selby (eds), *Expert Evidence in Family Law* (1999) LBC Information Services, 789. The National Association of Testing Authorities, Australia (NATA) stipulates that two or more exclusions are necessary for the putative father to be excluded as the biological father of a child.

9 Ibid, 789.

Social consequences of DNA parentage testing

31.22 Before the availability of serological and DNA parentage testing it was difficult to determine with scientific accuracy the biological parentage of a particular child. In the absence of scientific proof, parentage usually was accepted on the basis of certain social relationships between adult and child. For legal purposes, greater certainty was provided by common law or statutory presumptions of parentage. For example, a presumption of parentage arose from marriage, cohabitation, registration on a birth certificate, and so on.

31.23 The increased availability of scientific methods for determining biological parentage may result in a new emphasis on biological over social relationships. In the Australian context, this issue may arise where:

- a man seeks to avoid paying child support or maintenance for a child whom he discovers is not his biological child;
- a woman seeks to avoid sharing custody of her child with her former husband or partner, whom she knows is not the child's biological father;
- a child or adult seeks a share in the deceased estate of his or her biological parent, rather than social parent; or
- an adopted child, or child born as a result of an artificial reproductive technology procedure involving donated gametes, seeks information about his or her biological parents.

31.24 An underlying theme in the discussion of parentage testing is whether the law should emphasise biological parentage over social parentage in matters of parental responsibility, child support, succession and so on.¹⁰ The answers to these broad questions of social policy lie outside the Inquiry's terms of reference, but the Inquiry does address below particular issues that have been raised in so far as they impact on the conduct of DNA parentage testing.

The uses of DNA parentage testing

31.25 DNA parentage testing may be conducted in a number of contexts, each of which is discussed further below. These include family law and child support proceedings; paternity fraud proceedings; succession to estates; immigration applications; identification of human remains; incidental parentage testing; and personal interest.

¹⁰ In his submission to the Inquiry, Colin Andersen emphasised the need to counteract any tendency in Australian family law toward favouring genetic over other social or psychological criteria when making decisions about the legal rights and responsibilities associated with parenthood: C Andersen, *Submission G002*, 14 January 2002.

Family law and child support proceedings

31.26 A party to family law proceedings may seek to rely on DNA parentage test results where the biological parentage of a child is in issue; for example, in proceedings relating to child support, child maintenance or parental responsibility.¹¹

31.27 The *Family Law Act 1975* (Cth) (FLA) regulates applications for child maintenance in respect of a child born, or whose parents separated, before 1 October 1989. Proceedings after this date are regulated under the *Child Support (Assessment) Act 1989* (Cth) (CSAA).

31.28 The FLA provides that a child's parents are primarily responsible for his or her maintenance.¹² The Family Court has held that the natural meaning of the word 'parent' in the context of child maintenance orders is 'the biological mother or father of the child and not a person who stands in loco parentis',¹³ although the definition is extended by statute.¹⁴ To determine a child's parentage as a matter of law, rather than science, the FLA contains a number of presumptions of parentage. These presumptions arise from marriage; cohabitation; entry as a parent in a register of births or parentage information; a court finding of parentage; and execution of an instrument acknowledging paternity.¹⁵ DNA parentage testing may be used to rebut a presumption arising under the Act, or to establish evidence in circumstances where no presumption arises.

31.29 The CSAA provides a framework for administrative assessment of child support, by which a carer may lodge an application for assessment of child support against a child's parent.¹⁶ Child support is payable by a biological or adoptive parent of a child, or a person deemed to be a parent as a result of an artificial conception procedure;¹⁷ it is not payable by a non-adoptive step-parent or a foster parent. If the Child Support Registrar is satisfied that a person is a parent, and makes an administrative assessment against him or her, the person may apply for a court declaration that he or she is not liable on the basis that he or she is not the

11 'Parental responsibility' in relation to a child means all the duties, powers, responsibilities and authority that, by law, parents have in relation to children: *Family Law Act 1975* (Cth) s 61B.

12 Ibid, s 66C(1).

13 *In the Marriage of Tobin* (1999) 24 Fam LR 635, 645.

14 *Family Law Act 1975* (Cth) s 60D(1) and s 60H in relation to children born as a result of an artificial conception procedure.

15 Ibid, ss 69P–69T.

16 The CSAA applies at the federal level and in each state and territory jurisdiction except Western Australia, which has adopted the administrative scheme of assessment in the *Child Support (Adoption of Laws) Act 1990* (WA).

17 *Child Support (Assessment) Act 1989* (Cth) ss 5, 29(2). See also *In the Marriage of Tobin* (1999) 24 Fam LR 635, 648.

child's parent.¹⁸ To determine the question of parentage, the court may order a parentage testing procedure in accordance with the FLA and the *Family Law Regulations 1984* (Cth) (FL Regulations).¹⁹ If the court makes a declaration that a person is not a liable parent, the person may apply for recovery of child support moneys paid for the child up to that date.²⁰

Paternity fraud proceedings

31.30 A man might seek DNA parentage testing in order to obtain evidence of non-paternity for the purposes of civil proceedings instituted against the child's mother for what has been termed 'paternity fraud'. For example, it was recently reported that a Victorian man brought civil proceedings in fraud against his ex-wife after discovering that two of the children born during their marriage were not his biological children. It is alleged that the man had reared the children and had paid child support payments for them after the marriage ended. After discovering, through DNA parentage testing, that he was not their biological father, the man instituted proceedings against his ex-wife, alleging fraud and seeking \$400,000 in damages for the emotional stress and financial loss he had suffered.²¹ The use of DNA testing in civil proceedings is considered further in Chapter 39.

Succession to estates

31.31 A person may seek to rely on DNA parentage testing as evidence that he or she has a biological connection with a deceased person in order to claim a share in the estate. This may occur where:

- the deceased's will provides for general categories of relatives, such as 'children' or 'grandchildren' — and parentage testing may provide evidence that the person falls within such a category; or
- the deceased's will does not make provision for the person at all and parentage testing may provide evidence that that person falls within a category of relatives eligible for family provision pursuant to legislation;²² or

18 *Child Support (Assessment) Act 1989* (Cth) s 107(4)(c). Alternatively, if an application is refused, and an objection to the Registrar has failed, a carer applicant may apply for a declaration that he or she is entitled to administrative assessment on the basis that the putative parent is in fact the child's parent: ss 106(1), (1A).

19 *Family Law Act 1975* (Cth) s 69W(1).

20 *Child Support (Assessment) Act 1989* (Cth) s 143(1).

21 See G Bearup, 'The Doubt About Dad', *The Good Weekend* (*The Sydney Morning Herald*), 3 November 2001, 16, 19. ABC TV also carried a story regarding these proceedings in March 2001: 7.30 Report, *DNA and Paternity Case May Set Mammoth Precedent: Transcript*, ABC-TV, 5 March 2001.

22 *Family Provision Act 1982* (NSW) s 6(1); *Family Provision Act 1969* (ACT) s 7(1)(c); *Family Provision Act 1970* (NT) s 7(1)(c); *Succession Act 1981* (Qld) s 40; *Inheritance (Family Provision) Act 1972* (SA) s 6(c); *Testator's Family Maintenance Act 1912* (Tas) s 3A(b); *Inheritance (Family and Dependents) Provision Act 1972* (WA) s 7(1)(c); *Administration and Probate Act 1958* (Vic) s 91.

- the deceased has died intestate (ie without having made a will) and parentage testing may provide evidence that the person falls within a category of persons eligible to inherit the estate pursuant to the laws of intestacy.

31.32 Australian courts have heard a number of applications for access to stored tissue and blood samples of deceased persons for parentage testing in respect of succession.²³ Under the FLA, a parentage testing order may be made only in relation to procedures and testing of bodily samples taken from living persons, not human remains.²⁴

Immigration applications

31.33 The Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) uses DNA parentage test results as evidence of family relationships for the purposes of assessing immigration applications. DIMIA's Procedures Advice Manual outlines the Department's policy regarding the use of such testing.²⁵ The Manual provides that DNA parentage testing should be used as a last resort where claims are doubtful or if credible documentation cannot be provided to substantiate the claims.²⁶ The use of DNA testing in immigration is discussed in Chapter 33.

Identification of human remains

31.34 DNA parentage and relationship testing is increasingly used in identifying deceased persons and human remains where, due to the cause of death or delay in locating the body, the deceased is no longer recognisable. This form of testing is increasingly used in mass disasters, such as aeroplane crashes and the World Trade Centre collapse, to identify victims' remains. The use of DNA testing in this context is discussed in Chapter 36.

Incidental parentage testing

31.35 Certain types of genetic testing for medical or research purposes may also identify parentage as an incidental effect of the testing. For example, *The New York Times* recently reported a case in which a man's genetic test results disclosed that he was not a carrier of cystic fibrosis, the disease with which his youngest child had been born. As both parents must be carriers in order for the condition to be

23 *Roche v Douglas* [2000] 22 WAR 331; *Pecar v National Australia Trustees Limited* (Unreported, Supreme Court of NSW, Bryson J, 27 November 1996); *AW v CW* (Unreported, NSW Supreme Court, Barrett J, 17 April 2002).

24 *McK v O* (2001) FLC 93.

25 Department of Immigration and Multicultural Affairs, *Procedures Advice Manual 3* (1997).

26 *Ibid*, para 10.1.1.

passed on to their child, the man's doctor recommended he have a DNA paternity test. The results disclosed that he was not the father of that child.²⁷

31.36 The disclosure of misattributed parentage in diagnostic tests and medical research creates an ethical dilemma for the medical practitioner or researcher — namely, whether or not to inform the child and 'parents' of the results.²⁸ This issue also raises questions about access to the information; duties of confidentiality; the 'right not to know'; and post-test counselling. These issues are discussed in Part F of this Paper.

Personal interest

31.37 A person may wish to undergo DNA parentage testing for personal reasons, such as his or her own peace of mind or for family reunion. For example, if a woman had more than one sexual partner around the time her child was conceived, she may seek DNA parentage testing in order to determine her child's paternity for her own peace of mind. Alternatively, a man may seek parentage testing to confirm or deny his suspicions of misattributed paternity. While such tests may have the effect of allaying fears or suspicions, there is a possibility of an unexpected or adverse result and unanticipated consequences. Parentage testing may also be used to resolve a mix-up resulting from artificial reproductive technology using donated gametes.

Regulation of DNA parentage testing

31.38 It has been reported that an estimated 3,000 paternity tests are carried out each year in Australia.²⁹ The Family Court has advised the Inquiry that in the 2000–2001 financial year, parentage testing orders were made in a total of 103 matters before the Court — less than 4% of the total number of tests.³⁰ These figures suggest that a large number of paternity tests take place under the supervision of other courts, or (as is more likely) outside the court system altogether.

31.39 Parentage testing services may be accessed in Australia in a number of ways. A person wishing to undergo parentage testing may approach a laboratory or company offering these services directly, or may arrange testing through his or her medical practitioner or lawyer. A number of Australian and offshore laboratories advertise their services over the Internet and through the media.

27 T Lewin, 'In Genetic Testing for Paternity, Law Often Lags Behind Science', *The New York Times*, 11 March 2001.

28 The arguments are outlined in A Lucassen and M Parker, 'Revealing False Paternity: Some Ethical Considerations' (2001) 357 *The Lancet* 1033.

29 D Smith, 'Mothers Kept in the Dark on Paternity Tests', *The Sydney Morning Herald*, 27 March 2000.

30 *Correspondence*, Family Court of Australia, 22 January 2002.

31.40 Australia has a three-tiered system of DNA parentage testing. Testing may be conducted in accordance with the family law regulatory framework;³¹ in accordance with relevant state and territory legislation;³² or outside the regulatory framework altogether.

31.41 NATA operates a national system of accreditation for laboratories conducting parentage testing. The system does not extend to other forms of DNA kinship testing, which are therefore unregulated. The NATA system of laboratory accreditation is outlined in Chapter 5. The purpose of the accreditation system is to ensure the technical proficiency of genetic testing. It is a NATA accreditation requirement that parentage test reports must comply with the FL Regulations, which are discussed below.³³

31.42 The scientific reliability of parentage testing is of vital importance, whether the testing is conducted by accredited or unaccredited laboratories. In one case, the Family Court ordered a man to undergo DNA parentage testing in relation to a child of whom he claimed to have no knowledge. The test results disclosed a 98.5% probability that he was the father of the child. Although he had no explanation as to how he could be the father, he paid maintenance for the child. Years later, the man's brother admitted having had a relationship with the child's mother, and parentage testing showed a 99.5% probability that the brother was the child's father.³⁴ The social, psychological and economic consequences of unreliable testing suggests the need to maintain the highest technical and scientific standards in conducting parentage testing.

Parentage testing under the family law framework

Family Law Act

31.43 Parentage testing conducted under the FLA is regulated by Part VII Division 12 of the Act and by Part IIA of the FL Regulations.³⁵ The FLA gives the court a power to order a 'parentage testing procedure' where a child's parentage is

31 *Family Law Act 1975* (Cth); *Family Law Regulations 1984* (Cth).

32 See the status of children legislation: *Status of Children Act 1974* (Vic); *Status of Children Act 1978* (Qld); *Status of Children Act 1974* (Vic); *Status of Children Act 1996* (NSW); *Birth (Equality of Status) Act 1988* (ACT); *Family Relationships Act 1975* (SA); *Status of Children Act 1978* (Qld).

33 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia, Sec 3, Pt B Supplementary Requirements for Accreditation: Parentage Testing, para 5.10.2(a).

34 This case was reported in G Bearup, 'The Doubt About Dad', *The Good Weekend* (*The Sydney Morning Herald*), 3 November 2001, 16, 20.

35 Western Australia, unlike other Australian States, has its own state family court: *Family Court Act 1997* (WA). The courts with jurisdiction to hear matters arising under Pt VII of the FLA in relation to children are the Family Court of Australia, state Family Courts, the Federal Magistrates Court and, in some circumstances, courts of summary jurisdiction: *Family Law Act 1975* (Cth) ss 69H, 69J.

in issue in proceedings under the FLA or the CSAA.³⁶ The court may make the order in relation to the child, the mother, or any other person who might assist in determining the child's parentage.³⁷ The court may make such other orders as it considers necessary or desirable to enable the procedure to be carried out, or to make it more effective or reliable.³⁸

31.44 A report made in accordance with the provisions of the FL Regulations covering the preparation of reports may be received in evidence in any proceedings under the FLA.³⁹ This is one means of encouraging laboratories to comply with the FL Regulations in conducting parentage tests. Once the court has decided the issue of parentage for the purpose of proceedings under the FLA, it may also issue a 'declaration of parentage' that is conclusive evidence of parentage for the purposes of all Commonwealth laws.⁴⁰

Family Law Regulations

31.45 Part IIA of the FL Regulations applies to parentage testing procedures conducted pursuant to a court's parentage testing order.⁴¹ Part IIA may also be relevant to parentage testing that has not been ordered by a court under the family law provisions. This is because it is a NATA accreditation requirement that parentage test reports issued by NATA accredited laboratories comply with the FL Regulations. However, NATA also permits accredited laboratories to conduct parentage testing that does not comply with the FL Regulations, provided the laboratories do not hold themselves out as accredited for the purposes of that particular test.⁴²

31.46 The FL Regulations address two main aspects of scientific reliability in parentage testing: the protection of the integrity of bodily samples, and the technical accuracy of the testing process. The Regulations cover the collection of bodily samples, the storage of samples and their transport to the laboratory, the timeframe for testing samples, and the format of the parentage testing report.⁴³ The procedure for taking bodily samples is prescribed in some detail. A person providing a sample must complete a prescribed affidavit and declaration, and sign

36 See *Family Law Act 1975* (Cth) s 69W(1); *Child Support (Assessment) Act 1989* (Cth) s 100(1). Where a child's parentage is in issue in proceedings under state and territory status of children legislation, for example, in relation to an application for a declaration of parentage, a court may order a parentage testing procedure pursuant to the relevant legislation.

37 *Family Law Act 1975* (Cth) s 69W(3). The court may make the order on its own initiative or on the application of a party to the proceedings or a person separately representing the child: s 69W(2).

38 Ibid, s 69X.

39 Ibid, s 69ZC(1). See *Family Law Regulations 1984* (Cth), Pt IIA—Parentage Testing Procedures and Reports.

40 *Family Law Act 1975* (Cth) s 69VA.

41 *Family Law Regulations 1984* (Cth) r 21A.

42 National Association of Testing Authorities, Australia, *Correspondence*, 12 April 2002.

43 *Family Law Regulations 1984* (Cth) Pt IIA, Div 2, 3.

the label on the sealed container holding the sample.⁴⁴ The donor must also provide a recent photograph of him or herself (or make an arrangement to do so). The sampler must affix the photograph of the donor to the sampler's prescribed statement, and sign over the photograph and statement in a way that, if the photo were later removed, the removal would be evident. There is no requirement, however, that the sample donor provide any personal identification to the sampler for the purpose of verifying that he or she is in fact the person who should be providing the sample.

31.47 The prescribed affidavit and declaration outline aspects of the donor's recent medical history.⁴⁵ They do not refer to consent to the taking of the bodily sample or to the conduct of testing on the sample. Consent is inferred by the person's completion of the forms and provision of the sample, as well as by the completion of any application form that may be provided by the laboratory.

31.48 Laboratories follow their own policies regarding certain aspects of parentage testing not covered by the FL Regulations or NATA accreditation requirements. These aspects include the conduct of 'motherless testing',⁴⁶ which parent may consent on behalf of a child, the provision of counselling, and the persons to whom parentage testing results should be sent. These issues are discussed further below.

Parentage testing under state and territory legislation

31.49 Each Australian State and Territory (except Western Australia) has enacted status of children legislation in similar terms.⁴⁷ The purpose of the legislation is to give nuptial and ex-nuptial children equal status for the purpose of state or territory law. In Western Australia, the *Family Court Act 1997* (WA) contains similar provisions.

31.50 Each Act makes presumptions of parentage in relation to children born within the relevant jurisdiction, and also provides for the establishment of parentage.⁴⁸ The legislation in New South Wales, Tasmania, and the Northern Territory closely follows the parentage provisions of the FLA. The presumptions of

44 In the case of a child or a person suffering a mental disability, the person responsible for his or her long term care, welfare and development must do this.

45 *Family Law Regulations 1984* (Cth) r 21F. For example, whether the donor has suffered from leukaemia or has received a bone marrow transplant, a transfusion of blood or a blood product within a specified period before providing the bodily sample.

46 This involves testing the putative father and child's bodily samples only. In the absence of the mother's bodily sample, the analyst must test more loci on the DNA molecule to reach the level of statistical probability of parentage required by NATA accreditation requirements.

47 *Status of Children Act 1974* (Vic); *Status of Children Act 1978* (Qld); *Status of Children Act 1974* (Vic); *Status of Children Act 1978* (Qld); *Status of Children Act 1996* (NSW); *Birth (Equality of Status) Act 1988* (ACT); *Family Relationships Act 1975* (SA).

48 Except in South Australia, where parentage testing is regulated by the *Family and Community Services Act 1972* (SA).

parentage arising under state and territory legislation also apply to proceedings that fall outside the coverage of the FLA, such as in relation to succession.⁴⁹

31.51 The status of children legislation permits a person to apply to the Supreme Court of the relevant jurisdiction for a declaration of parentage, or an order annulling a declaration of parentage, even if there are no other legal proceedings on foot.⁵⁰

Unregulated parentage testing

31.52 As noted above, accredited laboratories may conduct parentage testing that does not comply with NATA accreditation requirements or the FL Regulations. Similarly, non-accredited laboratories do not have to comply with these requirements. As a result, both accredited and non-accredited laboratories may offer unregulated parentage testing. Practices and procedures regarding consent, collection of samples, transfer of samples to the laboratory, counselling, and technical proficiency can vary depending on individual laboratory policy.

31.53 One of the main differences between regulated and unregulated parentage testing is in the collection of bodily samples. The FL Regulations provide a detailed process for ensuring the integrity of the samples. By contrast, a number of laboratories offer home-based collection of bodily samples (for example buccal swabs or hair follicles) using mail order sampling kits. This enhances the prospect of non-consensual collection of bodily samples, provides more opportunity for the conduct of testing by one parent without the knowledge of the other, and exacerbates the risk of sample contamination.

Evaluating the regulatory framework

Issues and problems

31.54 Several concerns have been raised regarding the regulation of parentage testing in Australia. These concerns relate both to testing conducted under the family law scheme and to unregulated testing conducted by accredited and non-accredited laboratories. Arlette Mercae suggested:

The availability of mail order paternity tests from unlicensed laboratories can only jeopardise the well being of the child. Careful regulation of the circumstances under which paternity tests can be sought, and adequate counselling for the whole family should be put in place. This is primarily to ensure the security and physical and

49 See the discussion in H Finlay, R Bailey-Harris and M Otowski, *Family Law in Australia* (5th ed, 1997) Butterworths, Sydney, para 7.5.

50 For example, see *Status of Children Act 1996* (NSW) ss 21(1), 22(1).

emotional welfare of the child, whose needs in this situation should be paramount, not those of the parents.⁵¹

31.55 Colin Andersen submitted that the debate so far has been narrowly focussed on the activities of non-accredited, as opposed to accredited laboratories. He emphasised the need for reform not only of the non-accredited sector of the parentage testing industry, but also of the accredited sector.

Whatever regulatory regime is eventually adopted in Australia it has to be recognised that reining in the non-accredited laboratories alone is not in itself sufficient to clean up the industry — the practice of accredited agencies is also wanting, especially in allowing the unilateral, non-consensual initiation of paternity testing by mothers whose aim is to ensure that ex-husbands also become ex-fathers.⁵²

31.56 On the other hand, the Inquiry was informed that one of the benefits of testing outside the family law framework is that it is cheaper. Dr Geoffrey Edelsten, director of Gene-e Pty Ltd, submitted that accredited parentage testing involves high costs because of the legal costs involved in obtaining a parentage testing order and the actual cost of the accredited test.⁵³ One person attending a public meeting drew a link between the cost of testing and the ‘right’ of fathers to know who are their own children:

[Men] have a right to know whether the children that are presented to them are really their children. It seems to me that if we put barriers in place to them being able to access that information, such as having to go through the Family Court procedures, or having to pay excessive amounts for testing, that’s denying them their right to know if the children are theirs.⁵⁴

31.57 Others suggested that another benefit of testing outside the family law framework is that it allows parents to conduct ‘peace of mind’ testing without causing potentially unwarranted concern to the child. DNA Solutions Pty Ltd, a company that offers non-accredited DNA parentage testing, submitted:

We have evidence to illustrate that many people avoid courts due to cost and fear of ‘losing’ or fear or resentments or humiliation by the opposing party. We know that many persons will avoid DNA testing if forced to move through these channels ... DNA testing is a very sensitive issue and needs to be dealt with sensitively. Enforcing fathers to front the court is certainly not always the most sensitive method, and not always in the best interests of the child.⁵⁵

31.58 A number of submissions suggested ways to regulate the Australian parentage testing industry. The Human Genetics Society of Australasia suggested that parentage testing be supervised by courts to ensure both the accuracy and

51 A Mercae, *Submission G031*, 12 January 2002.

52 C Andersen, *Submission G002*, 14 January 2002.

53 G Edelsten, *Submission G117*, 14 March 2002.

54 ALRC–AHEC Public Meeting, Brisbane, 12 December 2001.

55 DNA Solutions, *Submission G162*, 30 May 2002.

reliability of the evidence admitted, and a mechanism to address issues arising from the test results.⁵⁶ By contrast, the Victoria Police Service suggested implementing an enforceable code of practice for the conduct of parentage testing.

Consideration should be given to requiring laboratories wishing to undertake any form of private or quasi-private genetic testing to be bound by an enforceable code of practice regulated through the provisions of the Trade Practices Act. Application of the standards contained in the Family Law Regulations 1984 (Cth) to any proposed code of practice would provide consistency.⁵⁷

31.59 The Inquiry has received several submissions addressing concerns about the accuracy and reliability of parentage testing conducted by both accredited and non-accredited laboratories. A particular concern was the possibility of 'DNA fraud' by laboratory staff in relation to paternity tests, which was discussed in Chapter 5. The author of one submission gave examples of alleged tampering with bodily samples, as well as alleged deliberate false reporting by a number of Australian accredited and non-accredited laboratories. The author raised concerns that current safeguards for protecting the integrity of the samples do not protect against tampering or deliberate fraud.⁵⁸

31.60 Another submission emphasised the opportunity and temptation for parents to obtain falsified results:

[T]here are ample opportunities for contamination, mislabelling and degradation of samples. ... A man who fathers a child outside marriage can expect to pay child support for at least 18 years. Depending on the relevant factors in the child support legislation and the *Family Law Act*, and inflation, his total liability is likely to be at least \$500,000 ... The temptation to obtain false testing must be great.⁵⁹

31.61 As indicted above, there also have been complaints about deliberate misattribution of parentage in order to secure child support payments.

Options for reform

31.62 The submissions made to the Inquiry identified two different approaches to the regulation of parentage testing. The first approach involved regulating access to genetic testing by imposing an additional hurdle between the individual seeking the test and the laboratory doing the testing. For example, a court order or the authorisation of a medical practitioner might be required. The second approach

56 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002. *Confidential Submission G022CON*, 3 December 2001, suggested that DNA paternity testing should only be allowed through a Family Court order.

57 Victoria Police, *Submission G086*, 21 January 2002.

58 *Confidential Submission G074BCON*, 13 January 2002. The media have reported allegations of inaccurate paternity reporting in relation to a testing laboratory in the United States: N Stancill, 'Paternity Lab May Have Overlooked Real Fathers', *Houston Chronicle* (Houston), 24 February 1993, 1, quoted in N Turner, *Submission G083*, 14 January 2002.

59 N Turner, *Submission G083*, 14 January 2002.

preserved the right of individuals to make a direct approach to a laboratory, but sought to regulate the laboratories themselves; for example by requiring laboratories to be accredited or comply with an industry code of practice.

Court supervision

31.63 The option of using court supervision would make access to parentage testing subject to a parentage testing order under the FLA, or relevant state and territory legislation. This would enable the courts to provide independent oversight of the testing, including in relation to the validity of consent. However, using a court in every case may be expensive, slow or inconvenient. It also may place in the public arena sensitive information that individuals would prefer to keep within the private realm. Additionally, there are constitutional difficulties in utilising federal courts to make orders in cases where parentage testing is not related to a legal dispute between parties.

Medical practitioners as gatekeepers

31.64 An alternative option would be to make medical practitioners the ‘gatekeepers’ of parentage testing conducted by Australian laboratories by specifying appropriate request pathways. Medical practitioners would be well placed to take a bodily sample from each person involved in the testing procedure, to protect the integrity of the samples, and to ensure informed consent is given by those from whom it is required. However, parentage testing is not inherently related to the health of the parties concerned. Involvement of a medical practitioner might be seen as compelling doctors to divert their resources to the provision of a social service that is unrelated to their medical expertise and might be more appropriately provided by others.

NATA accreditation

31.65 The Inquiry outlined the current system of accreditation of laboratories through NATA in Chapter 5. A principal advantage of NATA is that it provides an industry-based mechanism for independent oversight of laboratories that conduct genetic testing. A disadvantage is that current accreditation standards focus on technical proficiency and do not currently address the ethical issues associated with testing. For this reason, Chapter 5 proposed that the relevant bodies (NATA, NPAAC and RCPA) formally consider whether accreditation standards should be extended to cover issues such as consent to testing and procedures for protecting the integrity of the sample for all genetic testing. It should be noted, however, that NATA accreditation standards currently make provision for protecting the integrity of the sample in DNA parentage testing by adopting the requirements of the FL Regulations.

Code of practice

31.66 A final option would be to implement a voluntary code of practice for parentage testing conducted by Australian laboratories. The United Kingdom's Department of Health has implemented such a code, which applies to all organisations advertising and providing genetic paternity testing services direct to the public.⁶⁰ The greatest drawback of such a system is that it is not legally enforceable. Concerns about compliance have led the Human Genetics Commission to recommend a review of the effectiveness and relevance of the Code of Practice.⁶¹

Inquiry's views

31.67 The Inquiry has come to the preliminary view that DNA parentage testing should be conducted only by NATA accredited laboratories, and only in accordance with NATA accreditation standards. Adoption of this policy would eliminate DNA parentage testing that is currently performed in Australia by unaccredited laboratories. It would also eliminate the practice of allowing NATA accredited laboratories to conduct unaccredited parentage testing by the expedient of not holding themselves out as being accredited for the purposes of a particular test.

31.68 The Inquiry considers that a requirement of court supervision of parentage testing in every case would be overly prescriptive. The cost, delay and potential exposure of a court order is likely to act as a deterrent to testing, or to force interested persons 'underground' to unregulated parentage testing available through mail order or over the Internet.⁶² The Inquiry is also of the view that it is not appropriate to expect medical practitioners to provide a range of social services in relation to a genetic testing procedure that is unrelated to the present or future health of the sample donors.

31.69 The consequences of parentage testing can be of profound significance to the individuals tested and to others whose parentage status is affected by the results of the test. Test results may lead to the destruction of long-standing social relationships between adults and children, and between partners in a relationship. It is essential in this context to ensure that parentage testing is performed to the highest standards of technical proficiency and in accordance with sound ethical

60 Group on Genetic Paternity Testing Services, *Code of Practice and Guidance on Genetic Paternity Testing Services*, (2001) Department of Health, <<http://www.doh.gov.uk/genetics/paternity.htm>>, 11 February 2002. The Group comprised representatives from commissioners of genetic paternity testing services, providers of such services, patients' groups, clinicians, academics and scientists.

61 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, 166.

62 There is merit, however, in using courts to resolve disputes between parents regarding consent to the sampling and testing of a child who lacks the maturity to make a decision on his or her own behalf. See further below.

principles. Moreover, as discussed further below, testing should be performed in circumstances that facilitate counselling of the parties concerned.

31.70 In the Inquiry's view, these objectives can be achieved by requiring all parentage testing in Australia to be performed by NATA accredited laboratories in accordance with NATA standards, provided those standards are reformed to address the full range of scientific and ethical concerns, such as procedures for protecting the integrity of the sample, consent to testing, and the provision of counselling (the last two of which are considered in more detail below). To that end, NATA should review its accreditation requirements for DNA parentage testing and consider whether the requirements of the FL Regulations should be supplemented by additional standards. The FL Regulations should also be reviewed to ensure that the legislative requirements provide an acceptable minimum standard for parentage testing.

31.71 In particular, to minimise the opportunity for deliberate substitution of bodily samples, the Inquiry proposes that the procedures addressing the integrity of the samples be strengthened by requiring sample donors to provide the sampler with current photographic identification before they provide a sample. The sampler should check the identification against the name of each person named in the parentage testing documentation to ensure the correct person is providing a sample.

Proposal 31-1. Legislation should be enacted to ensure that DNA parentage testing in Australia is conducted only by laboratories accredited by the National Association of Testing Authorities, Australia (NATA), and only in accordance with NATA accreditation requirements.

Proposal 31-2. NATA should review its accreditation requirements for DNA parentage testing to ensure that they meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing counselling. (See also Proposals 31-6, 31-9, 31-11 and 31-12).

Proposal 31-3. Part IIA of the *Family Law Regulations 1984* (Cth) should be reviewed to ensure that the legislative requirements for parentage testing meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing counselling. (See also Proposal 31-7).

Home use DNA parentage testing

31.72 As discussed in Chapter 5, over-the-counter or home use DNA testing may refer to two different forms of testing. One form is similar to a home-based pregnancy test, in which the test is performed and interpreted by the person at home. This form of DNA parentage testing is not currently available but may become available in the future. The other form is a test in which the person collects a bodily sample at home and sends it to a laboratory for analysis.⁶³ This form of unregulated DNA parentage testing is currently available to Australian consumers by mail order and the Internet. The samples are forwarded through the mail to the company offering the services, and they may be tested either by an Australian laboratory or overseas laboratory. Test results may be conveyed to the customer by mail or telephone.

31.73 Policy comparisons may be made between home-based HIV testing and DNA parentage testing. Home-based sample collection raises a number of problems, including:

- the inability to guarantee proper storage and use within the shelf life;
- the possibility of contamination with other genetic material;
- diminished protection over the chain of custody of the sample; and
- the absence of counselling or other clinical interaction, leaving a possibility for self-harm or harm to others.⁶⁴

31.74 The regulation of home use genetic testing is addressed in Chapter 5. In that chapter the Inquiry proposed that home use genetic test kits be regulated by the *Therapeutic Goods Act 1989* (Cth) and associated regulations. The Inquiry is of the view that this proposal should also extend to DNA parentage testing.

Proposal 31–4. In accordance with Proposals 5–2 and 5–3, home use parentage test kits should be subject to regulation under the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth).

⁶³ The distinction between these two forms of home-based testing are outlined in relation to HIV testing in Australian National Council on AIDS and Related Diseases & Intergovernmental Committee on AIDS and Related Diseases, *HIV Testing Policy* (1998) Commonwealth of Australia, 35.

⁶⁴ See *Ibid.*, 35–36.

Access to offshore DNA parentage testing

31.75 Australian and foreign laboratories market DNA parentage testing services through the media, including the Internet. The availability of offshore testing raises concerns about the ability to regulate ethical and legal standards in the provision of services to Australian consumers.

31.76 Dr Geoffrey Edelsten submitted that his company, Gene-e Pty Ltd, uses an accredited laboratory in the United States to conduct its parentage testing. He suggested that this form of testing is cheaper and more accurate than accredited laboratories in Australia.

[T]he quality of testing is, it is submitted, of as high a standard as that conducted by laboratories in Australia. The consumer however can obtain this testing at approximately 50% less than that charged by Australian laboratories ... Our testing service provides a higher level of accuracy in paternity as 13 alleles are tested routinely.⁶⁵

31.77 Chapter 5 discusses access to offshore genetic testing generally. The Inquiry recognises the difficulty of regulating services that are provided overseas by foreign companies and are advertised through websites hosted on non-Australian servers. However, as discussed in that chapter, attempts have already been made to regulate Internet content in relation to offensive material and interactive gambling. The Inquiry invites further comment on whether any steps should be taken to regulate the availability of DNA parentage testing via the Internet.

Question 31–1. What steps, if any, should be taken to regulate Internet advertising of home use DNA parentage test kits and testing services?

Admissibility of parentage test reports

31.78 There is some uncertainty about the admissibility in evidence of a parentage test report that does not comply with the FL Regulations in proceedings under the FLA. Section 69ZC(1) of the FLA provides that a report made in accordance with the regulations covered by s 69ZB(b) 'may be received in evidence' in any proceedings under the Act. Section 69ZB provides that the regulations may make provisions relating to the carrying out of parentage testing procedures under parentage testing orders; and the preparation of reports relating to the information obtained as the result of carrying out such procedures. Regulation 21M(2) provides that the report must be in accordance with the form prescribed by

⁶⁵ G Edelsten, *Submission G117*, 14 March 2002.

the FL Regulations, and reg 21M(5) provides that the report is taken to be of no effect if completed otherwise than in accordance with reg 21M.

31.79 The question is whether a parentage testing report conducted by a non-accredited laboratory, or by an accredited laboratory that has not adhered to the FL Regulations, might also be admissible in proceedings under the FLA. This question would not arise if Proposal 31-1 were adopted, but until such time the issue remains a real one. There is little case law on this point.

31.80 In *Re C (No 1)*, the Family Court considered whether the results of parentage testing conducted pursuant to a parentage testing order were admissible despite a failure to comply with regulations regarding the collection, storage and testing of the sample. The court held that the non-compliance rendered the report inadmissible. Fogarty J considered the regulations to be mandatory in their terms, and stated that 'neither the Act nor the regulations seem to provide any discretion or capacity to admit the report notwithstanding non-compliance'.⁶⁶

31.81 In *McK v O*, the Family Court considered whether a DNA testing certificate was admissible when testing was conducted on the remains of a deceased person in the absence of a parentage testing order. Mullane J held that the FL Regulations relate to parentage testing procedures carried out pursuant to parenting testing orders. As the testing was not conducted pursuant to a parentage testing order, s 69ZC(1) did not apply to the testing certificate, which was thus inadmissible in the circumstances.⁶⁷

31.82 The Inquiry considers that s 69ZC(1) should be clarified. While the cases referred to above suggest a strict interpretation of the section, the permissive terms in which it is phrased may lead to uncertainty. For example, a party might argue that a non-complying report should be admissible subject to the general rules of evidence. The Chief Justice of the Family Court, Alastair Nicholson, has suggested in a TV interview that the Court has a discretion to admit the results of non-accredited parentage testing in certain circumstances subject to the rules of evidence.⁶⁸

31.83 The Inquiry considers that the FL Regulations provide an effective minimum standard for ensuring integrity of genetic samples and quality assurance in parentage testing. As suggested above, these standards can be supplemented by NATA standards for the purpose of laboratory accreditation. A legislative provision that excludes non-complying reports from being admitted into evidence would be an effective means of promoting the observance of minimum standards in

⁶⁶ *Re C (No 1)* (1991) 15 Fam LR 350, 352-353 (Fogarty J).

⁶⁷ *McK v O* (2001) FLC 93.

⁶⁸ Lateline, *DNA Testing and the Family Court: Transcript*, ABC TV, <<http://www.abc.net.au/lateline/s200192.htm>>, 16 October 2000.

DNA parentage testing. Accordingly, the Inquiry proposes that the FLA be amended to provide that parentage testing reports are admissible in proceedings under the FLA only if made in accordance with the FL Regulations.

Proposal 31–5. The *Family Law Act 1975* (Cth) should be amended to provide that parentage testing reports are admissible in proceedings under the Act only if made in accordance with the provisions of the *Family Law Regulations 1984* (Cth).

Consent to parentage testing

31.84 DNA parentage testing involves the submission of a genetic sample of a child and a parent for laboratory testing. Sometimes testing is performed on samples taken from a child and only one adult, as where a putative father submits his sample with that of his child. Sometimes parentage testing is performed on samples taken from a child and two adults. This might occur where a mother submits a sample from herself, her child and the putative father.

31.85 Two types of consent are at issue in the present context: consent to taking the genetic sample and consent to performing a genetic test upon that sample. At present, in parentage testing performed under the family law regime, consent appears to be implied from the act of providing the bodily sample and completion of the prescribed affidavit and declaration. In relation to unregulated parentage testing, there appears to be no specific requirement of consent from the person whose bodily sample is taken and tested. Some non-accredited laboratories seek to avoid potential legal liability for testing mail order samples by requiring the submitter to warrant that he or she is legally entitled to possession of the samples.⁶⁹

31.86 Serious privacy concerns arise from taking a bodily sample from a person, or from his or her personal effects, in order to perform a genetic test on the sample without the person's knowledge or consent. While many submissions to the Inquiry focused on the need to regulate consent in relation to the testing of children, the Inquiry considers that both adults and children should be protected from non-consensual parentage testing, unless such testing is authorised by law. The following sections consider consent in relation to the testing of adults and children, respectively.

⁶⁹ For example, DNA Solutions, which markets its parentage testing on the Internet: DNA Solutions Pty Ltd, *DNAnow.com*, <<http://www.dnanow.com/aussheet.html>>, 23 July 2002.

Decision making by adults

31.87 DNA parentage testing may be performed using a genetic sample from one or two adults, together with that of a child, depending on the circumstances. When each adult has made an informed and voluntary decision about whether to submit his or her genetic sample for parentage testing, there is no ethical objection to carrying out a genetic test on that person's sample. However, ethical concerns do arise where one adult obtains a genetic sample from another adult and submits it for testing surreptitiously.

31.88 Legal protection against the non-consensual collection and use of an adult's bodily sample for the purpose of parentage testing is currently limited. As discussed in Chapter 5, some protection exists under the common law, through the tort of trespass to the person (including assault and battery), but this does not apply to the collection of much genetic material, such as hair from combs, saliva from a glass, or cheek cells from a toothbrush.

31.89 Federal privacy legislation also has limited application to the collection of genetic samples by individuals for the purpose of parentage testing.⁷⁰ First, the collection and use of personal information is exempt under s 16E of the *Privacy Act 1988* (Cth) where done for the purpose of, or in connection with, a person's personal, family or household affairs. Second, s 7B exempts from the Act acts done by a person other than in the course of a business conducted by the person. While certain aspects of parentage testing might fall outside these exemptions, the majority of contexts would be exempt from the protection of the Act.⁷¹

31.90 For the reasons given in Chapter 5, the Inquiry considers that there should be greater legal protection afforded to adults against the non-consensual testing of their genetic material by another person. In that context, the Inquiry proposes a new criminal offence that would make it unlawful for a person to submit another person's sample for genetic testing in the knowledge that the individual from whom the sample has been taken has not consented to the testing. This proposal would apply to parentage tests, as it does to other genetic tests — such as where an employer surreptitiously tests an employee.

31.91 In order to promote the practice by which laboratories conduct DNA parentage tests only on samples that have been provided with consent (or other lawful authority), the Inquiry considers that reform to laboratory procedures is warranted. This reform should establish a mechanism by which laboratories can be satisfied that the sample was collected and submitted for testing with consent of the

70 The question whether genetic samples are 'personal information' for the purposes of the *Privacy Act 1988* (Cth) is discussed in Ch 7.

71 However, once the bodily sample has been forwarded to a private laboratory, the NPPs would apply. See Ch 7 for a full discussion.

sample donor, or under lawful authority. One way in which this might be achieved is by the development of appropriate NATA accreditation standards. In addition, FL Regulations could be amended to provide a minimum standard in relation to consent. To that end, the Inquiry proposes that the prescribed affidavit and declaration submitted to a laboratory for the purpose of parentage testing under the FL Regulations should be amended to include an express consent form in respect of each adult who has submitted a sample for parentage testing.

Proposal 31–6. NATA should develop accreditation requirements that require laboratories to be satisfied that the sample of each adult donor has been supplied for parentage testing with his or her consent.

Proposal 31–7. The *Family Law Regulations 1984* (Cth) should be amended to require that the prescribed affidavit and declaration submitted to a laboratory in relation to parentage testing include a signed consent form for each adult donor indicating that the sample has been supplied with his or her consent.

Decision making by mature children

31.92 Because DNA parentage testing is a form of relationship testing, it necessarily requires a comparison of genetic samples from at least two individuals. In most circumstances, one of those individuals will be a child, which is taken here to mean a person under the age of 18 years. Where the offspring in question is 18 years or older, and has thus attained his or her majority, the question of consent to sampling and testing should be answered in the same way as for other adults. Thus, if a man wishes to confirm that he is the biological father of his adult son, the consent of each adult party would be required for the testing, in accordance with the Inquiry's preceding proposals.

31.93 However, where one of the parties to be tested is a minor, how is the consent of the child to be assessed? In this section, the Inquiry examines the position of 'mature' children; that is, those of a sufficient age and mental capacity to be able to make an informed decision about parentage testing on their own behalf. In the following section, the Inquiry examines the position of children who, by reason of their age or mental capacity, lack that degree of maturity.

31.94 The current law draws a bright line between individuals of 18 years of age or more, who are treated as adults, and those under 18 years, for whom decisions are made by a parent or guardian. The FLA provides that a parentage testing procedure may be conducted on a child under the age of 18 years with the consent of a parent, guardian or person who, under a specific issues order, is

responsible for the child's long term or day to day care, welfare and development.⁷² There is no provision for children to consent. A person who carries out a parentage testing procedure with parental consent will not be liable for any civil or criminal action.⁷³ Where parentage testing is conducted outside this regulatory framework there is no specific requirement that the child, or his or her parent, consent to the procedure.

31.95 The Inquiry recognises that children develop at different rates in terms of emotional maturity and intellectual understanding. Many children reach a sufficient level of maturity to form their own opinions on important matters affecting their welfare before they reach the age of 18 years.

31.96 Concerns arise where a mature child's wishes do not accord with those of the parent or other person authorised to give or withhold consent on the child's behalf. This circumstance arose in *In the Marriage of F and R*. In that case, a man applied for a parentage testing order in relation to a 13-year-old girl born during his marriage to his former wife. The applicant had been paying maintenance for the girl, but had reason to doubt she was his biological daughter. The child understood the implications of the application and was willing to participate in the parentage testing, but her mother would not consent without certain conditions being satisfied.⁷⁴ Butler J commented that the relevant provision of the FLA worked 'a significant injustice to a mature child able and willing to make decisions affecting his/her person and future' and remarked that this was a poor law.⁷⁵

31.97 The right of a child with sufficient maturity and understanding to form his or her own views has been recognised in the *Convention on the Rights of the Child*, to which Australia is a party. Article 12(1) provides that:

States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.⁷⁶

72 *Family Law Act 1975* (Cth) s 69Z(2). See also *Family Law Regulations 1984* (Cth) r 21F(3)(a), which provides that the prescribed donor affidavit and declaration may be completed only by a person responsible for the long term care, welfare and development of the child.

73 *Family Law Act 1975* (Cth) s 69ZA(1).

74 *In the Marriage of F and R* (1992) 15 Fam LR 533.

75 *Ibid*, 538. This decision has been criticised on the basis that the interests of the child are not the paramount consideration in parentage testing: A Dickey, 'The Paramount Welfare Principle and Parentage Tests' (1993) 67 *Australian Law Journal* 47, 47-48.

76 *Convention on the Rights of the Child*, opened for signature 20 November 1989, UNTS 1588, (entered into force on 16 January 1991).

31.98 This approach is reflected in legislation in several States, and in common law principles regarding a child's consent to medical treatment.⁷⁷ While the *Privacy Act* does not specify an age at which young persons can make their own privacy decisions, the *Guidelines to the National Privacy Principles* reflect a similar approach to that in the *Convention on the Rights of the Child*.⁷⁸ The Inquiry supports the general principle that some minors are capable of making, and should be entitled to make, their own decisions about whether to provide a genetic sample for parentage testing.

Options for reform

31.99 In considering whether children under 18 years of age should be able to make their own decisions regarding parentage testing, two models of reform present themselves:

- the consent of mature children should be based on the understanding and maturity of the particular child in question; or
- the consent of mature children should be based on a presumed age of capacity, which may be rebutted in appropriate cases.

31.100 The first of these options has the advantage of accounting for differing rates of development among children, but the disadvantage of requiring a potentially time-consuming determination of a child's capacity on a case-by-case basis. To be effective, this model may require an independent assessment of a child's capacity to give or withhold consent.

31.101 This approach has been adopted in the common law with respect to a child's consent to medical treatment. Where a child has sufficient understanding and intellectual capacity to enable full comprehension of the nature and purpose of the treatment, he or she may give or withhold consent to that treatment.⁷⁹ If a child has such capacity, parental consent is not required. A similar position is adopted in relation to child consent to participation in medical research.⁸⁰

31.102 A second reform option is to enact a legislative presumption that children of a specified age have the maturity to give or withhold consent to parentage testing, subject to rebuttal in particular cases. This approach has the advantage of

77 See *Secretary, Department of Health & Community Services v JWB (Marion's Case)* (1992) 175 CLR 218.

78 Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), OFPC, Sydney, 15.

79 *Secretary, Department of Health & Community Services v JWB (Marion's Case)* (1992) 175 CLR 218.

80 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra cl 4.2. In addition, a Human Research Ethics Committee must not approve, and consent cannot be given for, research which is contrary to the child or young person's best interests: cl 4.3.

simplicity — it would avoid the need for minors who have attained the specified age to obtain independent assessments of their capacity, which might be costly and time consuming.

31.103 This approach has been adopted by several Australian States in legislation relating to consent to medical treatment.⁸¹ It has also been adopted in the United Kingdom's voluntary code of practice on genetic paternity testing services. In England, Wales and Northern Ireland, a child aged 16 years or over may give or withhold consent to paternity testing on his or her own behalf.⁸²

31.104 The FLA formerly provided a presumed age of capacity in relation to children's wishes. The now repealed s 64(1)(b) provided that:

where the child has attained the age of 14 years, the Court shall not make an order under this Part contrary to the wishes of the child unless the Court is satisfied that, by reason of special circumstances, it is necessary to do so.

31.105 In 1978, the Family Law Council commented that the provision was thought by some to place a heavy burden of responsibility upon children and to lead parents to exert unfair pressure on a child.⁸³ After due consideration, the Council recommended that the age requirement be removed from the section.⁸⁴

Inquiry's views

31.106 The Inquiry considers that the law should recognise a child's right to give or withhold consent to the testing of his or her own genetic sample where the child has sufficient maturity and understanding of the process and its implications to safeguard his or her own interests. The Inquiry also recognises that society has an underlying responsibility to protect children from their own misjudgement where they do not sufficiently comprehend the implications of the testing.⁸⁵ In order to ensure that the interests of children are properly protected, children's capacity to consent to the testing of their own samples for parentage purposes should be appropriately regulated.

81 *Minors Property and Contracts Act 1970* (NSW) s 49; *Consent to Medical Treatment and Palliative Care Act 1995* (SA) ss 6, 12. See also NSW Commission for Children & Young People, *Consent by Minors to Medical Treatment* (2001) unpublished, para 19.01, 25.07.

82 Group on Genetic Paternity Testing Services, *Code of Practice and Guidance on Genetic Paternity Testing Services*, (2001) Department of Health, <<http://www.doh.gov.uk/genetics/paternity.htm>>, 11 February 2002.

83 Family Law Council, *Children's Wishes: Section 64(1)(b) of the Family Law Act 1975 — Working Paper No 2* (1978) Commonwealth of Australia, 1.

84 *Ibid*, 10–11, 14.

85 NSW Commission for Children & Young People, *Consent by Minors to Medical Treatment* (2001) unpublished, para 15.01.

31.107 The Inquiry does not support a presumed age of capacity approach in relation to child consent to parentage testing. While some States and Territories have implemented this approach in relation to consent to medical testing, parentage testing can be distinguished because of the potential impact on a child's emotional relationships and sense of identity. In the light of the varying rates of emotional development of children, it would be difficult to settle on any particular age at which a child may safely be presumed to have sufficient capacity to make an informed decision about whether his or her genetic sample should be tested. Moreover, this approach appears to be contrary to the family law experience, where an early attempt to use this method was abandoned.

31.108 The Inquiry's preliminary view is that an appropriate balance can be struck between the competing considerations of autonomy and protection by adopting a two-tiered approach. First, young children (say those under the age of 12 years) should be regarded as lacking the capacity to make a free and informed decision in relation to parentage testing. For these children, a decision as to whether they should participate in parentage testing should be made by the adults who have parental responsibility in relation to the child, in accordance with the proposals described in the following section.

31.109 Children who have reached 12 years of age but are less than 18 years may or may not have sufficient maturity to enable full comprehension of the nature and purpose of the parentage testing. In such cases, an assessment should be made of each child's individual circumstances by a competent professional, the categories of which should be specified in legislation or NATA accreditation requirements. Where a child in this age band lacks the required degree of maturity, a decision as to whether the child should participate in parentage testing should be made on his or her behalf by the adults who have parental responsibility in relation to the child. Where a child in this age band has the required degree of maturity, he or she should be able to make that decision on his or her own behalf.

31.110 A question arises as to what type of professional would be appropriate to assess a child's capacity to make an informed decision, and in what circumstances. The Inquiry's present view is that such a person should have known the child for a sufficient period to have an understanding of the child's emotional and intellectual maturity (say two years), and that he or she should have independence from the family in question. Professionals such as teachers, social workers, counsellors, medical practitioners, and ministers of religion would be suitable for the task. Moreover, in order to provide additional protection from parental coercion, the Inquiry is of the view that a written assessment from two such persons should be required. The involvement of independent professionals also may provide the child with opportunities for impartial advice or counselling about the test and its potential consequences.

31.111 As in the case of adult testing, it is necessary to establish a mechanism by which testing laboratories can be satisfied that a child's sample has been collected and submitted for testing with appropriate consent or under lawful authority. To this end, the Inquiry proposes that appropriate documentation should accompany any genetic sample submitted for testing from a child who has attained 12 years of age but is less than 18 years. That documentation should be adequate to indicate either that the child has the capacity to make the decision on his or her own behalf, or that the child lacks that capacity and that the adults with parental responsibility for the child may make the decision for the child. In practice, this might necessitate:

- a form consenting to the testing, signed by the child; accompanied by a form completed by two independent professionals attesting that the child has sufficient maturity to make an informed decision regarding the testing, or
- a form signed by all adults with parental responsibility for the child, granting consent on behalf of a child who lacks the maturity to make an informed decision regarding the testing; accompanied by a form completed by two independent professionals attesting to the child's lack of maturity.

Proposal 31–8. Legislation should provide that a child who: (a) has attained 12 years of age; and (b) has sufficient maturity to make a free and informed decision, may decide on his or her own behalf whether to submit a genetic sample for parentage testing. The child's maturity should be assessed by two independent professionals, such as teachers, social workers, counsellors, medical practitioners, or ministers of religion, who have known the child for not less than two years.

Proposal 31–9. NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain the required child consent in accordance with Proposal 31–8.

Decision making on behalf of immature children

31.112 Many minors will not have the capacity to make an informed decision on their own behalf about submitting a genetic sample for parentage testing. This may arise because they are under 12 years of age or because they have attained 12 years of age but lack the maturity necessary to make an informed decision (see the preceding discussion). In these circumstances it is necessary to consider who should be authorised to make a decision, giving or withhold consent, on behalf of the child.

Regulation of parental consent

31.113 The current provisions of the FLA require the consent of *only one* parent, guardian or carer in relation to the conduct of a parentage testing procedure on a child under 18 years. There is no specification about which parent must give consent. Where parentage testing is conducted outside the family law framework, there is no regulation of parental consent.

31.114 In practice, these permissive rules are supplemented by the ethical policies developed by individual testing laboratories. Current practice reveals widespread variations between laboratories (whether accredited or non-accredited) as to which parents must be tested, and who may give parental consent on behalf of a child. Some accredited laboratories require the bodily samples of a mother, putative father and child (if under 18 years) for paternity testing. Some accredited laboratories conduct 'motherless' paternity testing provided they receive evidence of the mother's consent. Other laboratories offer 'motherless' paternity testing without requiring evidence of the mother's consent to, or knowledge of, the testing.

31.115 For example, it was reported in 2000 that 'paternity testing laboratories in Australia are routinely analysing children's DNA without their mothers' knowledge or approval'. The article reported that at least 80% of one non-accredited laboratory's paternity tests were requested by the father and conducted without the mother's permission.⁸⁶

Issues arising from current law and practice

31.116 A central question is whether the consent of an immature child may be given on his or her behalf by one parent or carer, or whether the consent of both parents or carers should be required. For example, should a father who has doubts about the paternity of his child be able to seek parentage testing by submitting bodily samples taken from himself and the child, without informing the child's mother? Should a mother who has doubts about her child's paternity be able to seek parentage testing by submitting bodily samples taken from herself, the child and a putative father, without informing her husband or partner of this testing?

31.117 One of the principles underlying the FLA is that, except when it would be contrary to a child's best interests, parents share duties and responsibilities concerning the care, welfare and development of their children. However, s 61C(1) provides that, subject to a court order, each of the parents of a child under 18 years has parental responsibility for the child. This leads to uncertainty about whether

⁸⁶ D Smith, 'Mothers Kept in the Dark on Paternity Tests', *The Sydney Morning Herald*, 27 March 2000. While one accredited laboratory contacted had a strict policy of requiring both parents' permission for parentage testing, another accredited laboratory admitted that some of its paternity tests were conducted without the mother's permission.

parental responsibilities for children should be exercised jointly or independently.⁸⁷ The Family Court has provided some guidance on this point. In *B and B*, the Full Court commented that, where parents have separated, as a matter of practical necessity either parent will have to make individual decisions when they have sole care of the children. However, both parents should consult in relation to major issues such as major surgery and place of education.⁸⁸

Submissions and consultations

31.118 The Inquiry has received a number of submissions criticising the current law and practice regarding parental consent on behalf of a child in respect of parentage testing. One accredited laboratory, Sydney IVF Limited, raised concerns regarding the parentage testing of children with the consent of only one parent, calling this ‘non consensual’ testing.

We draw attention to the fact that nonconsensual testing of minors takes place in Australia for paternity testing, “nonconsensual” in this circumstance meaning that only one of the child’s presumptive parents has consented and that the test is done without the knowledge of the other parent, usually with the intention of occasioning disadvantage ... The sample may be as apparently innocuous as a hair follicle mailed in an envelope. Typically there is little or no professional support for the individuals concerned, particularly the minor who has been tested.⁸⁹

31.119 By comparison, the Inquiry received several submissions that strongly asserted the right of a man to obtain DNA parentage testing without notifying the child’s mother.⁹⁰

31.120 Colin Andersen suggested there are disparities in access to accredited laboratory testing because some accredited laboratories have a policy requiring maternal consent to the testing of a child, rather than paternal consent. He suggested that this excludes access to testing for fathers who wish to undertake ‘peace of mind’ testing (without the mother’s knowledge), but allows mothers to do similar forms of testing without the consent or knowledge of her husband or partner.

It is the practice of the accredited laboratories to assume that the mother is the primary caregiver and therefore deem her responsible for signing the relevant affidavit on behalf of the child. A dubious assumption indeed ... An accredited laboratory does not require [the child’s legal father’s] consent, so long as a ‘putative father’ can be found. Nor does it require counselling or any examination of motive.⁹¹

87 See generally the discussion in H Finlay, R Bailey-Harris and M Otlowski, *Family Law in Australia* (5th ed, 1997) Butterworths, Sydney, para 7.58–7.60.

88 *B and B* (1997) 21 Fam LR 676, 729–730.

89 Sydney IVF Limited, *Submission G062*, 14 January 2002.

90 DNA Solutions, *Submission G162*, 30 May 2002; G Edelsten, *Submission G117*, 14 March 2002; *Confidential Submission G074BCON*, 13 January 2002; C Andersen, *Submission G002*, 14 January 2002.

91 C Andersen, *Submission G002*, 14 January 2002.

31.121 Chief Justice Nicholson of the Family Court also has expressed concerns that current practice may not reflect the joint nature of parental responsibility for a child. In an interview on the ABC program *Lateline* in October 2000, he stated:

The law is pretty clear that both parents, unless the court otherwise orders, are entitled to take part in decisions relating to children, such as — long term decisions such as medical treatment as so on. And it seems to me that for one parent to in effect go off and supply a piece of the child's DNA to a laboratory without regard to the other is probably in breach of the Act, and it's certainly in breach of the other parent's rights in relation to the child, or really the child's rights.⁹²

Inquiry's views

31.122 The Inquiry's preliminary view is that all those with parental responsibility for a child should be required to give consent to parentage testing on behalf of the child. This recognises that parents share duties and responsibilities concerning the care, welfare and development of children. This approach would protect children against testing by one parent, without the knowledge or consent of the other parent. This is particularly important because the implications of parentage testing for the whole family may make it difficult for parents to approach the question of the child's interests with impartiality. This approach would also eliminate the perceived disparity in access to accredited testing by ensuring that one parent is not favoured as a primary carer, for the purposes of consent, over another parent.

31.123 This approach is also consistent with current practice in relation to a child's participation in medical research. The National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans provides that consent to participation in research is necessary from both parents, other than in exceptional circumstances.⁹³

31.124 In practice, situations will arise in which one parent with parental responsibility for an immature child will refuse consent to the child's involvement in parentage testing, despite the other parent's consent. Situations also may arise in which one person with parental responsibility cannot be contacted despite reasonable efforts to do so. In each of these circumstances, the consenting parent should have the right to apply to a court for determination of the issue through an order granting consent on behalf of the child.

92 *Lateline, DNA Testing and the Family Court: Transcript*, ABC TV, <<http://www.abc.net.au/lateline/s200192.htm>>, 16 October 2000.

93 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, cl 4.2. In addition, the consent of the child is required where he or she has sufficient competence to make this decision.

31.125 In making this determination, the court should have regard to the interests of the child. One of those interests, as recognised by the FLA, is the child's right to know both parents, except when it would be contrary to a child's best interests.⁹⁴ However, consistent with existing family law, the child's interests need not be 'paramount' in the sense of trumping all other considerations in the context of parentage testing.⁹⁵

31.126 The requirement of court intervention to resolve a stalemate between parents may be thought by some to be too bureaucratic and to impose unnecessary hurdles in the path of an adult who seeks to have a paternity issue resolved. However, it is worth recalling that, under the Inquiry's current proposal, access to a court will not be necessary in the case of a mature child (who can make the decision on his or her own behalf), or in the case of an immature child whose parents agree on the desirability of testing the child's genetic sample. Where agreement is not possible, a court provides a neutral arbiter, which is able to assess the interests of all the affected parties. If jurisdiction were conferred on lower courts, such as the Federal Magistrates Service, obtaining a court order need not be too costly or time-consuming.

Proposal 31–10. Legislation should require that, where a child does not have sufficient maturity to make a free and informed decision whether to submit a genetic sample for parentage testing, such testing can be performed only with the written consent of all persons with parental responsibility for the child, or pursuant to other lawful authority. Where one person with parental responsibility withholds consent or cannot reasonably be contacted, a court should be authorised to make a decision on behalf of the child.

Proposal 31–11. NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain the required parental consents in relation to samples of every child who is under the age of 12 years or who, being over that age, lacks sufficient maturity to consent on his or her own behalf.

⁹⁴ *Family Law Act 1975* (Cth) s 60B(2)(a).

⁹⁵ The 'best interests of the child' principle is the paramount concern in a number of contexts arising under the FLA, but this does not include parentage testing. While the paramount welfare principle did apply to all proceedings under Pt VII of the FLA for several years, the principle has had more limited application since 1991: A Dickey, 'The Paramount Welfare Principle and Parentage Tests' (1993) 67 *Australian Law Journal* 47, 49.

Counselling in relation to parentage testing

Current law and practice

31.127 The provision of counselling before and after parentage testing is an important means of ameliorating the emotional impact of parentage testing and maintaining existing family relationships. By undergoing counselling before engaging in parentage testing, a child may gain an understanding of the reasons his or her parent is seeking the test and may discuss the possible impact of the test results on any existing relationships with his or her parent. Similarly, a parent may gain a better understanding of the consequences of the test for his or her relationship with the child or with the other parent.

31.128 At present, the FLA provides for counselling in a number of contexts, such as in proceedings relating to children.⁹⁶ Indeed, a court exercising jurisdiction in proceedings relating to children is obliged to consider whether or not to advise the parties about counselling in order to assist family members adjust to the consequences of a court order.⁹⁷ By contrast, where parentage testing is conducted outside of the family law framework, there is no requirement that those involved obtain counselling before or after testing.

31.129 It is difficult to assess how many persons undergoing parentage testing have an effective opportunity to be counselled. The Inquiry understands that neither accredited nor non-accredited laboratories commonly provide counselling services. Several accredited laboratories have onsite counsellors available, and several laboratories refer clients to other counselling services, or forward the test report to the client's medical or legal practitioner in the expectation that they will provide counselling, if necessary. One accredited laboratory, Medvet Science Pty Ltd, states on its Internet website:

Often the circumstances surrounding this testing may be difficult. You may wish to discuss this with a person you trust such as your family Doctor or Minister of religion. We are not trained in this area, however there are many professionals available.⁹⁸

31.130 Vern Muir, director of non-accredited DNA Solutions Pty Ltd, advised the Inquiry that his company's policy is to have persons dealing with clients undergo a qualified counselling course.⁹⁹ Dr Geoffrey Edelsten, director of non-accredited Gene-e Pty Ltd, advised the Inquiry that all putative fathers who discover that they are not the biological father of their child are offered counselling. He stated:

⁹⁶ *Family Law Act 1975* (Cth) ss 62C–62E.

⁹⁷ *Ibid*, s 62B(2).

⁹⁸ See Medvet Science Pty Ltd website: Medvet Science Pty Ltd, *Confidentiality*, <<http://www.medvet.com.au/dna/confid.htm>>, 23 July 2002.

⁹⁹ DNA Solutions, *Submission G162*, 30 May 2002.

There has not been one case of over 250 clients who have been offered counselling where this has been requested and undertaken. ... They are offered alternatively to have the counselling through their medical practitioner and other health services in their states. But again it is not known of any such cases where this has been undertaken.¹⁰⁰

Issues and problems

31.131 The Chief Justice Nicholson raised the potential emotional impact of parentage testing on a child in an interview on the ABC program *Lateline*, in October 2000:

[O]ne of the problems about these exercises is that a lot of people don't pay sufficient regard to the child, and of course, it's a terrible thing for a child who's been brought up, for example, for 11 or 12 years to believe that a person is their father and for all intents and purposes is their father, to be suddenly told that person is not. ... I've seen cases where it causes enormous resentment, indeed the fact of taking the test can cause a complete rupture in relationships between the child and the father.¹⁰¹

31.132 Concerns also arise regarding a parent's potential response to discovering, through parentage testing, that he or she is not the biological parent of a child. For example, if an unstable parent receives test results indicating misattributed parentage, in the absence of counselling he or she may in some circumstances become aggressive or violent toward the child or other family members. Geneticist, Dr Brian McDonald of DNA Consults, has stated:

This is potentially explosive information. A lot of these people are on the edge as it is. Don't you think that a mother might need to know that her former partner has just found out he is not the father of one or more of her children? It is vital that she knows. Even if it is just so she can leave town for a few days while he cools down ...¹⁰²

31.133 One further issue raised during the course of the Inquiry was the appropriateness of parentage test results being made available directly to the tested individuals. Some laboratories send the parentage test reports by mail directly to the client or to each person providing a bodily sample for testing. The Inquiry understands that at least one laboratory gives its clients parentage test results over the telephone. Other laboratories have better practices. For example, DNALABS.SIVF states on its Internet website that it will only forward test results to a nominated medical practitioner or lawyer of each person tested:

In the interests of the parties being tested, results are not given over the telephone. When the results are ready, the written reports are forwarded to the medical or legal professional nominated by each person being tested. This ensures the confidentiality

100 G Edelsten, *Submission G117*, 14 March 2002.

101 Lateline, *DNA Testing and the Family Court: Transcript*, ABC TV, <<http://www.abc.net.au/lateline/s200192.htm>>, 16 October 2000.

102 G Bearup, 'The Doubt About Dad', *The Good Weekend (The Sydney Morning Herald)*, 3 November 2001, 16, 19.

of the tests results as well as professional supervision of the circumstances of the paternity test.¹⁰³

Inquiry's views

31.134 The Inquiry considers that access to counselling before and after parentage testing is an important means of ameliorating the emotional and psychological impact of such testing on the affected parties. For this reason, the Inquiry proposes that all persons who provide genetic samples for parentage testing should be advised by the testing laboratories of the availability of counselling services, both at the time the bodily samples are provided and upon receipt of the test results.

31.135 Counselling could be provided directly by the laboratory conducting the parentage testing, a specialist counselling agency, a medical practitioner, or a court-based counselling service. Given the variety of options for potential counsellors, the type and level of counselling provided will depend on the experience and qualifications of the person providing it. In Chapter 20, the Inquiry makes a number of proposals for enhancing the professional role of genetic counsellors. The Inquiry notes, however, that the skills required of a counsellor in the context of parentage testing may differ from those required of someone who provides counselling in relation to genetic disorders. For that reason it is appropriate to take a broad view of the type of person who might perform this function.

31.136 Finally, with respect to the availability of direct access to parentage test results, some individuals suggested that certain state legislation with respect to HIV/AIDS provides an appropriate model to address this concern. This legislation requires HIV test results to be forwarded to a medical practitioner or approved health care worker, who is required to counsel the tested person in the event that the test result is positive.¹⁰⁴ The Inquiry agrees with this general approach. To ensure that each person directly involved in parentage testing has access to counselling upon receipt of test results, the Inquiry proposes that parentage testing reports be forwarded directly to a person nominated by the individual tested. Such a person might be a qualified counsellor, social worker, minister of religion, medical practitioner, lawyer or court officer.

¹⁰³ [DNALABS.SIVF website: Sydney IVF, DNA Paternity Testing, <http://www.sivf.com.au/dna_paternity_testing.htm>](http://www.sivf.com.au/dna_paternity_testing.htm), 23 July 2002.

¹⁰⁴ See *HIV/AIDS Preventative Measures Act 1993* (Tas) s 15.

Proposal 31–12. NATA should develop accreditation requirements that require laboratories performing DNA parentage tests to:

- inform all persons who provide genetic samples of the availability of counselling, both at the time the samples are submitted for testing and at the time the results are made available; and
- forward test results to an independent person who has the skills to counsel the tested individuals and other relevant family members. Such a person should be nominated by each individual who has provided a genetic sample, and might be a qualified counsellor, social worker, minister of religion, medical practitioner, lawyer or court officer.

Disclosure of parentage test results

Current law and practice

~~35.1 Aspects of the law and practice concerning the collection of genetic samples for the purpose of genetic testing are dealt with in other chapters of this Discussion Paper. The present discussion is confined to the privacy implications of the disclosure of parentage test information.~~

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~~31.138~~31.137 Once a genetic sample has been analysed by a private laboratory,¹⁰⁵ the DNA profile and test results created from the sample ~~would appear to bear~~ ‘personal information’ as defined by the *Privacy Act 1988* (Cth).¹⁰⁶ The acts and practices of the laboratory in relation to that information are subject to the National Privacy Principles (NPPs). ~~Provided the information is in identifiable form,~~ Laboratories attached to state and territory public hospitals are not bound by the *Privacy Act*, but must comply with similar state or territory privacy legislation, where it exists.¹⁰⁷

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~~31.139~~31.138 NPP 2 provides that an organisation must not use or disclose personal information about an individual for a purpose other than the primary purpose of collection, except in specified circumstances, such as where the

¹⁰⁵ Private sector laboratories generally fall within the definition of an ‘organisation’ under the *Privacy Act: Privacy Act 1988* (Cth) s 6C.

¹⁰⁶ Ibid, s 6. The profile is information about an individual whose identity can reasonably be ascertained from it. The parentage test report would likewise contain information about an individual whose identity is apparent. The possible application of the *Privacy Act* to the samples themselves is discussed in Ch 7.

¹⁰⁷ *Health Records (Privacy and Access) Act 1997* (ACT); *Health Records Act 2001* (Vic); *Privacy and Personal Information Protection Act 1998* (NSW); *Information Privacy Act 2000* (Vic).

individual has consented to the use or disclosure.¹⁰⁸ Disclosure of parentage test results to the individual who has contracted with the laboratory to receive them is clearly consistent with the primary purpose of collection.

31.139 In addition, NPP 2.1 permits the disclosure of personal information for secondary purposes that are related to the primary purpose of collection and within the reasonable expectations of the individual concerned. In the parentage testing context, the primary purpose of collection is to determine whether a particular individual is the biological parent of a particular child. Each person provides a bodily sample for this purpose and personal information is collected from it.

31.140 The personal information contained in parentage test results is inherently shared in nature. Parentage testing involves relationship testing, so it is not possible to separate results so that each person providing a sample receives personal information relating only to him or herself. Due to the shared nature of parentage information, it is reasonable to assume that disclosure of the test information to each person providing a bodily sample is either for the primary purpose of collection or a related secondary purpose. The disclosure of results to each person providing a genetic sample thus appears to comply with the *Privacy Act*.

31.14031.141 The position is less clear, however, where disclosure is to an individual who has not provided a sample and has not contracted with the laboratory to receive the results of the analysis. Consider, for example, the position of the social (and assumed biological) father where the mother arranges testing of her child and the actual biological father. Disclosure of the results by the laboratory to the social father is probably not a related secondary purpose (and might, in any case, constitute a breach of contract or duty of confidentiality). However, the social father might have grounds to argue that he should have a right to access the results on the basis that the test result is also about him (because it is information indicating that he is not the biological father) in terms of the *Privacy Act* access principle.¹⁰⁹

31.142 Whatever the position under the *Privacy Act*, as discussed earlier in this chapter, the Inquiry is of the view that the opportunity for counselling would be improved if test results were not forwarded directly to the individuals sampled, but to a nominated person such as a counsellor or medical practitioner. The Inquiry is concerned that variations in laboratory practices regarding the security of disclosure of test results may undermine the privacy of results, and minimise the clients' opportunities for counselling upon receipt of results.

108 ~~*Privacy Act 1988 (Cth)*~~ *Privacy Act 1988 (Cth)*, NPP 2.1(b).

109 Ibid, NPP 6.1. The laboratory might then argue that to disclose the results to the social father would have an unreasonable impact upon the privacy of other individuals or other exceptions to the access principle.

Other kinship testing

~~31.141~~^{31.143} DNA parentage testing is one form of kinship testing. Other forms of kinship testing may involve identifying or confirming biological relationships between twins, siblings, grandparents or other relatives.

~~31.142~~^{31.144} There are various reasons for conducting DNA tests in relation to these forms of kinship. As with parentage testing, a person might seek DNA testing to establish a biological connection with a deceased person to claim a share in his or her estate, or for identification purposes, such as after a mass disaster. A person also might seek to prove a biological relationship with a living family member for immigration purposes. Ascertaining personal identity is another reason for kinship testing, such as where a person has been separated from his or her biological family through adoption, past government policy, or other circumstances (for example, the ‘stolen generation’ of indigenous Australians — see Chapter 32).

~~31.143~~^{31.145} DNA testing for kinship, other than parentage, is not currently regulated within Australia. This form of DNA testing falls outside the FLA, the FL Regulations and the current NATA accreditation requirements. As a result, both accredited and non-accredited laboratories may offer these forms of kinship testing. There is currently no formal oversight of the collection of bodily samples, procedures for maintaining the integrity of the samples, consent to participation in testing, provision of counselling, conduct of the DNA analysis, or disclosure of test results.

~~31.144~~^{31.146} The Inquiry has some concerns about the lack of regulation of this form of DNA testing. However, the Inquiry also recognises that some of the special features of parentage testing, which justified heightened regulatory scrutiny, may be absent in the case of broader kinship testing. For example, kinship testing may be less sensitive because it concerns the identity of the extended family rather than the immediate family; the test outcome may have a lesser capacity to produce emotional or psychological harm; the testing may not involve children; and the financial consequences for the parties may not be as great. In these circumstances, the Inquiry invites further comment on how kinship testing (other than parentage testing) should be regulated and on the role, if any, of NATA accreditation standards.

Question 31–2. How should DNA kinship testing (other than parentage testing) be regulated? Should NATA accreditation standards be extended to cover this form of genetic testing?

32. Genetic Information and Aboriginality

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Introduction

32.1 IP 26 raised the question whether genetic testing and information could or should be used as a means of establishing or proving Aboriginal or Torres Strait Islander identity.¹ One of the outcomes of the Human Genome Project to date is that there is no clear genetic basis for the concept of 'race'.² However, as discussed in Chapter 36, scientists are currently conducting research into the identification of certain physical characteristics, such as eye, hair and skin colour, from a genetic sample. In addition, Chapter 31 discusses the use of genetic testing in establishing parentage and other kinship.

Establishing Aboriginal identity

32.2 Issues of Aboriginal or Torres Strait Islander identity arise in a number of contexts. These include determining eligibility for membership or voting rights in Indigenous organisations such as the Aboriginal and Torres Strait Islander Commission (ATSIC); determining eligibility for the provision of entitlements and services reserved for Indigenous people (such as Abstudy); and personal reasons, such as reconnecting families who were separated by circumstances or by former

¹ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 12.27.

² Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

government removal policies, resulting in what have been called the ‘Stolen Generations’.³

32.3 The Inquiry has heard from genetic counsellors and others about cases in which individuals have been reconnected with their families and communities through the use of genetic information. The Inquiry is also aware of similar uses in other countries, including Korea — where genetic information is being used to re-link families separated for several generations because of the North-South divide. Such uses are entirely positive; however, there are also concerns about using genetic testing and genetic information as a means of constructing a person’s racial, ethnic or communal identity.

Current law and practice

32.4 In one sense, cultural identity is purely a personal matter, relevant only to the individual and his or her community. However, as a number of Australian statutes make specific provision for Aboriginal or Torres Strait Islander persons, it is sometimes necessary to determine who falls within these categories of persons.⁴

32.5 The Australian Law Reform Commission discussed the definition of an ‘Aborigine’ in its report, *The Recognition of Aboriginal Customary Laws* (ALRC 31).⁵ The Commission commented that early attempts at a definition tended to concentrate on descent, without referring to other elements of ‘Aboriginality’. Problems arose in deciding whether descendants of unions between Aborigines and settlers were to be regarded as Aboriginal for the purposes of various restrictive or discriminatory laws (eg disentitling Aborigines from voting or enrolling to vote). In applying these restrictive laws, tests based on ‘quantum of blood’ were commonly applied.⁶

32.6 After the Commonwealth Parliament obtained the power to legislate with respect to people of ‘the aboriginal race in any State’ in the 1967 referendum, the Commonwealth’s advisory Council for Aboriginal Affairs developed a three-part definition of an Aborigine for administrative purposes, such as determining eligibility for various entitlements or programs. The Council defined an ‘Aborigine’ as a person of Aboriginal descent who identifies himself or herself as

³ Human Rights and Equal Opportunity Commission, *Bringing Them Home: Report of the National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families* (1997), Sydney.

⁴ For example, *Aboriginal and Torres Strait Islander Commission Act 1989* (Cth); *Native Title Act 1993* (Cth); *Employment, Education and Training Act 1988* (Cth); *Indigenous Education (Targeted Assistance) Act 2000* (Cth); *Indigenous Education (Supplementary Assistance) Act 1989* (Cth); and cultural heritage protection legislation.

⁵ Australian Law Reform Commission, *The Recognition of Aboriginal Customary Laws*, Report 31 (1986), Australian Government Publishing Service, Canberra, paras 88–95.

⁶ *Ibid.*, para 89.

Aboriginal and who is accepted as Aboriginal by other Aborigines.⁷ The Inquiry understands that this three-part definition continues to be applied administratively in relation to programs such as Abstudy funding for tertiary students.

32.7 There have been only a small number of judicial decisions that have discussed these questions in Australia.⁸ In *Commonwealth v Tasmania*, the High Court considered the definition of an 'Aborigine' for the purpose of s 51(xxvi) of the Constitution, in relation to laws with respect to 'the people of any race for whom it is deemed necessary to make special laws'. Deane J applied the three-part test stating:

By 'Australian Aboriginal' I mean, in accordance with what I understand to be the conventional meaning of that term, a person of Aboriginal descent, albeit mixed, who identifies himself as such and who is recognised by the Aboriginal community as Aboriginal.⁹

32.8 Brennan J supported this approach in his leading judgment in *Mabo v Queensland (No 2)*:

Membership of the Indigenous people depends on biological descent from the Indigenous people and on mutual recognition of a particular person's membership by that person and by the elders or other persons enjoying traditional leadership among those people.¹⁰

32.9 The Commonwealth has enacted a number of statutes for the purpose of providing certain rights and privileges for the exclusive benefit of Indigenous Australians.¹¹ These statutes generally define an 'Aboriginal person' as a person who is a descendant of an indigenous inhabitant of Australia;¹² or a member or a person of the Aboriginal race of Australia.¹³ Due to the broad terms in which they are stated, it has been necessary for the courts to interpret these provisions.

32.10 In *Attorney-General (Cth) v Queensland*, the Federal Court considered the meaning of the word 'Aboriginal' in relation to the Letters Patent authorising a Royal Commission to inquire into certain deaths in custody of 'Aboriginal and Torres Strait Islanders'. Queensland argued that the Royal Commission was not

⁷ R Bartlett, A Brown and G Nettheim, 'Aborigines and Torres Strait Islanders' in Garth Nettheim (ed), *The Laws of Australia: Aborigines* (1992) The Law Book Company Limited, Sydney, vol 1.1, [1].

⁸ The following analysis draws on a useful discussion in an unpublished paper: L de Plevitz and L Croft, *Proving Aboriginality: Legal and Genetic Constructs of Aboriginal Descent* (2002) unpublished.

⁹ *Commonwealth v Tasmania* (1983) 158 CLR 1, 274 (Deane J).

¹⁰ *Mabo v Queensland (No 2)* (1992) 175 CLR 1, 70 (Brennan J).

¹¹ For example, *Aboriginal and Torres Strait Islander Commission Act 1989* (Cth); *Native Title Act 1993* (Cth).

¹² *Racial Discrimination Act 1975* (Cth) s 3(1).

¹³ *Human Rights and Equal Opportunity Commission Act 1986* (Cth) s 3(1); *Indigenous Education (Targeted Assistance) Act 2000* (Cth) s 4; *Indigenous Education (Supplementary Assistance) Act 1989* (Cth) s 3; *Native Title Act 1993* (Cth) s 253; *Aboriginal and Torres Strait Islander Commission Act 1989* (Cth) s 4(1).

authorised to inquire into the death of a particular 17 year old boy in custody because the boy had not been Aboriginal. Queensland argued for the application of Deane J's three-part test of Aboriginality, stating that although the boy had mixed Aboriginal descent, he was not Aboriginal because of the absence of self-identification or recognition by the Aboriginal community.¹⁴

32.11 As the Letters Patent did not define the term 'Aboriginal', the Court looked for the meaning of the word in the light of vernacular usage. The Court did not adopt Deane J's test, instead finding that Aboriginal descent was, by itself, sufficient proof of Aboriginality for these particular purposes. Spender J held that once it is established that a person is non-trivially of Aboriginal descent, then he or she is Aboriginal within the ordinary meaning of that word. Neither self-recognition nor recognition by the Aboriginal community is necessary, and the presence of either factor, or even both, is not sufficient to satisfy the definition of an 'Aboriginal' person.¹⁵ Jenkinson J considered that descent (or at least a real possibility of it) is essential, but certainty as to descent is not necessary nor always sufficient.¹⁶ Spender and Jenkinson JJ both held that where Aboriginal descent is uncertain, or where the extent of Aboriginal descent might be considered insignificant, self-recognition or recognition by other Aboriginal persons may each have an evidentiary value in resolving the question.

32.12 French J commented that the three-part definition restricted the scope of the Royal Commission by adding two conditions to the meaning of 'Aboriginal'. This was contrary to the purpose of the inquiry or its Letters Patent. The better view was that Aboriginal descent alone is a sufficient criterion for classification as Aboriginal.¹⁷

32.13 Several cases have considered the meaning of s 4(1) of the *Aboriginal and Torres Strait Islander Commission Act 1989 (Cth)* (ATSIC Act), which defines an Aboriginal person as 'a member of the Aboriginal race of Australia'. In *Gibbs v Capewell*, Drummond J noted that as the legislature had not defined the term 'Aboriginal', the definition bore the meaning that it had in ordinary usage, subject to any statutory qualifications. After examining the preamble to the ATSIC Act and the Act's objectives, his Honour concluded that Parliament's intention was to refer to the group of persons in the modern Australian population who are descended from the inhabitants of Australia immediately prior to European settlement. Therefore, an 'Aboriginal person' is, for the purposes of the ATSIC Act, one of those descendants. His Honour stated:

¹⁴ *Attorney-General (Cth) v Queensland* (1990) 94 ALR 515.

¹⁵ *Ibid.*, 523–524 (Spender J).

¹⁶ *Ibid.*, 518–518 (Jenkinson J).

¹⁷ *Ibid.*, 538–539 (French J).

Since the Act itself makes it clear that proof of descent from the pre-European settlement inhabitants of Australia is essential before a person can come within the expression 'Aboriginal person' in the Act, I reject the suggestion ... that a person without any Aboriginal genes but who has identified with an Aboriginal community and who is recognised by that community as one of them can be an 'Aboriginal person' for the purposes of this particular Act. It follows that adoption by Aboriginals of a person without any Aboriginal descent and the raising of that person as an Aboriginal ... will not, because of the statutory requirement for descent, bring that person within the description 'Aboriginal person'.¹⁸

32.14 Drummond J commented that Deane J's three-part test should not be regarded as containing an exhaustive description of the meaning in ordinary speech of the term 'Aboriginal'.¹⁹ His Honour held that a person must have some degree of Aboriginal descent to satisfy the definition of an 'Aboriginal person'. A small degree of Aboriginal descent coupled with genuine self-identification or with communal recognition may be sufficient for eligibility; alternatively, a substantial degree of descent may by itself be sufficient.²⁰ Finally, Drummond J recognised the probative value of communal recognition as evidence of Aboriginal descent.

Aboriginal communal recognition will always be important, when it exists, as indicating the appropriateness of describing the person in question as an "Aboriginal person". Proof of communal recognition as an Aboriginal may, given the difficulties of proof of Aboriginal descent flowing from, among other things, the lack of written family records, be the best evidence available of proof of Aboriginal descent. While it may not be necessary to enable a person to claim the status of an "Aboriginal person" for the purposes of the Act in a particular case, such recognition may, if it exists, also provide evidence confirmatory of the genuineness of that person's identification as an Aboriginal.²¹

32.15 In *Shaw v Wolf*, the Federal Court again considered whether certain persons were eligible to stand for ATSIC elections as 'Aboriginal persons'. Merkel J agreed with Drummond J's conclusions in *Gibbs v Capewell*. His Honour held that if a person has no Aboriginal descent then the person cannot be an Aboriginal person for the purposes of the Act. However, evidence about the process by which self-identification and communal identification occurs can be probative of descent.²² His Honour referred to the lack of documentary records and to the reticence of some families of Aboriginal descent to publicly acknowledge that fact due to actual or perceived racism from the rest of the community.

In these circumstances Aboriginal identification often became a matter, at best, of personal or family, rather than public, record. Given the history of the dispossession and disadvantage of the Aboriginal people of Australia, a concealed but nevertheless passed on family oral 'history' of descent may in some instances be the only evidence available to establish Aboriginal descent. Accordingly oral histories and evidence as

¹⁸ *Gibbs v Capewell* (1995) 128 ALR 577, 580 (Drummond J).

¹⁹ *Ibid*, 583.

²⁰ *Ibid*, 584.

²¹ *Ibid*, 585.

²² *Shaw v Wolf* (1998) 163 ALR 205, 211–212 (Merkel J).

to the process leading to self-identification may, in a particular case, be sufficient evidence not only of descent but also of Aboriginal identity.²³

32.16 In his concluding observations, Merkel J emphasised that his decision was based on the definition of an 'Aboriginal person' in the ATSIC Act only.

[I]n seeking to redress some of the wrongs of the past as well as to assist Aboriginal persons a number of laws have been enacted and services provided by the state which understandably are solely for the benefit of Aboriginal persons. Consequently some criterion is necessary to define the beneficiary group. Aboriginality as such is not capable of any single or satisfactory definition. Clearly the Aboriginality of persons who have retained their spiritual and cultural association with their land and past will differ fundamentally from the Aboriginality of those whose ancestors lost that association.

The present case offers a good example of the difficulties thrown up by issues of Aboriginal identification. That some descent may be an essential legal criterion required by the definition in the Act is to be accepted. However in truth, the notion of "some" descent is a technical rather than a real criterion for identity, which after all in this day and age, is accepted as a social, rather than a genetic, construct. The solution to such problems is a matter for the legislature rather than the courts.²⁴

32.17 In summary, the Commonwealth government appears to apply the three-part test of Aboriginal descent, self-identification and community recognition for determining eligibility for certain programs and benefits. The courts, in interpreting general terms in federal laws, have also emphasised the importance of descent in establishing Aboriginal identity, but they have recognised that self-identification and communal recognition may be relevant to establishing Aboriginal identity.

Other jurisdictions

32.18 Dr William Jonas, the Aboriginal and Torres Strait Islander Social Justice Commissioner of the Human Rights and Equal Opportunity Commission made a detailed submission to the Inquiry, which provided an overview of the international position regarding identification definition of 'Indigenous' persons.

32.19 The submission noted that Indigenous peoples have resisted attempts internationally to prescribe an exhaustive definition of 'Indigenous'. The right of self-identification is one of the fundamental principles enunciated by Indigenous peoples, and is reflected in Article 2 of the ILO's *Indigenous and Tribal Peoples Convention 1989*:

²³ Ibid, 213.

²⁴ Ibid, 268.

Self-identification as indigenous or tribal shall be regarded as a fundamental criterion for determining the groups to which the provisions of this Convention apply.²⁵

32.20 This right has been affirmed by the United Nations Working Group on Indigenous Populations as an aspect of the right to self-determination, which is recognised in several international human rights instruments to which Australia is a party.²⁶ The international standard for identification of Indigenous peoples has also been adopted in the United Kingdom and New Zealand. In both countries, self-identification and acceptance by the community is the only legal basis for determining whether a person belongs to a particular ethnic group.²⁷

Issues and problems

32.21 IP 26 noted that suggestions for the use of genetic information and testing in establishing Aboriginality could be made from within, or outside of, Aboriginal communities. For example, genetic testing might be sought by a person asserting Aboriginal identity who has not been accepted by the community; by a government authority to determine an applicant's eligibility for a benefit reserved for Aboriginal persons; or by an Aboriginal person or community seeking to settle a dispute regarding another person's claims to Aboriginality.

32.22 The Inquiry understands that recent discord among certain Aboriginal communities regarding Aboriginal identity has led to calls for the use of DNA testing in proving Aboriginal descent.²⁸ According to current scientific knowledge, there is no genetic basis for race. Therefore it is not possible to identify a person's racial background from his or her genes alone. However, genetic testing, in the form of DNA parentage or kinship testing, could establish that a person is biologically related to another person who is accepted as an Aboriginal person.²⁹

32.23 DNA parentage or kinship testing has a number of advantages in the context of Aboriginal identification. Genetic testing could be used for personal reasons, for example to reconnect families that have been separated; or for the purpose of establishing Aboriginal descent to access certain benefits provided for Aboriginal persons, such as Abstudy or eligibility to vote in, or stand for, ATSIC elections.

²⁵ *Indigenous and Tribal Peoples Convention*, 1650 UNTS 383, (entered into force on 5 September 1991).

²⁶ For example, see Art 1(1) of the *International Covenant on Civil and Political Rights*, opened for signature 19 December 1966, UNTS 1197, (entered into force on 13 November 1980), *International Covenant on Economic, Social and Cultural Rights*, opened for signature 19 December 1966, 993 UNTS 3, (entered into force on 10 March 1976). See also Art 9 of the *Draft Declaration on the Rights of Indigenous Peoples 1994*, which expresses the right of Indigenous peoples to belong to an indigenous community or nation in accordance with their own traditions and customs.

²⁷ Aboriginal and Torres Strait Islander Social Justice Commissioner - Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

²⁸ R. Guilliatt, 'A Whiter Shade of Black?', *The Good Weekend (The Sydney Morning Herald)*, 15 June 2002, 18.

²⁹ In addition, it might be possible in the future to identify certain physical characteristics associated with Aboriginality from a genetic sample. Parentage testing is discussed further in Ch 31.

32.24 However, the potential use of genetic testing in establishing Aboriginal identity raises the concern that such testing might overly emphasise the importance of Aboriginal descent in determining identity, rather than self-identification or community recognition. This might disadvantage persons who are not able to prove their descent through family trees because of unreliable colonial record keeping and past policies of removal; or who, as a result of past removal from their families and communities, cannot locate an Aboriginal family member for kinship testing to establish Aboriginal descent.

32.25 In addition, the Inquiry has heard a further concern that members of the wider Australian community may now be claiming Aboriginal identity (and any associated benefits) where they are able to prove Aboriginal descent from distant ancestors, even though they have not had continuing affiliation with the Aboriginal community. Professor Larissa Behrendt, professor of Law and Indigenous Studies at the University of Technology, Sydney, has commented:

If we're going to talk about treaties and recognition of rights, the question of who's in and who's out is going to be the most important issue facing indigenous Australians. If that isn't resolved, you run the risk of having the parameters stretched to the ludicrous point where someone can say: "Seven generations ago there was an Aboriginal person in my family, therefore I am Aboriginal".³⁰

32.26 Finally, the potential use of genetic testing as evidence of Aboriginal descent raises a fundamental question whether proof of descent should be a necessary element of the legal definition of Aboriginality, and if so, what type of proof is required.

Submissions and consultations

32.27 IP 26 asked whether, as a matter of policy, genetic science should have any role to play in determining personal identity or in determining racial or ethnic identity and membership.³¹

32.28 Dr Loretta de Plevitz and Larry Croft commented that in our present state of knowledge there are four major barriers to proving Aboriginality by means of genetics.

Firstly, there is no such thing as a genetically differentiated "race": we are all one species. Secondly ... if race is defined by cultural and genetic context, then there are difficulties in proving membership of the "Aboriginal race" as on this definition there were hundreds of Aboriginal races pre-1788. Thirdly, looking at the polymorphisms in an individual's DNA shows us who they are related to. But this just defers the

³⁰ R. Guilliatt, 'A Whiter Shade of Black?', *The Good Weekend (The Sydney Morning Herald)*, 15 June 2002, 18, 21.

³¹ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 12.27.

problem of whether those people related to the claimant are Aboriginal or not. Fourthly, who could the claimant's genetic inheritance be tested against? It would be necessary to construct DNA reference groups based on "pure blood" Aboriginal people covering all geographic groups in Australia. If by chance one of the reference DNA groups was very similar to the claimant's then we can show descent ... as the Australian Aboriginal population is so genetically diverse, there would need to be a large reference set of people for all genetically distinct groups ... Where there has been the wholesale extermination of entire groups of people, claimants attempting to prove their Aboriginality may not be related to any of the reference groups because there is no longer a reference group for them.³²

32.29 A number of submissions commented on the appropriateness, or otherwise, of the current Australian legal definition of Aboriginality, in particular in relation to the requirement of Aboriginal descent.³³ Dr William Jonas commented:

While Aboriginal people may generally be direct descendants of the original inhabitants of a particular part of Australia, indigenous customary law does not rely on linear proof of descent in the Judeo-Christian genealogical form of 'Seth begat Enosh begat Kenan' in order to prove membership of the group. ... A person may have been adopted into a kinship group where there is no direct or suitable offspring to carry out ceremonial obligations. ... Genetic science should have no part to play in determining whether or not a person should be eligible for benefits. If the element of descent is to remain in Australian law as a test of Aboriginality, it should be interpreted in accordance with Indigenous cultural protocols.³⁴

32.30 In their submission, de Plevitz and Croft stated that proof of descent by a test that has no scientific basis affects those who will have the most difficulty asserting their Aboriginality, being those people taken from their parents as children and placed in welfare or adopted out, or persons whose ancestral group has been virtually wiped out:

Other disadvantaged groups such as the poor, the uneducated or the disabled do not have such requirements of proof to access benefits. ... Aboriginal people will walk away from such humiliation rather than face legal questioning on their identity. An Australian legal test based on cultural difference would fulfil the same purpose as the descent test without its potentially divisive effects.³⁵

32.31 The NSW Anti-Discrimination Board recognised that the use of genetic testing to determine Aboriginal or other communal identity is relevant to a person's entitlement to access Indigenous services, programs and benefits and to participate in Indigenous organisations. The Board commented that:

³² L de Plevitz and L Croft, *Submission G115*, 13 March 2002.

³³ See *Ibid*; Aboriginal and Torres Strait Islander Social Justice Commissioner - Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002; Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

³⁴ Aboriginal and Torres Strait Islander Social Justice Commissioner - Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

³⁵ L de Plevitz and L Croft, *Submission G115*, 13 March 2002.

[w]here programs and services are established for the benefit of ... particular racial groups or individuals, in order to redress disadvantage, and a person is refused access because they are not part of that racial group, they are unlikely to be able to argue they have been discriminated against on the basis of race. ... The central issue is not about the role of anti-discrimination legislation. It is whether it is appropriate to use genetic information to determine community, racial and ethnic affiliation. This is a question better answered by Indigenous communities themselves. We are concerned that should a purely genetic approach to community, racial and ethnic affiliation be adopted, it is conceivable that people who identify as indigenous and are accepted within Indigenous communities as Indigenous may be refused access to Indigenous services programs and benefits, which were specifically designed to address disadvantage of Indigenous people.³⁶

32.32 Dr Paul Henman, a Research Fellow in the Department of Sociology at Macquarie University, submitted that the shift to genetics to determine eligibility to Indigenous programs, policies and benefits should be resisted because social processes are much more significant than genetic processes in determining identity.

Policy makers should be encouraged to ensure that the eligibility criteria to policies and programs aimed at Aboriginal and Torres Strait Islanders give greater importance to cultural, rather than genetic, identity. Having said this, genetic information may be important in testing claims of genetic identity. Even so, genetic heritage should not necessarily constitute immediate eligibility to such programs. Programs aimed at individuals who have been forcibly removed from their cultural heritage — such as the ‘Stolen Generation’ — may also find it appropriate to use genetic information.³⁷

Inquiry’s views

32.33 While Australia does not have a uniform legislative definition of Aboriginality, evidence of Aboriginal descent generally has been accepted as a necessary element. DNA parentage or kinship testing might, in some circumstances, be used as evidence of such descent.

32.34 The availability of genetic testing as a form of evidence of Aboriginal descent raises a more fundamental question about the appropriateness of the current legal definition of Aboriginal identity. As noted above, the courts have emphasised the need to prove Aboriginal descent as the most important criterion of Aboriginal identity, while self-identification and community recognition have been used as evidence of such descent.

32.35 The emphasis on descent has been criticised for disadvantaging those who identify as Aboriginal and are recognised by their community as such, but who are unable to trace their family trees back to their Aboriginal ancestors. Descent has also been strongly criticised for its reliance on outmoded legal

³⁶ Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

³⁷ P Henman, *Submission G055*, 15 January 2002.

classifications of Aboriginality based on 'strains of blood'.³⁸ On the other hand, it has been suggested that requiring proof of descent is one way to protect against fraudulent or otherwise inappropriate claims of Aboriginality by non-Indigenous Australians.³⁹

32.36 The Inquiry recognises that there is a degree of discord among Australian Aboriginal communities regarding issues of Aboriginal identity. For example, in Tasmania there is dispute between those seeking to define themselves by way of self and community identification, and those who insist on evidence of Aboriginal descent. This has led ATSIC to trial an Indigenous Electoral Roll to ensure that only eligible persons are able to vote in the next Tasmanian Regional Aboriginal Council Elections.⁴⁰ In a recent magazine article on this controversy, it was stated that:

Tasmania's inaugural Aboriginal electoral roll ... the first of its kind in Australia — is aimed at settling a longstanding furore in the state about the growing numbers of people claiming to be indigenous. But more than that, it's a portent of what could become the most divisive issue facing the mainland indigenous community: who among us is entitled to declare, "I am Aboriginal"?⁴¹

32.37 The ATSIC Indigenous Electoral Roll applies a strict test of Aboriginality. If a person objects to an applicant being included on the roll, on the basis that he or she is not an Aboriginal or Torres Strait Islander, the applicant must provide evidence of his or her Aboriginal ancestry, self-identification, and communal recognition. To prove ancestry, the applicant is generally required to provide a verifiable family tree, or archival or historical documentation that links him or her to a traditional family or person.⁴²

32.38 This approach reflects an exercise in self-determination, which is consistent with the observation of Merkel J in *Shaw v Wolf*:

It is unfortunate that the determination of a person's Aboriginal identity, a highly personal matter, has been left by a Parliament that is not representative of Aboriginal people to be determined by a Court which is also not representative of Aboriginal people. Whilst many would say that this is an inevitable incident of political and legal life in Australia, I do not accept that that must always be necessarily so. It is to be hoped that one day if questions such as those that have arisen in the present case are again required to be determined that that determination might be made by

³⁸ Aboriginal and Torres Strait Islander Social Justice Commissioner - Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

³⁹ See R Guilliatt, 'A Whiter Shade of Black?', *The Good Weekend (The Sydney Morning Herald)*, 15 June 2002, 18.

⁴⁰ See ATSIC's website: Aboriginal and Torres Strait Islander Commission, *ATSIC Regional Council Elections 2002*, < http://www.atsic.gov.au/Events/Elections_2002/Tasmania/default.asp>, 22 July 2002.

⁴¹ R Guilliatt, 'A Whiter Shade of Black?', *The Good Weekend (The Sydney Morning Herald)*, 15 June 2002, 18.

⁴² See ATSIC's website: Aboriginal and Torres Strait Islander Commission, *ATSIC Regional Council Elections 2002*, < http://www.atsic.gov.au/Events/Elections_2002/Tasmania/default.asp>, 22 July 2002.

independently constituted bodies or tribunals which are representative of Aboriginal people.⁴³

32.39 While the Inquiry questions whether documented proof of Aboriginal descent always should be necessary to prove Aboriginal identity, the Inquiry agrees with the view that matters of Aboriginal identity are primarily ones for Aboriginal communities to determine. Recognising that different tests might be appropriate in different circumstances, the Inquiry proposes that ATSIC — as the democratically elected vehicle for indigenous governance — should consider the appropriate test or tests to be applied in determining Aboriginal or Torres Strait Islander identity. To the extent that any test requires evidence of Aboriginal or Torres Strait Islander descent, ATSIC also should consider the appropriateness or otherwise of using genetic testing and genetic information for this purpose.

Proposal 32–1. The Aboriginal and Torres Strait Islander Commission (ATSIC) should consider the appropriate test or tests to be applied in determining Aboriginal or Torres Strait Islander identity. To the extent that any such test requires evidence of Aboriginal or Torres Strait Islander descent, ATSIC should consider the appropriateness or otherwise of using genetic testing and genetic information for this purpose.

Access to native title

Current law and practice

32.40 Native title was recognised at common law in *Mabo v Queensland (No 2)*.⁴⁴ The source of native title is the traditional Aboriginal occupancy of, or connection with, the land by the people as a community or society, in accordance with its laws and customs.⁴⁵

32.41 The *Native Title Act 1993* (Cth) provides a statutory framework for claiming native title. Section 223(1) defines native title as

the communal, group or individual rights and interests of Aboriginal peoples or Torres Strait Islanders in relation to land or waters, where:

- (a) the rights and interests are possessed under the traditional laws acknowledged, and the traditional customs observed, by the Aboriginal peoples or Torres Strait Islanders; and

⁴³ *Shaw v Wolf* (1998) 163 ALR 205, 267–268 (Merkel J).

⁴⁴ *Mabo v Queensland (No 2)* (1992) 175 CLR 1.

⁴⁵ R Bartlett, A Brown and G Nettheim, 'Aborigines and Torres Strait Islanders' in Garth Nettheim (ed), *The Laws of Australia: Aborigines* (1992) The Law Book Company Limited, Sydney, vol 1.3, [11].

- (b) the Aboriginal peoples or Torres Strait Islanders, by those laws and customs, have a connection with the land or waters; and
- (c) the rights and interests are recognised by the common law of Australia.

32.42 Section 61(1) provides that a native title determination application may be made to the Federal Court by:

a person or persons authorised by all the persons (the native title claim group) who, according to their traditional laws and customs, hold the common or group rights and interests comprising the particular native title claimed, provided the person or persons are also included in the native title claim group.

32.43 One of the conditions for registration of a native title claim is that the Registrar of the National Native Title Tribunal must be satisfied that the persons in the native title claim group are named in the application; or the persons are described sufficiently clearly so that it can be ascertained whether any particular person is in that group.⁴⁶ For example, the native title claim group could be described as ‘all descendants of X’.

Issues and problems

32.44 IP 26 asked whether genetic information could or should be used as a means of establishing Aboriginal or Torres Strait Islander identity in the context of native title determination applications. For example, where a native title claim group is defined as the biological descendants of certain known ancestors, DNA parentage or kinship testing could be used, if necessary, to establish a biological relationship with those ancestors, through their known descendants.

Submissions and consultations

32.45 Dr William Jonas submitted that the use of DNA technology in native title claims might be indicated where

persons want to be identified as members of a claimant group, for example because they are from the Stolen Generation, but have been excluded from the native title claim for some reason. Being an identified member of a native title group could also serve as a defence to a statutory offence such as taking of undersize fish, the killing of a protected species or trespass to land. In the United States people have tried to prove by DNA analysis that they are members of particular First Nation groups in order to access royalties and profits from indigenous enterprises.⁴⁷

32.46 After considering the potential application of genetic information under the *Native Title Act 1993*, Dr Jonas concluded:

⁴⁶ *Native Title Act 1993* (Cth) ss 190A(6), 190B(3).

⁴⁷ Aboriginal and Torres Strait Islander Social Justice Commissioner - Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

Genealogists and anthropologists give evidence in tribunals to prove descent from original owners. However their role is to elucidate descent according to Indigenous kinship rules. Genetic information does not follow those rules and therefore would probably be unacceptable as a means of proving membership of the group. Like the issue in relation to benefits, membership of a native title group should be decided according to the customary laws of the Indigenous group. This conforms to international principles in relation to the identification of Indigenous people.⁴⁸

32.47 The submission of the Commonwealth Attorney-General's Department gave a lengthy discussion of the potential use of genetic information in the native title context.

While registration of a native title determination application requires the Native Title Registrar to be satisfied that the persons in the native title claim group are named in the application, or are described sufficiently clearly so that it can be ascertained whether any particular person is in the group, it is not necessary to be registered in order to have native title recognised by the Federal Court. Membership of a claim group is primarily determined by the group itself — through identification and acceptance. ... The definition of the group requires a consideration of the social structure of the group, now and in the past. In native title determination hearings the native title applicants have relied on expert genealogical, anthropological and historical evidence, in addition to lay evidence from members of the native title claim group to demonstrate the necessary connection. This evidence is relied on to demonstrate the nature of the connection between the original community and the native title claim group, and to identify the structure of the community. It is most likely that native title applicants will continue to rely on evidence of this kind to establish the necessary traditional continuing connection because it is only evidence of this kind that can deal with the complex social and historical material relevant in native title cases.⁴⁹

Inquiry's views

32.48 There appears to be little scope at present for using genetic testing or information in the context of a native title claim. For example, it is unlikely that genetic testing could help establish that a native title claim group is comprised of the descendants of the original native title holders because this would require genetic samples from members of the original group.

32.49 In some circumstances, DNA parentage or kinship testing might be used to establish that a person is a member of a native title claim group. For example, where the native title claim group is defined as 'the descendants of X', genetic testing might be used to show that the person is biologically related to a known descendant of X. However, this would only be necessary where the person is not otherwise recognised as a member of the native title claim group, and in these circumstances other evidence may be available to establish membership.

⁴⁸ Ibid.

⁴⁹ Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

32.50 The Inquiry welcomes further comments from the public on the use that may be made of genetic information in the context of native title claims.

Question 32–1. Are there circumstances in which genetic information may be relevant to a native title claim made under the *Native Title Act 1993* (Cth)? If so, how should genetic information be regulated to protect privacy and prevent unfair discrimination?

33. Immigration

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Introduction

33.1 This chapter examines current law and practices that regulate the use of genetic testing for migration decision making under the *Migration Act 1958* (Cth) (*Migration Act*) and the *Migration Regulations 1994* (Cth) (*Migration Regulations*).

33.2 Genetic testing has two possible applications in the migration context:

- to confirm family relationships for 'Family Stream applications' (kinship testing); and
- to make determinations on the health status of people applying to migrate (health testing).

33.3 There have also been media reports about the potential use of genetic tests or other biometric tests to identify asylum seekers in order to detect whether they have applied for asylum previously.¹ However, the Inquiry understands that the Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) does not currently use genetic testing for this purpose and does not intend to do so.

¹ L. Porter, 'DNA Tests to Screen Migrants', *Sunday Age* (Melbourne), 5 May 2002, 3; Minister for Immigration and Multicultural and Indigenous Affairs, *Ruddock Announces Tough New Initiatives*, Media Release, 13 October 1999.

- | ~~33.333.4~~ Prospective migrants may be invited to undergo genetic testing to substantiate claimed family relationships as part of the process of applying to migrate to Australia. Currently, genetic testing is used almost exclusively for kinship testing. On rare occasions, a genetic test might be performed as part of the medical examination that prospective migrants undergo.
- | ~~33.433.5~~ At present, genetic testing is not used to help establish the identity of asylum seekers. However, the Minister for Immigration and Multicultural and Indigenous Affairs has indicated that, in future, genetic testing might be used (along with other biometric tests) to identify asylum seekers; to ensure that they do not already have protection elsewhere; and to ensure that they have not previously been refused refugee status by another country.
- | ~~33.533.6~~ The use of genetic testing in migration decision making raises different issues depending on the purpose for which the test is performed. For example, the major concerns raised by kinship testing relate to the integrity of the testing process and the possibility that testing may reveal sensitive information about the composition of a family. A concern in relation to the use of genetic testing to ascertain the health status of a prospective migrant is the manner in which the test results are interpreted and used.
- | ~~33.633.7~~ The use to be made of genetic test results in migration decision making falls within the responsibilities of DIMIA. DIMIA has developed internal policies and practices on the use of genetic tests for these purposes, which are set out in its Procedures Advice Manual.²
- | ~~33.733.8~~ Genetic test results held by DIMIA are subject to the *Privacy Act 1988* (Cth) (*Privacy Act*) and to the Information Privacy Principles (IPPs), even where test information is collected by DIMIA officers overseas.³ Test results held by private testing laboratories are generally subject to the private sector provisions of the *Privacy Act* and the National Privacy Principles (NPPs).⁴
- | ~~33.833.9~~ The *Disability Discrimination Act 1992* (Cth) (DDA) contains a specific exemption in relation to migration. Section 52 provides that any discriminatory provisions in the *Migration Act*, any regulation made under the Act, or any act done by a person in relation to the administration of the Act or regulations, are not unlawful under the DDA. As a result, conduct that would otherwise be unlawful under the DDA because it involves discrimination on the basis of genetic status is lawful, provided the conduct complies with the migration legislation. The framework of Australian anti-discrimination law is discussed further in Chapter 8.

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2 Department of Immigration and Multicultural Affairs, *Procedures Advice Manual 3* (1997) Commonwealth of Australia, Canberra.

3 *Privacy Act 1988* (Cth) s 8(1).

4 Unless the laboratory is a contracted service provider under a Commonwealth contract: *Ibid* s 6A.

Kinship testing

~~33.9~~33.10 Some visas granted under the *Migration Act* require an applicant to demonstrate certain familial relationships. These applications fall into one of two streams:

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- the Family Stream of the Non-Humanitarian Migration Program; or
- the Humanitarian Stream.

~~33.10~~33.11 Under the Family Stream, individuals can apply to migrate to Australia by establishing that they have a familial connection to an Australian sponsor. This includes parent-child relationships and may extend in some cases to more remote ties such as sibling relationships.⁵

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~~33.11~~33.12 Under the Humanitarian Stream, individuals can apply for humanitarian entry to Australia where they can show an immediate familial relationship to a person holding a permanent protection visa inside Australia, or to a person holding a permanent entry visa outside Australia.⁶

~~33.12~~33.13 DIMIA uses genetic test information to help determine the existence of family relationships in a very small proportion of cases that fall within the two streams outlined above. This use is regulated by the Procedures Advice Manual, which provides policy and procedural guidance for DIMIA officers regarding the use of genetic parentage and other kinship testing. The advice extends to the standards that testing procedures must meet, the circumstances in which testing should be offered, and how the integrity of the sample is to be protected.

~~33.13~~33.14 The Procedures Advice Manual notes that officers may only offer genetic testing; they do not have power to compel an applicant to undergo genetic testing.⁷ In Family Stream cases, the applicant or sponsor pays the costs of testing.

~~33.14~~33.15 Genetic testing is also used in some other countries to determine family relationships for the purpose of migration. The Inquiry understands that Canada, the United States and the United Kingdom allow genetic kinship testing to be conducted in relation to migration, subject to procedures similar to those used in Australia.⁸

⁵ Department of Immigration and Multicultural Affairs, *Fact Sheet 27, Family Stream Migration: An Overview*, Commonwealth of Australia, <<http://www.dima.gov.au/facts/27family.htm>>, 2 August 2001.

⁶ Department of Immigration Multicultural and Indigenous Affairs, *Form 964i — Entry to Australia (Offshore Humanitarian Program)* (2002), Commonwealth of Australia, Canberra.

⁷ Department of Immigration and Multicultural Affairs, *Procedures Advice Manual 3* (1997) Commonwealth of Australia, Canberra, para 19.1.1.

⁸ See eg Citizenship and Immigration Canada, *Overseas Processing Manual, Chapter OP1 — General Procedural Guidelines*, Canada, <<http://www.cic.gc.ca/manuals-guides/english/>>, 31 July 2002.

Family Stream

33.1533.16 The Inquiry understands that DIMIA uses about 200 genetic tests per year to help verify claimed relationships in Family Stream cases.⁹ This represents less than 1% of the overall family migration intake.

33.1633.17 Genetic testing may be required to establish the relationship between the applicant and sponsor, or to establish the applicant's family composition. Generally, genetic testing will involve parentage testing but it might also be used to test extended family connections, such as sibling or grandparent-grandchild relationships.¹⁰ Genetic testing is considered most useful in regions where there is a high incidence of document fraud or in countries where official documentation is unavailable.

33.1733.18 The Procedures Advice Manual states that genetic testing should be used as a 'last resort' where claims are doubtful or if credible documentation cannot be provided to substantiate the claims.¹¹ The Manual suggests that, as the costs of genetic testing may be prohibitive for some applicants, an officer should give no weight to an applicant's decision not to undergo testing, when making a decision on a case.¹² Where an applicant privately arranges genetic testing but does not provide the test results to DIMIA, the guidelines suggest that this may increase existing doubts about the relationship, but that the person should be given an opportunity to explain. In tests offered by DIMIA, the person tested consents to the laboratory providing the results directly to DIMIA.

33.1833.19 The Procedures Advice Manual notes that different cultures have different concepts of the family unit and that applicants may not fully appreciate that genetic testing is a test of biological parentage. The guidelines state that suspected 'non-birth' children may still be eligible as 'members of the family unit', and advises case officers to consider different concepts of family before offering genetic testing, or when negative test results are returned.¹³

33.1933.20 In less straightforward cases, the Procedures Advice Manual suggests that the laboratory may require samples from relatives who are not directly involved in the migration application. For instance, if it is suspected that either of two brothers may be the father of a child, more extensive testing may be required to exclude individuals who are not the parents.¹⁴

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⁹ L. Porter, 'DNA Tests to Screen Migrants', *Sunday Age* (Melbourne), 5 May 2002, 3.

¹⁰ Ibid, para 12.1.1–12.1.3.

¹¹ Ibid, para 10.1.1.

¹² Ibid, para 19.1.1.

¹³ Ibid, para 11.1.1–11.1.2.

¹⁴ Ibid, para 17.1.3.

Humanitarian Stream

~~33.20~~33.21 The Procedures Advice Manual notes that although its guidance is primarily directed to Family Stream cases, in certain circumstances it may be applicable in Humanitarian Stream decision making. Examples are where a child has different physical features to other family members; the claimed date of birth seems improbable; or certain background issues raise questions of bona fides. Testing in these cases is performed in the same way as testing in Family Stream cases and is subject to the same guidelines.

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~~33.21~~33.22 However, the Procedures Advice Manual suggests that humanitarian and refugee assessment officers should only offer testing in Humanitarian Stream cases as a last resort. This is due to the cost of testing and the sensitivities involved in the assessment of humanitarian cases. As with Family Stream cases, the applicant bears the cost of testing, except in special cases where testing is conducted at the government's expense.¹⁵

Genetic testing laboratories

~~33.22~~33.23 The Procedures Advice Manual states that DIMIA adopts the benchmark guidelines established in the *Family Law Regulations 1984* (Cth) (*Family Law Regulations*) in relation to the level of accuracy required for genetic parentage testing (see Chapter 31). As a matter of policy, it is recommended that cases be referred to Australian laboratories that have been accredited by the National Association of Testing Authorities, Australia (NATA) for parentage testing.¹⁶

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~~33.23~~33.24 The Procedures Advice Manual specifies circumstances in which it might be appropriate to use different testing laboratories. These include situations where all sample donors are offshore or where clients refuse to use the DIMIA-recommended laboratories. While DIMIA cannot prohibit an applicant from having a test performed at a laboratory of their choice, the Manual states that applicants should be warned that test results, other than from accredited laboratories, may not be accepted as evidence of parentage.¹⁷

Identity fraud

~~33.24~~33.25 The Procedures Advice Manual notes the possibility of 'identity fraud' in relation to sample collection.

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¹⁵ Ibid, para 13.1.1–13.1.2.

¹⁶ Ibid, para 14.1.1.

¹⁷ Ibid, para 15–16.

The recommended laboratories have measures in place to minimise the incidence of identity fraud at the time of sample collection. Even so, there are still avenues for fraud through the presentation at sampling of a birth child instead of a non-birth child, exchange of samples or collusion with doctors. In the case of suspected 'sibling' marriages, it would be a simple matter for an applicant to send a completely unrelated person to donate a sample, thereby achieving the desired result.¹⁸

33.25 **33.26** DIMIA has procedures to address concerns about identity fraud. In relation to offshore sample collection, the Procedures Advice Manual suggests that a migration officer should be present at the time of collection to verify the donor's identity, witness the test and ensure secure dispatch of the sample. In relation to onshore sample collection, the Manual suggests that sample collectors at pathology outlets should check the donor's identity against photographs, driver's licence, passport and so on. For residence cases in Australia, regional offices are advised to send a migration officer to witness the sample taking.¹⁹

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33.26 **33.27** In Australia, witnessing of sample collection is advised only when a migration officer suspects identity fraud is a real risk.²⁰ Otherwise, reliance is placed on the laboratory's own measures to check the identity of persons supplying samples for testing. Outside Australia, policy requires an Australian based officer or expatriate staff member to witness the test and ensure the secure dispatch of the sample.

Issues and problems

33.27 **33.28** A range of concerns may arise from the use of genetic testing to establish familial relationships for the purposes of migration decision making. These include:

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- the lack of express backing for genetic testing in legislation or regulations;
- the absence of a requirement that applicants be given information about the possible consequences of kinship testing or that they be informed about counselling;
- the potential for identity fraud in the collection of samples for testing; and
- the cost of testing for migration applicants.

¹⁸ Ibid, para 17.1.10.

¹⁹ Ibid, para 17.1.10–17.1.12.

²⁰ Ibid, para 17.1.10, 17.1.12.

Lack of legislative backing for testing

~~33.28~~**33.29** At present, there is no backing for genetic kinship testing in migration decision making in either the *Migration Act* or *Migration Regulations* because DNA testing is not a legal requirement for the grant of a visa. The procedures for requesting and administering testing are covered only by departmental guidelines contained in the Procedures Advice Manual. This raises questions about the strength of protections afforded to applicants.

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33.30 As previously mentioned, Family Stream applicants are not compelled to undergo genetic testing. The Inquiry understands that, because the purposes for which genetic testing is used in Family Stream cases are distinct, DIMIA has no immediate intention to legislate for genetic testing in the Family Stream.

Consent, counselling and the provision of information

~~33.29~~**33.31** Chapter 31 discussed the emotional impact that parentage testing may have on children and parents. These effects result from the potential of tests to reveal sensitive information about the composition of a family. For example, kinship testing may reveal the unexpected information that a child is not the biological offspring of his or her 'social' parent.

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~~33.30~~**33.32** While applicants must be made aware that kinship testing is voluntary and not a requirement of a migration application, the Procedures Advice Manual does not require the provision of information about the potential consequences of testing. However, officers are required to advise the applicant of why testing is being offered, the right to refuse testing, the conclusive nature of results, the sampling procedure and its cost.

~~33.31~~**33.33** Additionally, the Procedures Advice Manual does not require applicants to be informed of the availability or desirability of counselling. In Chapter 31, the Inquiry suggests that counselling can be an effective means of ameliorating some of the potentially adverse consequences of parentage testing, especially for children. The same is true of kinship testing.

Integrity of the testing process

33.34 The Procedures Advice Manual requires migration officers to be present when samples are collected offshore. In low risk onshore cases, a migration officer need not be present to check the identity of a donor. This could provide an opportunity for applicants to give false samples.

33.3333.35 As discussed in Chapter 31, NATA accredited laboratories are generally required to comply with the *Family Law Regulations* in the conduct of parentage testing. However, NATA permits accredited laboratories to conduct testing that does not comply with these requirements in certain circumstances.²¹ The *Family Law Regulations* prescribe procedures in relation to the collection, storage and transportation of samples to the laboratory.²²

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33.3433.36 As already noted, the Procedures Advice Manual does not require onshore testing to be undertaken by NATA accredited laboratories, although migration officers should endeavour to ensure testing is carried out at laboratories recommended by DIMIA. The Manual states that laboratories will usually have their own procedures for ensuring the integrity of testing, and these procedures are relied upon as protection against identity fraud. As migration officers do not require applicants to use a particular laboratory to perform the tests, this may allow applicants to have testing carried out at laboratories with less stringent controls.

33.37 With the applicant's permission, DIMIA may request evidence of the identity checking measures undertaken by a laboratory, as well as its testing system. If the applicant refuses permission, or if DIMIA is not satisfied of the integrity of the testing procedure, DIMIA may request the applicant to undergo testing through a DIMIA-approved laboratory, or may decide the case on the existing evidence.

Inquiry's views

33.3533.38 In view of the potential social and psychological consequences of kinship testing, the Inquiry has formed the preliminary view that migration officers should inform applicants about the possible consequences of kinship testing and the desirability of seeking counselling before or after testing. To this end, DIMIA should include guidance on the provision of such information in the Procedures Advice Manual.

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33.3633.39 The Procedures Advice Manual should also be reviewed in relation to the adequacy of procedures to protect against identity fraud. This review should take into account the procedures and protections contained in the *Family Law Regulations*, having regard to the Inquiry's proposals in Chapter 31.

33.3733.40 In order to secure adequate protection of the genetic information of migration applicants, it may also be desirable for aspects of genetic testing procedures in migration decision making to be given more formal status, for example under the *Migration Regulations*. However, the Inquiry has formed no clear view on this issue and invites further comment.

²¹ National Association of Testing Authorities Australia, *Correspondence*, 12 April 2002.

²² *Family Law Regulations 1984* (Cth) Pt IIA, Div 2, 3.

~~Proposal 33-1.~~ **Proposal 33-1.** The Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) should review its policies and procedures on the provision of information to applicants about kinship testing. Relevant officers should be required to advise applicants about the potential implications of kinship testing and the desirability of seeking counselling before or after testing.

~~Proposal 33-2.~~ **Proposal 33-2.** DIMIA should review the adequacy of its policies and procedures for dealing with identity fraud in relation to kinship testing.

~~Question 33-1.~~ **Question 33-1.** Should procedures for conducting genetic kinship testing for the purpose of migration decision making be given more formal status, for example in the *Migration Regulations 1994* (Cth)?

Health testing

~~33.38~~ **33.41** In addition to meeting the specific requirements of different types of migration visa, people who wish to migrate to Australia must also meet a general health requirement. This requirement may result in refusal of applicants who pose a public health risk, such as people who are carrying infectious diseases. Applicants who are likely to need significant access to health care or community services in the future may also be excluded under the health requirement. The standards expressed in the health criteria and migration legislation are established on the advice of the Department of Health and Ageing, as are the routine assessments to be made for all applicants.

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~~33.39~~ **33.42** Because genetic information can reveal important information about an applicant's current or future health, it has the potential to be useful and relevant in making determinations about the health requirement. This raises issues about how that information is collected, used and disclosed.

Current law and practice

~~33.40~~ **33.43** To meet the health requirement to migrate to Australia, an applicant must:

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- be free from tuberculosis; and

- be free from a disease or condition that is, or may result in the applicant being, a threat to public health in Australia or a danger to the Australian community; and
- not have a disease or condition such that he or she would be likely to require health care or community services while in Australia, where the provision of the health care or community services relating to the disease or condition would be likely to:
 - (a) result in a significant cost to the Australian community in the areas of health care or community services; or
 - (b) prejudice the access of an Australian citizen or permanent resident to health care or community services.²³

| ~~33.41~~33.44 Failure to meet these criteria may cause a migration application to be refused, even if the applicant promises not to seek access to services once in Australia.²⁴

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| ~~33.42~~33.45 To determine whether an applicant meets the health requirement, the migration officer dealing with an application must seek the opinion of a Medical Officer of the Commonwealth (MOC).²⁵ There are only a small number of cases in which an MOC forms an opinion that applicant does not meet the health requirement — usually only 1–2% of all cases considered by an MOC. As MOCs often discuss the rejected cases with each other to form a collegiate opinion, applications are generally refused only when the health criteria are clearly not met.

Medical examinations

| ~~33.43~~33.46 Under the *Migration Act*, the Minister may require an applicant to be examined by a qualified person to determine the applicant's health, physical condition or mental condition.²⁶ This involves taking a detailed medical history that covers all previous medical conditions, injuries and any treatments received, and performing a physical examination that encompasses all the major bodily systems, evidence of drug-taking, and the senses. A chest x-ray and blood test is standard for adults and older teenagers.²⁷ MOCs assess the results of such medical

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23 *Migration Regulations 1994* (Cth) Sch 4, ss 4005(1), 4006A(1), 4007(1).

24 *Ibid*, Sch 4, 4005(1), 4006A(1), 4007(1). The Minister may waive the requirements relating to cost and access in some circumstances. These include situations where an applicant's employer undertakes to cover the costs of health care and community services or where the Minister does not consider the costs to be unduly high: *Migration Regulations 1994* (Cth), Sch 4, 4006A(2), 4007(2).

25 *Migration Regulations 1994* (Cth) reg 2.25A.

26 *Migration Act 1958* (Cth) s 60.

27 Department of Immigration and Multicultural and Indigenous Affairs, *Form 26A — Medical Examination for an Australian Visa: For Use in Australia Only* (2002), Commonwealth of Australia, Canberra.

examinations performed by doctors selected at overseas locations, for the purpose of forming an opinion about whether an applicant meets the health requirement.

~~33.44~~33.47 Procedures for performing medical examinations are governed by policies and practices developed by the Department of Health and Ageing in consultation with DIMIA. The *Migration Regulations* do not impose restrictions on the type of tests that may form part of this examination. MOCs may request any test that is relevant to forming an opinion about whether the applicant meets the health requirement criteria, although in practice an invasive or risky procedure would only be requested with circumspection.²⁸

~~33.45~~33.48 In practice, tests beyond the standard set of observations are requested only where a condition is indicated by physical symptoms or a clear family history. For example, an MOC may order tests where an applicant shows both the physical signs of haemophilia and there is a family history of the condition.²⁹

Determining whether the health requirement is met

~~33.46~~33.49 Once an MOC has excluded the risk of tuberculosis and any other public health risk diseases, he or she must calculate how much access to health and community services an applicant may require while in Australia. The purpose of this calculation is to assess whether a 'significant cost' would be incurred, or whether access by Australians to health care or community services would be prejudiced.

33.50 The *Migration Regulations* are silent on how this is to be determined, except that the MOC must estimate the extent of use of costly treatment or resources, whether or not the resources will actually be used. The Inquiry has not been made aware of any official guidelines about how this is to be done, as Notes for the Guidance of Medical Officers for the Commonwealth have yet to be finalised.

33.51 As indicated above, the *Migration Regulations* require that an applicant be free from a disease or condition that would be likely to result in a 'significant cost' to the Australian community in the areas of health or community services. What is a 'significant cost' is not defined, but departmental practice, stemming from Department of Health and Ageing advice, is to make a monetary allowance over and above a multiple of the average cost of health and community services incurred by Australian citizens or permanent residents over their lifetime.³⁰ MOCs, in partnership with the Department of Health and Ageing, calculate the cost of

28 Department of Immigration and Multicultural and Indigenous Affairs, *Telephone Communication*, 26 July 2002.

29 Ibid.

30 Ibid.

health care and community services from Pharmaceutical Benefits Scheme data, hospital costs data, Centrelink benefits data, and other similar sources.

33.52 The *Migration Regulations* also require that an applicant be free from a disease or condition that will prejudice the access of other Australian citizens to services. This might include access to scarce services such as organs for transplantation, some forms of respite and specialised nursing care, or dialysis. The demand for scarce resources is derived from Department of Health and Ageing advice, as well as individual state or territory health authorities.

33.53 The *Migration Regulations* do not specify a temporal dimension to the health requirement. Thus, the Regulations make no distinction between a significant cost that is likely to be incurred in the near future and one that is likely to be incurred in many years time.

Predicting the need for health care and community services

33.54 Genetic information can reveal a variety of things about an individual's health status, which may have a bearing on his or her need for health care and community services. This includes information that demonstrates:

- current conditions (such cystic fibrosis — a congenital genetic disorder);
- conditions that will definitely develop in the future (for example, Huntington's disease);
- the presence of genetic mutations that are predictive of the potential development of conditions in the future (for example, breast cancer); and
- carrier status for a condition that might affect offspring.

33.55 The Inquiry understands that predictive genetic tests are not ordered under current DIMIA policy because they are regarded as incapable of predicting, with sufficient certainty, that an applicant will develop a condition requiring access to health services.³¹ MOCs focus on diagnosing conditions suffered by an applicant at the time of the examination and the likelihood that the condition will require care and treatment later, rather than looking for possible future conditions.³² However, the permissive nature of the *Migration Regulations* would allow such testing if it were considered relevant.

³¹ Ibid.

³² Ibid.

Consent and counselling

33.56 There are no prescribed procedures for dealing with issues of consent or counselling. In relation to consent, applicants are informed that they are not required to undergo tests, but that it is necessary for them to do so if their application is to be processed. In this environment, applicants may feel under some pressure to agree to a requested test and this may have implications for an applicant's 'right not to know' about his or her genetic status.

33.57 In relation to counselling, where potentially distressing results have been returned (whether genetic or otherwise) and are known to MOCs, but possibly not to the applicant, an MOC recommends that the applicant choose a medical practitioner to whom the results can be delivered. This practitioner will then deliver the results and is requested, through the conditions attached to his or her status as a panel doctor, to provide such counselling as would normally be delivered in the course of medical treatment in that country.

Issues and problems

33.58 A number of submissions expressed concern about the possible use of predictive genetic information in migration decision making. The Human Genetics Society of Australasia submitted:

While DNA profiling is legitimate to establish family relationships upon which applications for immigration may be based, it would be as unacceptable for further genetic information to be used to select against individuals on the basis of projected disorders as it would be to use such information against citizens.³³

33.59 The NSW Anti-Discrimination Board stated:

While we have concerns about the extent to which it is necessary to exempt the [*Migration Act*] from the DDA, we recognise that people's health status is a relevant factor in determining applications under the Migration Act, given that consideration needs to be given to the future burden on the Australian health system.

Nonetheless ... the scientific reliability of genetic information in determining the extent to which people are likely to develop health conditions in future, is far from clear. It is certainly conceivable that people's immigration applications may be refused on the basis of their genetic make up, even where the possibility of developing the condition is remote or where their health is unaffected and therefore there is no likelihood that they present a future burden on the health system. ... There is a need to ensure that immigration department decision makers understand the different types and implications of genetic information.³⁴

33 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

34 Anti-Discrimination Board of New South Wales, *Submission G157*, 1 May 2002.

33.60 The Centre for Law and Genetics commented that many of the considerations that apply in relation to discrimination in employment and insurance also apply in the context of migration:

The difficulty is that the focus of attention has been almost exclusively on insurance and employment. There is an awareness of the potential for unfair discrimination amongst the various employment and insurance groups and a number of policy statements have been made to guard against it. There has not been adequate discussion of the potential for discrimination in ... other contexts and there has been no systematic study as to the impact that unfair discrimination could have in these contexts. Yet it is likely that unfair discrimination in these contexts as a result of unfair or improper use of genetic information may have equally as serious an impact as in the contexts of insurance and employment.³⁵

33.61 A particular concern is the potential use of genetic information in predicting late-onset genetic disorders. Consider the example of a young woman who has a genetic mutation that indicates her susceptibility to a late-onset disorder. Although she may not suffer from the disorder at the time of her migration application, there may be a reasonable probability that she will have special need to access health services in the future. In such a case, what effect should the futurity of the health care burden have on her migration application now?

Inquiry's views

33.62 At present, DIMIA does not use genetic testing for the purpose of predicting the future health of migration applicants, in order to assess their compliance with the health requirement in the *Migration Regulations*. Yet, as the cost of testing falls, as the range of available genetic tests expands, and as the predictive power improves, there is clear potential to use genetic testing more widely as a guide to future health.

33.63 An expanded use of genetic testing for migration purposes may, in certain circumstances, be a legitimate use of new genetic technologies. However, such use should also be attended by suitable safeguards. As indicated in this chapter and elsewhere in this Discussion Paper, the use of genetic testing for predictive health purposes raises a number of ethical concerns ranging from the scientific reliability of the testing to the need for patient counselling. The link between a genetic mutation and a specific disorder is often complex, and may involve an assessment of multiple genes, the penetration of those genes, and environmental factors.

33.64 In light of these considerations and of the migration exemption under the DDA, the Inquiry considers that the Department of Health and Ageing, in consultation with DIMIA, should develop policies on the use of predictive genetic testing and information for the purpose of assessing the health requirements under

35 Centre for Law and Genetics, *Submission G048*, 14 January 2002.

migration legislation. While the Inquiry understands that DIMIA does not presently use predictive genetic testing in this fashion, the potential for such use highlights the desirability of articulating appropriate policies.

33.65 In Chapter 3 it was proposed that a Human Genetics Commission of Australia (HGCA) be established to perform a number of functions, including providing expert advice on matters relating to human genetics, upon the request of a responsible minister. The Inquiry considers that departmental policies in relation to predictive genetic testing should be developed in consultation with the HGCA.

~~Proposal 33-3.~~ **Proposal 33-3.** The Department of Health and Ageing, in consultation with DIMIA and with the proposed HGCA, should develop policies on the use of predictive genetic testing and information for the purpose of assessing the health requirements under migration legislation.

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Part J. Law Enforcement and Evidence

34. Forensic Use of Genetic Information

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Introduction

34.1 This chapter examines the current and potential uses of DNA profiling in criminal investigations, and provides an overview of the regulatory framework for the forensic use of genetic information in Australia and overseas jurisdictions.

Use of genetic information

DNA profiling

34.2 Forensic analysis of DNA usually involves comparisons between two bodily samples to determine the likelihood that they came from the same person. About 99.9% of the DNA molecule found within human cells is identical between

any two persons. The remaining 0.1% is specific to the individual.¹ DNA profiles are created from sections of non-coding DNA found within bodily samples such as blood, semen, hair, skin, urine, bone marrow and cells found in saliva, sweat and tears.²

34.3 All Australian forensic laboratories regularly involved in criminal casework use a profiling kit known as Profiler Plus. This kit uses the Polymerase Chain Reaction (PCR) method, involving extraction of the DNA from the sample, amplification, and analysis to create the DNA profile. The profile comprises a set of numbers and an indicator of sex. A typical example of a DNA profile looks like 'XY 10,12 18,19 14,14 15,16 25,28 16,12 11,10 29,30 17,18'. The numbers indicate the number of short tandem repeats (STRs) found at nine sites, or loci, along the DNA molecule. There are two sets of numbers for each loci, one inherited from each parent.³

34.4 As a DNA profile represents only a small number of loci along the DNA molecule, it is possible that two persons who are not identical twins might coincidentally have the same profile. However, the chance of such coincidence will decrease inversely as the number of loci examined increases. Chapter 37 discusses coincidental matching.

34.5 Forensic analysis usually involves analysis of nuclear DNA, which is inherited from both parents in random combinations. Mitochondrial DNA, which is inherited through the maternal line, is less widely used in forensic analysis, partly because it is less discriminating than nuclear DNA.⁴ Mitochondrial DNA may be useful where a sample contains too little nuclear DNA for analysis and typing.

Uses for DNA profiling

34.6 DNA profiling is used as an intelligence tool to identify or eliminate a suspect in a criminal investigation. It may also be used to identify victims of crime or a mass disaster, or to link crimes by comparing profiles created from DNA samples found at different crime scenes.

- 1 With the exception of identical twins. See D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 491–492.
- 2 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.11, quoting the evidence of Linzi Wilson-Wilde.
- 3 J Gans and G Urbas, 'DNA Identification in the Criminal Justice System' (2002) 226 *Australian Institute of Criminology: Trends & Issues* 1, 2. The Inquiry understands that in some circumstances a number may appear in a DNA profile as an 'NR' (ie not recordable), or may be followed by a 'V' (ie variant): CrimTrac, *Consultation*, Canberra, 23 August 2001.
- 4 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.4–2.5.

34.7 If a suspect's DNA matches the DNA found at a crime scene, this match may be used as evidence pointing to the suspect's guilt. However, a DNA match cannot be considered conclusive of guilt for a number of reasons, including the possibility that the match in profiles occurred by coincidence, as a result of error, contamination or tampering,⁵ or the possibility that the suspect's DNA sample was 'planted', or was innocently left at the crime scene before or after the crime was committed.

34.8 DNA profiling also has become a useful tool in exonerating convicted offenders (see Chapter 38). Finally, DNA profiling could potentially be used as a form of unique personal identification — for example, in a DNA identity card.⁶

DNA profiling and conventional fingerprints

34.9 The Inquiry has heard suggestions that DNA profiles are simply a modern form of fingerprint identification. In fact, DNA profiles differ from conventional fingerprints in several respects. First, DNA holds more information than fingerprints; while a DNA profile does not contain predictive health information, it can be used in establishing biological relatedness between known persons.⁷ Second, genetic information is shared with biological relatives. Third, DNA is perceived to be more reliable than fingerprints, for example because it is durable, can be amplified from tiny samples, and may be recovered from almost any cell or tissue.⁸

Development of the Model Bill

34.10 The Standing Committee of Attorneys-General (SCAG) established the Model Criminal Code Officers Committee (MCCOC) in 1990 to advise on the development of model criminal law for adoption on a national basis. MCCOC was requested to formulate a model forensic procedures bill. The first draft of the model bill was circulated for comment in 1994, redrafted in 1995 and 1999, and finalised in 2000.⁹

5 Ibid, para 3.22.

6 Eg, a 'genotype ID card' has been developed by Zhongnan (Central-South) Hospital Gene Diagnostic Center under Wuhan University in China. The card contains a genetic profile representing 18 loci along the DNA molecule: *China's First Genotype ID Card Comes Out in Wuhan*, People's Daily Online, <http://english.peopledaily.com.cn/200206/20/eng20020620_98228.shtml>, 20 June 2002.

7 However, the bodily sample from which the DNA profile is obtained holds predictive health information.

8 See the discussion in Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 9.2.

9 Model Criminal Code Officers Committee, *Final Draft: Model Forensic Procedures Bill and the Proposed National DNA Database* (2000), Standing Committee of Attorneys-General, Canberra; see the discussion in Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.17–2.18.

34.11 The final draft of the Forensic Procedures Model Provisions (Model Bill) provided the power to request or require forensic procedures on suspects, convicted offenders and volunteers; procedures for carrying out forensic procedures, including safeguards for those undergoing forensic procedures; evidentiary rules for evidence improperly obtained from forensic procedures; the establishment of a DNA database system; and a scheme for interstate jurisdiction.¹⁰

Commonwealth legislation

34.12 Part 1D of the *Crimes Act 1914* (Cth) (*Crimes Act*) closely follows the Model Bill provisions. Briefly, Part 1D provides for the conduct of intimate forensic procedures¹¹ and non-intimate forensic procedures¹² on suspects, serious offenders and volunteers; and establishes a DNA database system for storing and matching of DNA profiles.

34.13 The Inquiry understands that MCCOC developed the ‘intimate’ and ‘non-intimate’ distinction in forensic procedures at a time when intimate procedures involved taking blood by syringe or other invasive methods. As technology has developed, many procedures that are characterised as ‘intimate’ have come to involve less invasive methods. For example, a ‘buccal swab’ involves scraping the inside of a person’s cheek with a swab to collect saliva and mouth cells; and taking blood now is generally done by finger prick, rather than syringe. In any case, MCCOC classified buccal swabs as ‘intimate’ procedures on the basis that placing something inside a person’s mouth against his or her consent is an invasive procedure.¹³

Suspects

34.14 A ‘suspect’ is a person whom a constable suspects on reasonable grounds has committed an indictable offence; a person charged with an indictable offence; or a person who has been summonsed to appear before a court in relation to an indictable offence. An indictable offence is a Commonwealth offence punishable by imprisonment for a period exceeding 12 months.¹⁴ According to information

10 For a concise summary of the Model Bill, see Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.20.

11 An ‘intimate forensic procedure’ includes an external examination of, photographing, videotaping etc or taking a sample by specified methods from the genital or anal areas, the buttocks, or female breasts (including transgender persons); taking blood, pubic hair, a dental impression, saliva, or a sample by buccal swab: *Crimes Act 1914* (Cth) s 23WA(1).

12 A ‘non-intimate forensic procedure’ includes an examination of, photographing, videotaping etc or taking a sample by specified methods from a part of the body other than the genital or anal area, buttocks, or breasts, that requires touching the body or removing clothing; taking a hair sample other than pubic hair; taking a sample from a nail, or under a nail; or taking a hand, finger, foot or toe print: *Ibid* s 23WA(1).

13 Model Criminal Code Officers Committee, *Report: Model Forensic Procedures Bill and the Proposed National DNA Database* (1999), Standing Committee of Attorneys-General, Canberra, 11.

14 *Crimes Act 1914* (Cth) ss 4G, 23WA(1).

provided by the Australian Federal Police (AFP), as of June 2002, 14 forensic procedures had been conducted on suspects under Part 1D of the *Crimes Act*. All procedures were conducted by mouth swab; thirteen were conducted with the suspect's consent, and one by court order.

Forensic procedures by consent

34.15 A constable may ask a suspect (other than a child or incapable person)¹⁵ to consent to a forensic procedure if the constable is satisfied on the balance of probabilities that the person is a suspect; there are reasonable grounds to believe that the forensic procedure is likely to produce evidence tending to confirm or disprove that the suspect committed a relevant offence; the request for consent is 'justified in all the circumstances'; and the suspect is not a child or an incapable person.¹⁶

34.16 In determining whether a request is justified in all the circumstances, the constable must balance the public interest in obtaining evidence tending to confirm or disprove that the suspect committed the offence concerned against the public interest in upholding the physical integrity of the suspect. In balancing these interests, the constable must have regard to specified matters.¹⁷

34.17 A suspect (other than a child or incapable person) gives informed consent to a forensic procedure if he or she consents after a constable asks the suspect to consent, and gives the suspect a written statement setting out specified information, informs the suspect about the forensic procedure in accordance with s 23WJ, and gives the suspect a reasonable opportunity to communicate, or attempt to do so, with a legal practitioner of the suspect's choice.¹⁸

Forensic procedures without consent

34.18 If a suspect who is in custody withholds consent, a senior constable may order the carrying out of non-intimate forensic procedure if satisfied on the balance of probabilities that the suspect is in lawful custody; there are reasonable grounds to believe the suspect committed a relevant offence, and that the forensic procedure is likely to produce evidence tending to confirm or disprove that he or she

15 A child or incapable person cannot consent to a forensic procedure: Ibid, s 23WE.

16 Ibid, ss 23WH, 23WI(1).

17 Ibid, ss 23WI(2),(3). These matters include the seriousness of the circumstances surrounding the commission of the offence and the gravity of the offence, and the degree of the suspect's alleged participation.

18 Ibid, s 23WF(2). The matters specified in s 23WJ include the purpose for which the forensic procedure is required; the way it will be carried out; that it may produce evidence against the suspect; and that information obtained from analysis of the forensic material obtained may be placed on the DNA database system and the rules that will apply to its disclosure and use.

committed a relevant offence; and the carrying out of the forensic procedure without consent is 'justified in all the circumstances'.¹⁹

34.19 A magistrate may order the carrying out of a forensic procedure on a suspect who is in or out of police custody, or who is a child or incapable person. The magistrate must consider similar matters as a senior constable before ordering the forensic procedure.²⁰

Serious offenders

34.20 A 'serious offender' is a person under sentence for a Commonwealth offence punishable by a maximum penalty of imprisonment for life or five or more years.²¹ According to information provided by the AFP, as of June 2002, 174 forensic procedures had been carried out on serious offenders with consent, and all were conducted by mouth swab. Court orders were being sought for those persons who withheld consent to the carrying out of a forensic procedure.

Forensic procedures with consent

34.21 A constable may ask a serious offender (other than a child or incapable person) to consent to a forensic procedure if he or she is satisfied on the balance of probabilities that the request for consent is justified in all the circumstances, and in the case of persons not serving a sentence of imprisonment, that the person is an offender.²²

34.22 A serious offender (other than a child or incapable person) gives informed consent to a forensic procedure if he or she consents after a constable asks the offender to consent, informs the offender about the forensic procedure in accordance with s 23XWJ, and gives the offender the opportunity to communicate, or attempt to do so, with a legal practitioner of the offender's choice.²³

Forensic procedure without consent

34.23 If the offender withholds consent, a constable may order the carrying out of a non-intimate forensic procedure if the constable has taken into account whether Part 1D would authorise the forensic procedure to be carried out in the absence of an order; the seriousness of the circumstances surrounding the offence

19 Ibid, ss 23WN, 23WO(1). See ss 23WO(2)–(3) regarding the balancing of interests test to be applied by the senior constable, and the matters to which the senior constable must have regard in applying the test.

20 Ibid, ss 23WS, 23WT.

21 Ibid, s 23WA(1).

22 Ibid, ss 23XWH, 23XWI.

23 Ibid, s 23XWG(1). The matters specified in s 23XWJ include the purpose for which the forensic procedure is required; the way it will be carried out; that it may produce evidence against the suspect; and that information obtained from analysis of forensic material obtained may be placed on the DNA database system, and the rules that will apply to its disclosure and use.

committed by the offender; whether the carrying out of the forensic procedure 'could assist law enforcement' (whether federal or otherwise); and whether the carrying out of the forensic procedure without consent is 'justified in all the circumstances'.²⁴

34.24 A magistrate or judge may order the carrying out of an intimate forensic procedure, or a non-intimate forensic procedure in relation to a child or incapable person, if the magistrate or judge is satisfied that it is justified in all the circumstances. The magistrate or judge must take into account the same matters as a constable when making this determination.²⁵

Volunteers

34.25 A 'volunteer' is a person who volunteers to undergo a forensic procedure, or in the case of a child or incapable person, whose parent or guardian volunteers on his or her behalf.²⁶ According to information provided by the AFP, as of June 2002, no forensic procedures had been conducted under the volunteers provisions of Part 1D of the *Crimes Act*.

Forensic procedures with consent

34.26 A volunteer (or his or her parent or guardian) gives informed consent to a forensic procedure if he or she consents in the presence of an independent person after a constable informs the person of the matters specified in s 23XWJ.²⁷ For example, the constable must advise the person that he or she may consult a legal practitioner before giving consent; that the forensic procedure might produce evidence that might be used in a court of law; and to the extent relevant, that information obtained from the forensic materia may be placed on the DNA database system, and that the person may choose the particular volunteer's index in which the profile should be stored.²⁸

Forensic procedures without consent

34.27 A magistrate may order the carrying out of a forensic procedure on a volunteer who is a child or incapable person if the consent of the parent or guardian cannot reasonably be obtained; the parent or guardian withholds consent and the magistrate is satisfied there are reasonable grounds to believe the child or incapable person is a suspect and the forensic procedure is likely to produce evidence tending to confirm or disprove that he or she committed the offence; or the parent or

24 Ibid, ss 23XWK, 23XWL.

25 Ibid, s 23XWO.

26 Ibid, s 23XWQ(1).

27 Ibid, s 23XWR.

28 Ibid, s 23XWJ.

guardian consented to the carrying out of the forensic procedure, but subsequently has withdrawn consent. In making this decision, the magistrate must take into account matters specified in the legislation.²⁹

Vulnerable persons

34.28 Part 1D provides procedural safeguards for certain categories of vulnerable persons. For example, children and incapable persons cannot consent to a forensic procedure in any context.³⁰ In addition, Aborigines and Torres Strait Islanders are generally entitled to the presence of an 'interview friend' when being asked to consent to a forensic procedure.³¹

Carrying out forensic procedures

34.29 Division 6 of Part 1D regulates the carrying out of forensic procedures on suspects, serious offenders and volunteers.³² The Division specifies who may carry out different forensic procedures, and provides procedural safeguards including the provision of reasonable privacy, videotaping the procedure, the presence of an interview friend for certain vulnerable persons, prohibiting cruel, inhuman and degrading treatment, and providing the subject of the procedure with part of the sample for his or her own analysis.

DNA database system

34.30 Division 8A of Part 1D provides for a DNA database system, with specified indexes in which DNA profiles may be held. This Division contains rules governing index matching, and criminal offences for certain unauthorised activities in relation to forensic material and information held on the DNA database system.

34.31 Division 11 deals with inter-jurisdictional enforcement. The responsible Minister may enter into arrangements with participating jurisdictions for inter-jurisdictional sharing of information held on the database system.³³

34.32 The Commonwealth has established a DNA database that complies with the statutory definition of a DNA database system, known as the National Criminal Investigation DNA Database (NCIDD). An executive agency of the Commonwealth government, known as CrimTrac, operates NCIDD. The AFP has advised the Inquiry that it also operates its own DNA database.

29 Ibid, s 23XWU.

30 Ibid, s 23WE.

31 Ibid, s 23WG(3).

32 Ibid see Div 6, ss 23XWE, 23XWQ(5).

33 See Ibid, s 23YUD.

Other Australian jurisdictions

34.33 The Model Bill has not been uniformly adopted in Australia. The Commonwealth, New South Wales and the Australian Capital Territory closely follow the Model Bill, with variations.³⁴ Tasmania, Victoria and South Australia have followed the Model Bill in some respects, with more variations;³⁵ however Victoria has recently amended its legislation to bring it into closer conformity with the Model Bill provisions.³⁶ Western Australia has recently implemented forensic procedures legislation that in some respects conforms to the Model Bill, but some significant variations remain.³⁷ Finally, Queensland and the Northern Territory have not followed the Model Bill at all.³⁸

Other regulation

34.34 IP 26 discussed the use of Guthrie cards in the context of criminal investigations.³⁹ Chapter 16 of this Paper discusses Australia's various regulatory frameworks for collecting, storing, accessing and destroying Guthrie cards, including access for law enforcement purposes.

Overseas jurisdictions

United States of America

34.35 All 50 states in the United States have implemented legislation to create state criminal DNA databases. Many states provide for collection of DNA samples only from persons convicted of sex offences and violent felonies, but some states include persons convicted of any felony.⁴⁰

34.36 At the federal level, the FBI operates the Combined DNA Index System (CODIS), containing local, state and national tiers of information. CODIS is used to facilitate the exchange of DNA profiles among jurisdictions. CODIS initially had three indexes for convicted offenders, unknown suspects (ie crime scenes), and

34 Ibid, Pt 1D; *Crimes (Forensic Procedures) Act 2000* (NSW); *Crimes (Forensic Procedures) Act 2000* (ACT).

35 *Forensic Procedures Act 2000* (Tas); *Crimes Act 1958* (Vic); *Criminal Law (Forensic Procedures) Act 1998* (SA).

36 See *Crimes (DNA Database) Act 2002* (Vic), which amended the *Crimes Act 1958* (Vic).

37 *Criminal Investigation (Identifying People) Act 2002* (WA).

38 *Police Powers and Responsibilities Act 2000* (Qld); *Police Administration Act 1978* (NT); *Juvenile Justice Act 1983* (NT). See generally, Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.64.

39 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 13.100–13.101.

40 D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London, para 1.73–1.74.

population samples (for statistical purposes only).⁴¹ An unidentified human remains index and relatives of missing persons index subsequently have been added.⁴² In December 2001, CODIS held over 708,000 profiles of convicted offenders, and 29,000 profiles from crime scenes.

England and Wales

34.37 The *Police and Criminal Evidence Act 1984* (UK) (PACE) regulates the taking of bodily samples in England and Wales. Non-intimate samples (mouth swabs and hair) may be taken without consent from any person suspected of being involved in, charged with or about to be reported for, or convicted of a 'recordable offence'. Intimate samples may be taken provided the appropriate consent is given.⁴³

34.38 Initially, police forces focussed on taking samples from suspects for the most serious arrestable offences, such as murder and sexual offences. More recently, this has been extended to include a range of less serious offences.⁴⁴ The Forensic Science Service (FSS) operates the national DNA database, which contains three indexes for suspects, serious offenders and unknown samples (ie crime scenes). In May 2002, the database held about 1.5 million profiles.⁴⁵

34.39 As a result of legislative amendments in 2001, a suspect's sample and profile may be retained even if he or she is acquitted of the crime for which the sample was taken. In addition, persons who volunteer samples for elimination purposes in police 'intelligence screens' may be asked to sign a non-revocable consent form for the permanent retention of their samples and profiles.⁴⁶ As a result, the database is expected to hold 3.5 million profiles within three years.⁴⁷

Canada

34.40 Canada authorises the taking of DNA samples from suspects for certain categories of offence pursuant to court warrants.⁴⁸ A judge may grant a warrant if satisfied of specified matters, and the sample only may be used to investigate the

41 Legislative Council Legislation Committee, *Forensic Procedures and DNA Profiling: The Committee's Investigations in Western Australia, Victoria, South Australia, the United Kingdom, Germany and the United States of America*, Report No 48 (1999), Parliament of Western Australia, Perth, para 6.25–6.27.

42 Office of the Inspector General, *Audit Report: The Combined DNA Index System* (2001), Department of Justice, Washington, 9.

43 'Recordable offences' include the majority of offences investigated by police, including those involving violence or dishonesty and that can lead to a prison sentence: Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, paras 9.9–9.10.

44 Ibid, para 9.16.

45 Ibid, para 9.3.

46 See *Criminal Justice and Police Act 2001* (UK) ss 81, 82. See also Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 9.13–9.14.

47 S Morris, 'Police Allowed to Retain DNA of Ex-Suspects', *The Guardian* (London), 23 March 2002.

48 *Canadian Criminal Code; DNA Identification Act 1998* (Canada).

designated offence for which it was taken. In addition, a judge may order that DNA samples be taken from persons convicted of designated offences, or from persons declared dangerous or who have been convicted of multiple murder or multiple sexual crimes. The judge must consider specified matters before making an order.⁴⁹

34.41 The Royal Canadian Mounted Police operates the national DNA databank. The databank contains a crime scene index and an offenders index.⁵⁰ As at April 2002, the databank held 20,338 profiles in the offenders index, and 4,835 profiles in the crime scenes index.⁵¹

New Zealand

34.42 The *Criminal Investigations (Blood Samples) Act 1991* (NZ) permits the taking of blood samples for DNA profiling from suspects and certain convicted offenders, by consent or court order. A sample may be taken from a person suspected of an indictable offence by informed consent. If consent is withheld, a court may order the taking of a blood sample is satisfied of specified matters, including that a crime scene sample is available for matching and, in all the circumstances, it is reasonable to make the order. In addition, persons convicted of specified offences may be subject to a court order to provide a blood sample for the database.⁵²

34.43 The Institute of Environmental Science and Research (ESR) administers the national DNA databank on behalf of the New Zealand police. The databank contains suspects and offenders profiles, which are matched against a crime sample database.⁵³

Germany

34.44 In Germany, DNA samples may be taken from a suspect where there is a justified suspicion that the person from whom the sample is taken has committed an offence of some gravity. DNA samples may also be taken from persons convicted of 'serious crimes'. A court order is generally required if the DNA

49 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.85–2.88. See also D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London, para 1.58.

50 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.90.

51 Royal Canadian Mounted Police, *National DNA Data Bank: Statistics*, <http://nddb-bndg.org/stats_e.htm>, 9 May 2002.

52 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 2.82–2.84.

53 Institute of Environmental Science and Research, *The DNA Databank*, ESR, <http://www.esr.cri.nz/features/esr_and_dna/databank/index.htm>, 27 July 2002.

sample must be obtained by an invasive procedure, but buccal swabs are not considered invasive.⁵⁴

34.45 Initially, each of the 16 German states operated their own DNA databases. Germany now operates one national database that contains indexes of suspects, convicted offenders and unknown samples (ie crime scenes). Each State provides information directly to the central database.⁵⁵

Approach taken by the Inquiry

34.46 Part 1D of the *Crimes Act* provides that the Attorney-General must cause an independent review of the operation of the Part as soon as possible after June 2002. If the written report identifies inadequacies in respect of the review matters, the Minister must cause a further independent review to be undertaken within two years of the tabling of the first report, to ascertain whether the inadequacies have been effectively dealt with.⁵⁶

34.47 The Inquiry has confined its consideration of the use of genetic information in law enforcement to matters with clear privacy, discrimination or ethical implications. The Inquiry has identified several other concerns and issues with Part 1D of the *Crimes Act*, but considers that these concerns are more appropriate for consideration by the independent review.

34.48 Chapter 35 contains the Inquiry's primary proposal in this area, being the harmonisation of Australian forensic procedures legislation. Each proposal in Chapter 36 should be read in light of this proposal, so that any proposed amendments to Part 1D of the *Crimes Act*, or to forensic procedures legislation generally, would necessitate similar amendment of corresponding State and Territory legislation.

54 Legislative Council Legislation Committee, *Forensic Procedures and DNA Profiling: The Committee's Investigations in Western Australia, Victoria, South Australia, the United Kingdom, Germany and the United States of America*, Report No 48 (1999), Parliament of Western Australia, Perth, para 6.33, 6.35.

55 Ibid, para 7.35.

56 *Crimes Act 1914* (Cth) s 23YV.

35. Harmonisation of Forensic Procedures Legislation

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Introduction

35.1 Chapter 34 examined the current and potential uses of DNA profiling in criminal investigations, and gave an overview of the Australian regulatory framework for the use of genetic information in law enforcement.

35.2 This chapter discusses issues and concerns arising from the lack of harmonisation between the forensic procedures legislation of the Commonwealth and each state and territory jurisdiction. The chapter includes the Inquiry's primary proposal in relation to this area, being the harmonisation of Australian forensic procedures legislation.

Lack of harmonisation

35.3 Each Australian jurisdiction has implemented forensic procedures legislation. As Chapter 34 discussed, some jurisdictions have followed the Model Bill¹ closely, some have followed the Model Bill with significant variations, and others have not followed the Model Bill provisions at all. These jurisdictional variations gain significance in light of the proposed inter-jurisdictional sharing of information.

¹ Model Criminal Code Officers Committee, *Final Draft: Model Forensic Procedures Bill and the Proposed National DNA Database* (2000), Standing Committee of Attorneys-General, Canberra.

35.4 Examples of jurisdictional variations are the differences in the classification of intimate and non-intimate forensic procedures; the definitions of suspects, offenders and volunteers; and the provisions for the carrying out of forensic procedures on child and other suspects and serious offenders.

35.5 As an example, the Model Bill classifies a ‘buccal swab’ as an intimate forensic procedure. The Commonwealth, South Australia and Victoria also classify a buccal swab as intimate, while Tasmania, the Australian Capital Territory, the Northern Territory and Western Australia classify it as a non-intimate forensic procedure. New South Wales defines buccal swabs separately, as neither intimate nor non-intimate forensic procedures; and Queensland does not make a distinction between intimate and non-intimate procedures.²

Sharing of forensic material and information

35.6 Division 11 of Part 1D of the *Crimes Act 1914* (Cth) (*Crimes Act*) provides for the sharing of information held on the DNA database system between participating jurisdictions. Section 23YUD(1) provides that the Minister may enter into arrangements with participating jurisdictions for the sharing of information on the national DNA database system for the purpose of criminal investigations.

35.7 A ‘participating jurisdiction’ is a State or Territory in which there is a corresponding law in force. A ‘corresponding law’ is a law relating to the carrying out of forensic procedures and DNA databases that substantially corresponds to Part 1D or is prescribed by the regulations for the purpose of the definition.³

35.8 Under s 23YP(2)–(3), the Commonwealth may retain or use forensic material or information obtained from another jurisdiction for investigative, evidentiary or statistical purposes provided the material or information was taken in accordance with a state or territory law.

Concerns with sharing of information

35.9 It has been suggested that in the absence of real harmonisation, a jurisdiction that has loose controls and allows the collection of samples in a wider range of circumstances could undermine appropriate restrictions on the use of the DNA database in another jurisdiction. The Model Criminal Code Officers’ Committee (MCCOC) provided the following example in its discussion paper:

² See Centre for Law and Genetics, *Submission G048*, 14 January 2002; see also Model Criminal Code Officers Committee, *Final Draft: Model Forensic Procedures Bill and the Proposed National DNA Database* (2000), Standing Committee of Attorneys-General, Canberra, cl 1(1); and *Criminal Investigation (Identifying People) Act 2002* (WA) s 8(1).

³ *Crimes Act 1914* (Cth), s 23YUA.

For example, State A may only allow taking samples from serious offenders while State B might allow them to be taken from any offender. A law enforcement officer in State A could then check to see if the suspect had committed an offence in State B through a criminal records check. The officer discovers the person committed a traffic offence after which a person had been required to give a sample for DNA analysis. The law enforcement officer then conducts matching on the DNA database against someone who would not be on the database in the same circumstances under local legislation.⁴

35.10 MCCOC considered it undesirable that jurisdictional variations should be able to undermine the legislative requirements of the DNA database:

It is not desirable that variations of the nature described ... should be allowed to undermine the DNA databases legislative requirements. The Committee therefore believes that a consistent approach between jurisdictions is very important in combating this type of problem. Therefore the Committee only favours recommending the first provision [ss 23YP] if there is consistency and does so on the basis that in preparing the model it must assume there will be consistency.⁵

35.11 The Senate Legal and Constitutional Legislation Committee (Senate Committee) expressed a similar concern in the report on the Crimes Amendment (Forensic Procedures) Bill 2000 (Cth) (Forensic Procedures Bill). The Senate Committee commented that the provisions on the sharing of data were the most contentious aspect of the bill, and concluded that uniform adoption of the highest standards in the collection, use and disposal of information was fundamental to the effectiveness of the legislation.⁶

35.12 A number of submissions raised concerns regarding the lack of harmonisation in forensic procedures legislation.⁷ Most of these concerns focussed on the potential undermining of privacy and other legislative safeguards if forensic material or information obtained in one jurisdiction is shared with a jurisdiction that does not have equivalent legislative safeguards. While Part 1D of the *Crimes Act* affords certain safeguards against disclosure or misuse of forensic material and information obtained from it, if these safeguards do not exist in the jurisdiction with which this information is shared, this could significantly undermine the value of the safeguards, as well as public confidence in the national DNA database system.

4 Model Criminal Code Officers Committee, *Report: Model Forensic Procedures Bill and the Proposed National DNA Database* (1999), Standing Committee of Attorneys-General, Canberra, 87.

5 Ibid, 87, 89.

6 Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, para 3.63.

7 For example, Centre for Law and Genetics, *Submission G048*, 14 January 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

35.13 The Office of the Federal Privacy Commissioner (OFPC) commented that the relative vagueness or inconsistency in legislative obligations across jurisdictions regarding retention and destruction of data leaves much room for inconsistency in data handling, and significant potential for undermining privacy. The OFPC commented that in the absence of harmonisation, ‘different jurisdictions have developed, for instance, differing numbers and categories of indexes for forensic samples matching’. The submission stated:

Consistent enactment of the Model Bill’s provisions across all participating jurisdictions would resolve matters of legislative inconsistency and vagueness, thereby lending assurance to the community that forensic DNA testing occurs with adequate reference to individuals’ privacy and other private interests.⁸

35.14 Privacy NSW also expressed concerns resulting from the lack of uniformity:

A uniform national legislative approach is very important as a means of holding the line against ad hoc and incremental arrangements which would undermine the protective provisions of forensic legislation. I am concerned that Police Services have been exploiting the political appeal of crime control to play off the different jurisdictions so as to weaken the safeguards provided in the *Model Forensic Procedures Bill*. Ministerial agreements would simply promote this process.⁹

35.15 The Legal Aid Commission of NSW (LACNSW) emphasised the need for national standards for the collection of DNA samples. The LACNSW outlined variations in provisions for the collection of forensic material from suspects in New South Wales and South Australia as an indication of the lack of consistency between jurisdictions. The submission noted that both of these jurisdictions have based their forensic procedures legislation on the Model Bill, and commented that the difference is even more pronounced in other jurisdictions.¹⁰

35.16 The LACNSW submitted that uniform legislation should be introduced in all jurisdictions covering the circumstances in which a DNA sample may be taken, and procedures for taking the sample.¹¹

35.17 Adam Johnston suggested a new approach to the inter-jurisdictional sharing of information, by making sharing of data conditional on a court order:

⁸ Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

⁹ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

¹⁰ Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

¹¹ Ibid. Adam Johnston submitted that ‘liberty’ could be better protected by ensuring that information is not easily transferred from the state and territory databases to the Commonwealth DNA database, or vice versa. He suggested that any transfers of information should occur only upon a court order, and that further tests should be applied before the information would be admissible in proceedings: A Johnston, *Submission G042*, 13 January 2002.

To obtain such an order, authorities should have to show that they were unsuccessful in genuine attempts to obtain a sample from a suspect. As well, they should have to satisfy a judge that on the basis of other evidence collected there is probable cause to believe that a suspect has a case to answer and, that obtaining DNA evidence from another jurisdiction's database is necessary to assist the case. Presuming the court agreed, this would not necessarily make the DNA evidence admissible at trial.¹²

35.18 The Commonwealth Attorney-General's Department submission recognised the need for greater harmonisation of forensic procedures legislation. The Department submitted that although complete consistency between the jurisdictions has not yet been achieved, Australia's federal structure permits the existence of legislation containing variations on the same subject matter. The Department also submitted that s 23YP is consistent with the approach taken in the *Evidence Act 1995* (Cth). In relation to ministerial arrangements, the Department submitted:

While important matters should be spelt out in the legislation, there is a degree of interstate enforcement that is appropriate to be the subject matter of arrangements. Clearly, there is scope for arrangements concerning the reciprocal registration of forensic procedure orders and the transmission of information that may be relevant to the investigation of an offence in another jurisdiction. Consistent legislation between jurisdictions based on the Model Bill is the key to ensuring that information transmitted to another jurisdiction is protected by the same safeguards as those in the originating jurisdiction.¹³

35.19 The Institute of Actuaries of Australia expressed the view that while uniformity in forensic procedures legislation is preferable, state boundaries should not impose excessive restrictions on law-abiding citizens or on corporations:

It is our view that those who act outside the law should not be able to escape detection by hiding across State boundaries. A uniform, national approach to regulation is preferable. Uniformity or greater harmonisation of Federal, State and Territory laws concerning forensic material, DNA profiles or other uses of human genetic information in law enforcement is most desirable.¹⁴

Harmonisation of legislation

35.20 The Inquiry considers that harmonisation of forensic procedures legislation is a necessary precondition for the effective operation of a national DNA database system, or of any inter-jurisdictional information sharing.

35.21 First, greater harmonisation would avoid complexity in the operation of the National Criminal Investigation DNA Database (NCIDD). Once CrimTrac commences inter-jurisdictional index matching on NCIDD, it will need to comply

12 A Johnston, *Submission G042*, 13 January 2002.

13 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

14 Institute of Actuaries of Australia, *Submission G105*, 7 March 2002.

simultaneously with the forensic procedures legislation of each participating jurisdiction. The greater number of variations in the rules, the greater complexity and difficulty there will be in administering the matching regime, which may create operational problems for police as well as making it more difficult to ensure compliance with all of the legislative safeguards.¹⁵

35.22 Second, variations in forensic procedures legislation may tend to result in a lowest-common-denominator approach. Where a sample or profile is transferred from a jurisdiction with strong privacy and civil liberties protections to a jurisdiction with lesser protections, the safeguards applying in the first jurisdiction could be undermined. For example, where a person in the first jurisdiction volunteers for a forensic procedure for 'limited purposes', that persons' sample or profile should not be subjected to use for other purposes in any jurisdiction to which it is legitimately transferred. This would always raise the prospect that police investigators could rely on sampling and matching performed in jurisdictions that have lesser protections.¹⁶

Harmonisation in practice

35.23 As noted above, a 'participating jurisdiction' must have forensic procedures legislation that either substantially corresponds to Part 1D, or that is prescribed in regulations under the *Crimes Act*. The responsible Commonwealth Minister may enter into arrangements with each participating jurisdiction for sharing information held on the national DNA database system.¹⁷ In addition, each participating jurisdiction would need to enter into arrangements with each other jurisdiction for the sharing of information.

35.24 The Commonwealth Attorney-General's Department noted in its submission that although harmonisation has not yet been achieved, the Commonwealth government has been working closely with the States and Territories to achieve consistent procedures based on the Model Bill.¹⁸

35.25 The Commonwealth has recognised several state and territory jurisdictions as participating jurisdictions by prescribing this in the regulations. By July 2002, the Commonwealth had prescribed the forensic procedures legislation of New South Wales, the Australian Capital Territory and Tasmania.¹⁹ Each of these

15 J Gans, *Correspondence*, 24 July 2002.

16 Ibid.

17 The form or content of these arrangements is not detailed in the legislation but the Explanatory Memorandum refers to ministerial 'agreements': Revised Explanatory Memorandum to the Crimes Amendment (Forensic Procedures) Bill 2001 (Parliament of Australia), para 224.

18 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

19 *Crimes Regulations 1990* (Cth) reg 6E.

jurisdictions has substantially followed the Model Bill, however some significant variations remain.²⁰

35.26 In May 2002, Victoria passed legislation amending its forensic procedures legislation to bring it into closer conformity with the Model Bill.²¹ In June 2002, Western Australia passed the *Criminal Investigation (Identifying People) Act 2002* (WA), which varies significantly from the Model Bill in some respects but is considered by Western Australia to be sufficiently similar for participation in NCIDD.²²

35.27 Also, in April 2002, the Commonwealth entered into an agreement with State and Territory leaders providing for modernisation of the criminal law by legislating in the area of model forensic procedures during 2002; and the enhancement of capacity in each jurisdiction for the collection and processing of samples to create DNA profiles, and the uploading of profiles onto the national DNA database.²³ It is not yet known what amendments will result from this agreement.

35.28 The Inquiry understands that the Commonwealth is currently negotiating ministerial agreements with each State and Territory, and the intention is for ministerial agreements to contain tables outlining the index matching permitted between each participating jurisdiction. The more variations between the provisions of each jurisdiction's forensic procedures legislation, the more complexity the index matching tables or protocols will contain, and the greater the difficulties of operation in practice.

35.29 Already, New South Wales and Western Australia have prescribed the forensic procedures legislation of all other Australian jurisdictions in regulations, despite significant variations between the jurisdictions.²⁴ New South Wales also has entered into a ministerial agreement for the sharing of information with the Northern Territory despite significant variations between the jurisdictions,

20 For example, Tasmania defines a 'buccal swab' as a non-intimate procedure; makes no provision for an 'interview friend' and/or legal representative to be present when a forensic procedure is carried out on a child; permits children aged 15 years and over to consent to a forensic procedure, and children aged 10–14 years to consent with their parent; and permits the carrying out of a forensic procedure on a child without a magistrate's order. See R Johnson, 'Two Steps Forward, One Big Step Back' (2001) 26(5) *Alternative Law Journal* 236, 238, 240.

21 *Crimes (DNA Database) Act 2002* (Vic), which amended *Crimes Act 1958* (Vic).

22 Parliament of Western Australia, *Parliamentary Debates*, Legislative Council, 6434 (Honourable ND Griffiths).

23 Council of Australian Governments, *Commonwealth and States and Territories Agreement on Terrorism and Multi-Jurisdictional Crime* (2002), Commonwealth of Australia.

24 See *Crimes (Forensic Procedures) Regulation 2001* (NSW) reg 12; *Criminal Investigation (Identifying People) Regulation 2002* (WA) reg 6. However, as at 29 June 2002, certain parts of the *Criminal Investigation (Identifying People) Act 2002* (WA) had not yet commenced operation.

including in relation to the use, storage and destruction of forensic material and information.²⁵

Inquiry's views

35.30 The need for harmonisation in this area has been well recognised, and a number of States and Territories have amended, or are moving to amend, their forensic procedures legislation to effect greater conformity with the Model Bill.

35.31 However, the Inquiry would be concerned if these efforts at harmonisation take a 'lowest common denominator' approach. This could occur at two levels. First, several jurisdictions have amended their laws to effect greater conformity with the Model Bill in such a way as to be recognised as a 'corresponding law' by other Model Bill jurisdictions.²⁶ However, these amendments have not gone so far as to mirror fully the Model Bill provisions (or Part 1D of the *Crimes Act*), so that some significant variations remain.

35.32 Second, several jurisdictions formally have prescribed the forensic procedures laws of other jurisdictions as constituting 'corresponding laws', despite some significant variations. For example, as noted above, both New South Wales and Western Australia have prescribed the forensic procedures legislation of every jurisdiction — including the Northern Territory and Queensland — even though the laws in these jurisdictions were developed independently of the Model Bill.²⁷

35.33 The Inquiry has concerns whether full uniformity in forensic procedures legislation is now attainable, given the piecemeal nature of the development to date. If it is not possible, or realistic, to achieve fully harmonised forensic procedures legislation, the Inquiry considers that the Commonwealth should specify the important features of the legislation upon which it would be reasonable for the public to expect commonality. Only those jurisdictions that achieve commonality on those points should be permitted to engage in inter-jurisdictional sharing of forensic material and information obtained from it. The Inquiry considers that, at a minimum, it would be necessary to achieve commonality in relation to the collection, use, storage, destruction and index matching of forensic material and information obtained from it.

25 It is understood the New South Wales took these action in the context of a criminal investigation into the presumed murder of British backpacker, Peter Falconio. The ministerial agreement was finalised so that forensic material taken from a New South Wales prisoner, who was identified as one of a number of 'persons of interest' in the investigation, could be forwarded to the Northern Territory investigators: R Rose, 'DNA Law Reform to Ease Falconio Inquiry', *The West Australian* (Perth), 13 June 2002, 5; see also 'Prisoner Investigated over Falconio Murder', *The Canberra Times*, 12 June 2002.

26 For example, see *Crimes (DNA Database) Act 2002* (Vic); *Criminal Investigation (Identifying People) Act 2002* (WA). The Criminal Investigation (Identify People) Bill 2002 (WA) was amended to bring it into closer conformity with the Model Bill prior to being passed by the Western Australian Parliament.

27 See *Crimes (Forensic Procedures) Regulation 2001* (NSW); *Criminal Investigation (Identifying People) Regulations 2002* (WA).

35.34 Further, while ministerial agreements for the sharing of information are expected to make some provision for privacy and other protections, these agreements do not have the same status as legislation or regulations, and sometimes there even can be problems with gaining public access to them. The Inquiry considers that in order to afford greater transparency, ministerial agreements for the sharing of information and inter-jurisdictional matching protocols should be prescribed in regulations.

Proposal 35–1. The Commonwealth, States and Territories should work together to achieve harmonisation in Australian forensic procedures legislation, in particular in relation to the collection, use, storage, destruction and index matching of forensic material and the DNA profiles created from such material. Inter-jurisdictional sharing of forensic material and DNA profiles, whether on a bilateral basis or via the national DNA database system, should be permitted only after such harmonisation has been achieved.

Proposal 35–2. In order to achieve greater transparency, ministerial agreements for the sharing of information and inter-jurisdictional matching protocols should be prescribed in regulations.

36. Criminal Investigations

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Introduction

36.1 Chapter 35 contained the Inquiry's primary proposal in this area, being the harmonisation of Australian forensic procedures legislation. This chapter discusses specific issues arising from the regulatory framework, in particular in relation to the operation of a national DNA database system for the storage and matching of DNA profiles, and the inter-jurisdictional sharing of information for criminal investigations.

36.2 Each proposal discussed below should be read in light of this primary proposal, so that any proposed amendments to Part 1D of the *Crimes Act 1914* (Cth) (*Crimes Act*), or to forensic procedures legislation generally, would necessitate similar amendment of corresponding state and territory legislation.

Approach taken by the Inquiry

36.3 Part 1D of the *Crimes Act* provides that the Attorney-General must cause an independent review of the operation of the Part as soon as possible after June 2002.¹ The Inquiry has confined its consideration of the use of genetic information in law enforcement to matters with clear privacy, discrimination or ethical implications. While the Inquiry has identified other issues and concerns in relation to the provisions of Part 1D, it considers these would be more appropriately addressed by the independent review.

Informed consent to a forensic procedure

Informed consent provisions

36.4 Part 1D of the *Crimes Act* authorises the carrying out of a forensic procedure on a suspect, serious offender or volunteer with the 'informed consent' of that person.²

36.5 The informed consent provisions regarding suspects and serious offenders are similar in nature. A constable must ask a suspect or a serious offender to consent to a forensic procedure before making an order, or applying to a magistrate for an order for a compulsory forensic procedure. The constable must give the suspect or serious offender information specified in the legislation, and give the person a reasonable opportunity to communicate, or attempt to do so, with a legal practitioner before consent may be given. A volunteer (or his or her parent or guardian) gives informed consent if he or she consents in the presence of an independent person after a constable informs the volunteer, or parent or guardian of specified matters. See Chapter 34 for more detail.

¹ *Crimes Act 1914* (Cth) s 23YV.

² Except in relation to children and incapable persons.

36.6 Where a suspect or serious offender withholds consent to the carrying out of a forensic procedure, a specified decision maker may order the carrying out of the procedure without consent provided he or she is satisfied as to the balancing of interests specified in the legislation.³ Consistent with other areas of operational policing, these tests give the decision maker a broad discretion in deciding whether or not to order a compulsory forensic procedure.

The principle of informed consent

36.7 Concerns have been raised about the appropriateness of the term informed consent in the context of criminal investigations.⁴ The Inquiry understands the consent provisions in forensic procedures legislation were borrowed from the medico-legal area with the intention of providing a procedural safeguard to protect personal autonomy. That is, if a person does not wish to consent to a forensic procedure, he or she should not have to do so unless ordered by a constable or magistrate.⁵

36.8 If a suspect or serious offender is asked to consent to a forensic procedure, and perceives — correctly or otherwise — that if he or she withholds consent a compulsory procedure will be ordered anyway, this may undermine the free nature of the ‘consent’ given, and the purpose of this safeguard. In such circumstances, this is not a valid ‘informed consent’ as the term has come to be known and used.⁶

Submissions and consultations

36.9 Several submissions commented on the appropriateness of the term ‘informed consent’ in the law enforcement context. The Human Genetic Society of Australasia (HGSA) commented:

The use of genetic technologies by the State for broad-scale, population-based applications outside of a clinical context should be evaluated very carefully and critically. Within the clinical context, respect for the autonomous choice of a fully informed adult seeking genetically-based services is based on firm bioethical principles; the presence of coercion in an individual’s decision to undertake any form of genetic testing is strongly counter-indicated within the clinical context.⁷

3 See Ch 34 for more detail.

4 See, for example, J Gans, ‘Something to Hide: DNA, Surveillance and Self-incrimination’ (2001) 13(2) *Current Issues in Criminal Justice* 168.

5 Evidence and Law Enforcement Working Group, *Meeting*, 5 March 2002.

6 See Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 5.115, citing Dr Jeremy Gans.

7 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

36.10 The Androgen Insensitivity Syndrome (AIS) Support Group Australia questioned the ethics of asking a person for informed consent to the use of their genetic information, about which they have limited understanding.

In short, asking a lay person to consent to the use of information about which they have limited understanding is ethically questionable, especially where application for collection of samples may be heard ex-parte. Given that there is an alternate process in place, that of going before a member of the judiciary to make application to obtain samples, it is not unreasonable given the type of information concerned to have all requests for samples dealt with in this manner.⁸

36.11 The Centre for Law and Genetics commented that while there must be provision in forensic procedures legislation for obtaining samples without consent, adequate safeguards must be in place to ensure that the requirements for first attempting to obtain consent are not rendered illusory. The Centre submitted that the procedures contained in Part 1D of the *Crimes Act* ‘appear to adequately balance the public interest in law enforcement with the protection of privacy rights’, but noted deficiencies in other jurisdictions’ provisions.⁹

Inquiry’s views

36.12 The Inquiry understands that the informed consent provisions contained in the Model Bill are based on traditional notions of ‘policing by consent’ as well as a concern to protect an individual’s personal autonomy by allowing him or her to give or withhold consent to a procedure involving some invasion of bodily and information privacy.

36.13 However, the inherently coercive nature of criminal investigations suggests that any consent given by a suspect or serious offender, or in some circumstances even a volunteer (for example, where the volunteer is a potential suspect) may not be an informed consent in the sense in which the term is usually understood. In addition, in light of the decision maker’s broad discretion to order a compulsory forensic procedure on a suspect or serious offender where consent has been withheld, it is arguable that a request for consent from persons within these categories is in practice unnecessary.

36.14 In relation to suspects and serious offenders, the Inquiry proposes that the consent provisions be removed from Part 1D of the *Crimes Act*, rendering compulsory procedures the only means by which a forensic procedure may be carried out on a suspect or serious offender. The Inquiry considers this proposal better reflects the coercive nature of the procedures in these circumstances, and would remove potential arguments that consent given by a suspect or serious offender was not a valid informed consent. However, where appropriate, persons

⁸ Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

⁹ Centre for Law and Genetics, *Submission G048*, 14 January 2002.

subjected to compulsory orders should be given the option to self-administer the forensic procedure, under strict supervision.

36.15 Finally, implementation of this proposal would necessitate a further amendment to Part 1D of the *Crimes Act*. Presently, the prescribed information in relation to the purpose and nature of the forensic procedure must be given to a suspect or serious offender before he or she is asked to consent to the procedure. If the consent provisions are removed, Part 1D should be amended to instead provide that such information should be given to a suspect or serious offender prior to the carrying out of the forensic procedure.

Proposal 36–1. Except in relation to volunteers, the consent provisions should be removed from forensic procedures legislation so that an order by the appropriate Australian Federal Police officer or judicial officer is required before a forensic procedure can be carried out on a suspect or serious offender.

Proposal 36–2. Notwithstanding Proposal 36–1, forensic procedures legislation should continue to provide that suspects and serious offenders must be given prescribed information about the nature and consequences of the forensic procedure prior to it being carried out.

Procedural safeguards for vulnerable persons

36.16 IP 26 raised a number of concerns in relation to the procedural safeguards provided in Part 1D for vulnerable persons, including children, incapable persons and Aboriginal and Torres Strait Islanders. The Inquiry considers that many of these concerns could be addressed by the independent statutory review.

Information for children and incapable persons

36.17 Chapter 34 outlines the volunteer provisions of Part 1D. A child or incapable person is a volunteer if his or her parent or guardian volunteers on his or her behalf to the conduct of a forensic procedure. The parent or guardian must be given specified information before giving consent to the carrying out of a forensic procedure.¹⁰

36.18 There is no provision, however, for informing the child or incapable person about the nature, purpose or implications of carrying out the forensic procedure, even though the child or incapable person is the subject of the proposed

¹⁰ *Crimes Act 1914* (Cth) ss 23XWQ, 23XWR.

procedure. The Inquiry understands this has resulted from an oversight by MCCOC in drafting the Model Bill, rather than a policy decision to exclude these persons from the information-giving process.¹¹

36.19 In addition, there appears to be no legislative requirement for informing a child or an incapable person who is a suspect or serious offender, and who is subject to a compulsory order for the carrying out of a forensic procedure, about the nature, purpose or implications of that procedure.¹² Proposal 36–2 addresses this concern.

36.20 The Inquiry recognises that some children may not fully comprehend the prescribed information due to their youth or immaturity; and some incapable persons may not fully comprehend this information due to their particular disabilities. However, exclusion from the information-giving process could cause confusion or distress to a child of any age, or to some incapable persons. As a result, the Inquiry considers these persons should be entitled to receive the prescribed information at the same time as the parent or guardian.

Consent by mature child volunteers

36.21 An additional question is whether children and incapable persons should have some capacity to consent as volunteers to the carrying out of a forensic procedure.¹³

36.22 IP 26 noted that a parent or guardian might not always act in a child's best interests when giving informed consent to a forensic procedure.¹⁴ For example, where a child is a potential suspect in a criminal investigation, the parent or guardian might consent to the carrying out of a forensic procedure on the child as a volunteer in the mistaken belief that this will exclude the child from suspicion. If the forensic procedure incriminates the child in the offence, this will not have been in the child's best interests.¹⁵

11 Evidence and Law Enforcement Working Group, *Meeting*, 5 March 2002.

12 Part 1D specifies certain information that must be given to a suspect or serious offender before he or she gives or withholds consent to the forensic procedure. However, as children and incapable persons cannot give consent to a forensic procedure, they are not privy to the information-giving process.

13 This discussion is limited to child volunteers. Part 1D currently provides that a child suspect or serious offender cannot consent to a forensic procedure and the Inquiry sees no policy reason to alter this procedural safeguard.

14 Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, para 13.43.

15 While s 23XWQ(4) provides that a child volunteer has an ultimate right to object to the conduct of a forensic procedure, in practice a child whose parent or guardian has given consent to the procedure may feel obliged to comply with the procedure.

36.23 In addition, conflicts of interest might arise for parents or guardians where the child is accused of assault in relation to another family member, of theft or destruction of family property, or simply where there is a history of antagonistic relations.

36.24 The Commonwealth Attorney-General's Department submitted:

While it may be the case that a parent or guardian may not act in the best interests of the child, it is anticipated that this will be in the vast minority of cases in view of the strict informed consent provisions which must be complied with.¹⁶

36.25 The Victoria Police submission commented that the alternative to parental decision-making is state control:

As a fundamental rule, the Australian community accepts the right of the parent to make decisions on behalf [of] a child. While it is true that they may not always act in the best interest of the child, the alternative (state control) is only acceptable when it can be demonstrated that the parent does not act in the best interest of the child and that the actions will do harm to the child.¹⁷

36.26 Privacy NSW submitted that:

The legal climate in relation to children's rights generally is still in a process of evolution from the traditional view which treated children as the property of their parents to the assumption that parental rights are held in trust to be exercised in the best interests of the child, having regard to his or her growing capacity for personal autonomy. The safeguards for children when DNA is collected should be flexible enough to reflect this evolving approach.¹⁸

36.27 The Inquiry recognises that circumstances of conflict of interest will be rare, and that the requirement of parental consent is normally an important safeguard of children's rights. However, the current provisions may be out of step with other areas of law that increasingly recognise a child's right to participate in decisions that impact on their lives. For example, the Australian common law provides that once a child achieves a sufficient understanding and intelligence to enable full comprehension of a proposed medical treatment and the consequences and risks entailed, the child may give valid consent to that medical treatment.¹⁹

36.28 The NSW Legislative Council Standing Committee on Law and Justice (NSW Standing Committee) considered a child's capacity to give valid informed consent to the carrying out of a forensic procedure under that jurisdiction's forensic

16 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

17 Victoria Police, *Submission G086*, 21 January 2002.

18 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

19 See *Secretary, Department of Health & Community Services v JWB (Marion's Case)* (1992) 175 CLR 218. This reflects Art 12(1) of the *Convention on the Rights of the Child*, opened for signature 20 November 1989, UNTS 1588, (entered into force on 16 January 1991).

procedures legislation. The Committee recommended that the New South Wales Attorney-General consider amending the child volunteer provisions for children aged between 10 and 14 years to require the consent of both the child and the parent; and for children between 15 and 17 years to allow them to consent on their own behalf.²⁰

36.29 This Inquiry does not propose to adopt that approach. While children who have sufficient intellectual capacity and emotional maturity to understand the proposed procedure and its implications should have a role in the decision making process, society has an overriding responsibility to protect children from the consequences of their own misjudgment.²¹ The potentially serious implications of a child's decision to give or withhold consent to a forensic procedure, as part of a criminal investigation, requires greater procedural safeguards.

36.30 The Inquiry instead agrees with the approach suggested by the Youth Justice Coalition in the context of the New South Wales forensic procedures legislation. The Coalition recommended that forensic procedures should be conducted by consent on child volunteers only with the informed consent of the parent or guardian *and* the child.²²

36.31 This approach is consistent with the position in relation to child consent to participation in research. The NHMRC's National Statement on Ethical Conduct in Research Involving Humans (National Statement) provides that consent to a child or young person's participation in research must be obtained from the child or young person when he or she has sufficient competence to make this decision; *and* either the parents/guardian in all but exceptional circumstances, or any organisation or person required by law. Unlike the common law position, where a child has such capacity, the consent of both parents remains necessary (except in exceptional circumstances).²³

36.32 This approach would not be appropriate for children of insufficient capacity to form their own opinions in relation to a proposed procedure. Rather than leave the determination of capacity to a case-by-case basis, the Inquiry proposes that children of 12 years or above should be presumed to have such capacity.

20 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, rec 39.

21 See the discussion in relation to child consent to medical testing in NSW Commission for Children & Young People, *Consent by Minors to Medical Treatment* (2001) unpublished, para 15.01.

22 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 5.217. The Coalition also suggested that the child should be required to have independent advice (preferably legal advice) before giving consent as a volunteer.

23 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 4.2.

Proposal 36–3. Forensic procedures legislation should provide that children and incapable persons who are volunteers should be given the prescribed information about the nature, purpose and consequences of a forensic procedure prior to it being carried out. (See also Proposal 36–2).

Proposal 36–4. Forensic procedures legislation should provide that a forensic procedure may be carried out on a child volunteer of 12 years or above only with the consent of a parent or guardian and the child.

Volunteers

Definition of volunteer

36.33 Part 1D of the *Crimes Act* does not specify each of the contexts in which a person might be asked to consent to a forensic procedure as a volunteer. The Model Bill also does not contain a comprehensive definition of volunteers.

36.34 MCCOC’s discussion paper noted that volunteers would include potential suspects (for example, where suspicion is based on a ‘hunch’ rather than on reasonable grounds); persons in a large pool for comparison purposes (for example, persons involved in mass screening programs); and victims of crime.²⁴ Volunteers might also include people whose DNA profiles were left at the crime scene innocently — for example the victim’s flatmates in relation to a burglary, or the victim’s sexual partner in relation to a sexual assault conducted by an unknown person; police officers asked to provide an elimination sample to avoid contamination with a crime scene sample; or relatives of missing persons or mass disaster victims.

36.35 The Inquiry considers the volunteers provisions of Part 1D require clarification. Part 1D should be exhaustive of all circumstances in which a person might be requested, or compelled, to provide a genetic sample in the context of a criminal investigation, and in particular where the resulting profile might be stored on a DNA database system.

Victims of crime

36.36 Police investigators might need to conduct a forensic procedure on a victim of crime where, for example, the offender has left a bodily sample on or in the victim’s body during an assault, or the victim’s DNA has become mixed with

²⁴ Model Criminal Code Officers Committee, *Report: Model Forensic Procedures Bill and the Proposed National DNA Database* (1999), Standing Committee of Attorneys-General, Canberra, 61.

the offender's sample. Alternatively, a DNA sample found at a crime scene might include the DNA of the victim only, or a mixture of samples from the offender and victim.

36.37 The Inquiry understands that where a DNA sample contains a mixture of the victim and offender's DNA, the forensic laboratory usually will attempt to separate the victim's profile from that of the offender. Where this is not possible, the resulting DNA profile will to some extent include the victim's genetic information, making it more difficult to match against suspects.

36.38 The AFP has advised the Inquiry that victims of crime are 'volunteers' for the purposes of Part 1D of the *Crimes Act*. This interpretation is consistent with the guidance provided in MCCOC's discussion paper, noted above.²⁵

36.39 Where the offender's sample is obtained from the victim's body by a forensic procedure — and the victim's DNA cannot be separated from that of the offender — Part 1D provides that the victim, as a volunteer, should have a choice whether the resulting DNA profile will be stored in the volunteers (limited purposes) index or the volunteers (unlimited purposes) index of the DNA database system. If stored in the former index, strict index matching rules apply; if stored in the latter index, more general index matching is permitted.²⁶ As a volunteer, the victim also should have the power to withdraw consent to retention of the forensic material or the DNA profile, subject to a magistrate's order that it be retained.²⁷

36.40 However, the Inquiry understands that, in practice, victims are not always dealt with as volunteers under Part 1D — because of a lack of clarity in the provisions, victims sometimes could be treated as volunteers; sometimes they could be treated as falling outside the provisions of Part 1D; and sometimes their profiles could be stored in the crime scene index (where the victim and offender's profiles cannot be separated).

36.41 In addition, the Inquiry understands that Part 1D would not apply where a victim's sample is found at a crime scene, or is obtained by a procedure that falls outside the definition of a 'forensic procedure'. In these circumstances, if it is not possible to remove the victim's DNA from the offender's sample, or the victim is unknown, the resulting DNA profile could be stored on the crime scene index of the DNA database system.²⁸

25 In addition, s 23XWU(1) appears to deal with children and incapable persons who are victims of sexual or other assaults.

26 See *Crimes Act 1914* (Cth) ss 23XWR(2), s 23YDAF(1).

27 Ibid, ss 23XWU(2), 23XWV.

28 The crime scene index includes DNA profiles derived from forensic material found on or within the body of a victim, or a person reasonably suspected of being a victim, of a prescribed offence: Ibid, s 23YDAC.

36.42 The crime scene index may be matched against any other index in the database, including other crime scenes. As a result, the victim could be implicated in outstanding offences if there is a 'cold hit' with a profile stored in the crime scene index. In addition, there is no legislative provision for destruction of crime scene samples or profiles.

36.43 The Inquiry considers that the regulatory framework for dealing with DNA samples and profiles containing a victim's DNA is unclear. To the extent that a victim's DNA cannot be removed from the offender's sample, the victim's profile could be stored in a volunteers index, or the crime scene index of the DNA database system, depending on the circumstances in which it was found or collected. In light of the varying index matching rules, there are potentially significant privacy implications for the victim, depending on the respective index in which his or her profile is stored.

36.44 There is a public interest in protecting the privacy of victims of crime, and also in ensuring real victims are not reluctant to report crime through fear of implicating themselves in other unrelated offences. The Inquiry has heard a number of options to address this problem. One possibility is to identify the profile as an 'identified victim's profile', with specific index matching rules applying to this category. Another option is to exclude victims from the volunteer provisions, so that they could be treated in the same way as crime scenes. If the latter approach were adopted, the Inquiry has heard a suggestion that tighter controls should apply on crime scene to crime scene index matching.²⁹

36.45 The Inquiry considers that it would be better to clarify the legislative provisions in relation to victims of crime. Forensic procedures legislation should be amended to specify that identified victims of crime should be treated as 'volunteers'. In the rare circumstances in which a victim's profile might be stored on a DNA database system, the Inquiry considers that the victim should be protected against potentially implicating him or herself in outstanding offences through the generation of 'cold hits' on the DNA database system. Therefore, Part 1D of the *Crimes Act* should be amended by inserting a new index for 'identified victims' profiles' into the DNA database system, with limited index matching rules that exclude comparisons between this index and the crime scene index; and by providing specified information to be given to victims regarding the storage of their profiles.

29 Evidence and Law Enforcement Working Group, *Meeting*, 5 March 2002.

Proposal 36–5. Forensic procedures legislation should be amended by:

- specifying that known victims of crime should be treated as volunteers;
- inserting a new index for ‘identified victims’ profiles’ into the DNA database system, with limited index matching rules that exclude comparisons between this index and the crime scene index; and
- providing that specified information should be given to victims regarding the storage of their profiles.

Potential suspects

36.46 The volunteer provisions of Part 1D allow police investigators to ask a potential suspect to submit to the carrying out of a forensic procedure for the purpose of eliminating him or herself from suspicion. Police might ask a small number of potential suspects to volunteer in the context of a criminal investigation, or they might conduct a mass screening program in which they ask a section of a workplace, neighbourhood or town to submit to a forensic procedure.³⁰

36.47 The Inquiry has heard concerns that members of the community might feel pressure to submit to a forensic procedure as a volunteer in order to eliminate themselves from potential suspicion in a criminal investigation. It has been suggested that such requests might be used as an intelligence tool known as ‘DNA request surveillance’, whereby a person requested to submit to a forensic procedure as a volunteer becomes a suspect in the investigation solely as a result of refusing to provide a sample.³¹

36.48 In June 2002, Queensland police investigating the death of an English backpacker who is believed to have fallen, or to have been pushed, from a bridge in the town of Bundaberg, announced a mass screening program to identify the male whose DNA sample was found on the bridge. It was reported that close to 2,500 men and boys in north Bundaberg would be asked to submit to DNA testing, and police would record the name of any person who refused to submit.³²

30 Australia’s first mass screening program involved the DNA testing of about 500 men in the NSW town of Wee Waa to identify the offender in a sexual assault investigation. A number of mass screenings have subsequently been conducted around Australia.

31 J Gans, ‘Something to Hide: DNA, Surveillance and Self-incrimination’ (2001) 13(2) *Current Issues in Criminal Justice* 168, 170–176.

32 A Wilson, ‘City’s Males Face DNA Testing in Hunt for Killer’, *The Australian*, 10 June 2002, 3.

36.49 The delineation between a suspect and a potential suspect is often fuzzy. For example, it might be explained to a potential suspect that if he or she submits to a forensic procedure as a volunteer, the person may decide in which volunteer index the profile will be stored,³³ and the retention period of the forensic material and profile. However, if the person will not consent as a volunteer, he or she may be considered a suspect, in which case the police might seek a compulsory order for a forensic procedure. If the order is given, the resulting profile would be stored in the suspects index for at least 12 months, during which time it could be matched against all outstanding crime scene profiles.

36.50 The HGSA submitted that where members of the community feel pressure to consent to a forensic procedure to eliminate themselves from suspicion:

This seems to reverse the fundamental legal principle from one of 'innocent until proven guilty' to the opposite; the potential merits or disadvantages of this will be an issue for more informed debate and deliberation within legal and community contexts.³⁴

36.51 The Legal Aid Commission of New South Wales raised concerns regarding the use of mass screening programs:

This Commission had concerns about the use of mass population screening programs to identify suspects. This process places great pressure on affected individuals to consent. People who decline to participate may come under unreasonable suspicion. Innocent people may decline to participate for a number of reasons, including a concern to retain the privacy of their genetic information, or concerns about how the samples may be used. There is also a problem associated with the media coverage that such mass screenings receive. This coverage could have a prejudicial effect on any suspect charged following the screening program. The cost and time expended on the screening program could create a strong impression on the public that the person identified through the screening is the offender, even though the DNA evidence is not conclusive evidence of guilt.³⁵

36.52 The Australian Privacy Charter Council submitted that steps must be taken to prevent circumstances such as the Wee Waa mass screening program, 'where individuals were put under great pressure to participate and refusal to do so led to stigmatisation and abuse'.³⁶

36.53 The Commonwealth Attorney-General's Department submitted that the effect on the right to silence, the privilege against self-incrimination, and the onus of proof were matters considered extensively during the parliamentary

33 The volunteer has a choice whether the profile will be stored in the volunteers (limited purposes) index, or the volunteers (unlimited purposes) index. The index matching rules vary according to the index.

34 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

35 Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

36 Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

consideration of Part 1D of the *Crimes Act*. The Department submitted that the provisions of Part 1D do not abrogate these traditional safeguards:

The Issues Paper ... appears to be concerned that, in mass DNA screening exercises, people may be pressured into providing a forensic sample to demonstrate their innocence. While there may be a need to further examine how such exercises are to be conducted, the strict informed consent and safeguard provisions in the Model Bill (developed in consultation with the Privacy Commissioner) are intended to ensure that such problems are minimised ... The effect of the Model Bill provisions is that volunteers now have comprehensive safeguards.³⁷

36.54 It has been suggested that police requests for persons to submit to a forensic procedure as a volunteer (other than a victim of crime), should receive some form of oversight, either by a court or senior police management.³⁸

36.55 The Inquiry considers that some form of supervision is important in light of the absence of any legislative guidance regarding the definition of a volunteer, or the circumstances in which a person may be asked to consent to a forensic procedure. The intention is not to inhibit people from volunteering for a forensic procedure where this would be of real value to a criminal investigation. However, in some circumstances individuals who would not otherwise be suspects might feel undue pressure to 'volunteer' for a forensic procedure. Consequently, the Inquiry proposes that regulations or police guidelines be developed about the conduct of mass screening programs, with respect both to the approval process for initiation as well as the manner in which such programs are conducted.

36.56 Oversight of police compliance with such guidelines could be handled through the existing mechanisms for external scrutiny. For example, complaints can be made about the actions of AFP appointees³⁹ to either the Commonwealth Ombudsman or to the AFP. The Ombudsman has oversight of investigations conducted by AFP Internal Investigations, and only the Ombudsman can decide an investigation should not be conducted.⁴⁰

Proposal 36–6. Regulations or police guidelines should be developed in every jurisdiction on the conduct of mass screening programs, both in relation to the approval process for initiation as well as the manner in which such programs are conducted.

³⁷ Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

³⁸ Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 5.72, citing a suggestion by Dr Jeremy Gans.

³⁹ An 'AFP appointee' is a Deputy Commissioner of the AFP, an AFP employee or a special member of the AFP: *Complaints (Australian Federal Police) Act 1981* (Cth) s 3(1).

⁴⁰ See *Ibid.* See also Australian Law Reform Commission, *Integrity: But Not by Trust Alone*, Report 82 (1996), ALRC, Sydney.

Relatives of missing persons

36.57 DNA identification testing is increasingly used in identifying deceased persons and human remains where, due to the cause of death or delay in locating the body, the deceased is no longer recognisable. This form of kinship testing involves comparing DNA taken from the body of the deceased with DNA taken from close biological relatives, using nuclear or mitochondrial DNA analysis.

36.58 DNA identification testing may be used to identify missing persons, homicide victims or victims of mass disasters. For example, DNA testing has been used to identify the victims of the destruction of the World Trade Center towers in New York on 11 September 2001, following a terrorist attack. Investigators have attempted to identify victims by comparing the DNA taken from bodily parts or tissue recovered from the site, with DNA taken from the personal effects of the missing (eg combs and toothbrushes), as well as from the DNA of their close relatives.⁴¹ By 29 May 2002, 1,092 of the estimated 2,823 victims had been identified, including about 300 through DNA analysis alone.⁴²

36.59 The Inquiry understands that relatives of missing or deceased persons would be 'volunteers' for the purposes of Part 1D.⁴³ As a result, a relative of a missing or deceased person would have a choice whether his or her DNA profile will be stored in the volunteers (limited purposes) index or the volunteers (unlimited purposes) index of the DNA database system. As a volunteer, the relative also could withdraw consent to retention of the forensic material or the DNA profile, subject to a magistrate's order that it be retained.⁴⁴

36.60 Under Part 1D, the missing persons index of the DNA database system includes DNA profiles derived from the forensic material of missing persons, and volunteers who are blood relatives of missing persons.⁴⁵ Therefore, it is at least technically possible that a profile relating to a relative of a missing person will be stored on the missing persons index, rather than on one of the volunteer indexes. If this occurs, it could have significant privacy implications for these relatives due to the broad index matching rules applying to this index.⁴⁶ For example, while, a 'cold hit' between a relative's profile on the missing persons index and the crime scene index could help to identify the missing person as a victim of a crime, it could also implicate the relative in any outstanding offences.

41 L. Altman, 'Now, Doctors Must Identify the Dead Among the Trade Center Rubble', *The New York Times*, 25 September 2001. See also D Chen, 'Grim Scavenger Hunt for DNA Drags on for September 11 Families', *The New York Times*, 9 February 2002.

42 Associated Press, 'Some Trade Center Remains Not Found', *The New York Times*, 29 May 2002.

43 The AFP has advised the Inquiry that relatives of missing persons are treated as 'volunteers' for the purposes of Part 1D.

44 *Crimes Act 1914* (Cth) ss 23XWU(2), 23XWV.

45 *Ibid*, s 23YDAC.

46 See *Ibid*, s 23YDAF(1).

36.61 One mass disaster might result in the collection of forensic material from hundreds, or possibly thousands, of relatives. The Inquiry considers there is a public interest in protecting the privacy of persons who volunteer their bodily samples in these contexts, and in ensuring relatives are not reluctant to notify police of a disappearance, or to assist in identifying victims of a mass disaster, through fear of implicating themselves in outstanding or future offences. At the same time, relatives who volunteer their forensic material for these purposes are entitled to the security of knowing when that material and profile has been destroyed.

36.62 The Inquiry proposes that Part 1D of the *Crimes Act* be amended to delete reference to the DNA profiles of blood relatives of missing persons from the definition of the ‘missing persons index’. This amendment would make it clear that relatives of missing persons should be treated as volunteers in relation to the collection, use, storage and destruction of their forensic material and DNA profiles. As a result, the missing persons index should contain only profiles derived from the forensic material of persons who are missing or presumed dead.⁴⁷

Proposal 36–7. Forensic procedures legislation should be amended to delete reference to the DNA profiles of blood relatives of missing persons from the definition of the ‘missing persons index’.

Forensic material

36.63 Part 1D of the *Crimes Act* defines ‘forensic material’ as samples; hand, finger, foot or toe prints; photographs or video recordings; or casts or impressions taken from or of a person’s body by a forensic procedure.⁴⁸ The discussion below is generally limited to genetic samples.

Regulation of forensic material

Crimes Act provisions

36.64 Part 1D regulates the collection, use, disclosure and destruction of forensic material obtained under the legislation. Section 23YO(1) provides that a person is guilty of an offence if he or she has access to information stored on the DNA database system or any other information revealed by a forensic procedure carried out on a suspect, offender or volunteer, and intentionally or recklessly causes the disclosure of the information other than as provided. Section 23YO(3)

⁴⁷ Eg, DNA profiles created from bodily samples found on the missing or deceased person’s personal effects, such as a toothbrush, hairbrush or other items.

⁴⁸ *Crimes Act 1914* (Cth) s 23WA(1).

provides an exhaustive list of permitted disclosures, including disclosure ‘for the purpose of the investigation of any offence or offences generally, or in accordance with any other provision of Part 1D’.⁴⁹

36.65 Section 23YDAD of the *Crimes Act* provides that a person is guilty of an offence if his or her conduct results in forensic material which is required to be destroyed, or which is not ‘excluded forensic material’,⁵⁰ being supplied to another person for the purpose of deriving a DNA profile for inclusion on an index of the DNA database system.

Privacy Act

36.66 Australian forensic laboratories are generally attached to a police service or a state or territory health department. The AFP operates its own forensic laboratories, which are subject to the Information Privacy Principles (IPPs) in the *Privacy Act 1988* (Cth) (*Privacy Act*). Forensic laboratories in other jurisdictions operate subject to privacy legislation applying in that State or Territory, where it exists.

36.67 As discussed in Chapter 7, it is doubtful whether the *Privacy Act* regulates the collection, use, storage, disclosure or destruction of forensic bodily samples, since genetic samples currently do not appear to fall within the definition of ‘personal information’ as defined in the *Privacy Act*.

NATA accreditation requirements

36.68 The National Association of Testing Authorities, Australia (NATA) accredits laboratories in the field of forensic science, including crime scene examination. NATA applies international standards in its accreditation program, as well as its own supplementary requirements.⁵¹ Laboratories must comply with these accreditation requirements to obtain and maintain accreditation in the field of forensic science, with re-assessments conducted every two years.

36.69 NATA’s supplementary requirements for accreditation in the field of forensic science include provisions addressing: the control of records; accommodation and environmental conditions; test and calibration methods and

49 Ibid s 23YO(3)(f).

50 ‘Excluded forensic material’ means forensic material found at a crime scene; taken from a suspect, serious offender or volunteer under Part 1D or under a corresponding law of a participating jurisdiction; taken from the body of a deceased person; that is from the body of a missing person; or taken from a volunteer who is a blood relative of a deceased or missing person: Ibid, s 23YDAD(3).

51 See National Association of Testing Authorities (Australia), *AS ISO/IEC 17025: 1999 General Requirements for the Competence of Testing and Calibration Laboratories* (1999), National Association of Testing Authorities, Australia; National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia.

method validation; measurement traceability; sampling; handling of test and calibration items; quality assurance of test and calibration results; and reporting of results. Accredited laboratories are required to establish procedures for storage and security of forensic samples and other records.⁵²

36.70 The Inquiry understands that, with one exception, all laboratories used by law enforcement agencies for DNA analysis have NATA accreditation in forensic science.⁵³ The AFP's laboratories are accredited for forensic science and crime scene investigation. While the police services in some state and territory jurisdictions operate laboratories that are not NATA-accredited, the Inquiry has been advised that in practice these police services usually forward genetic samples to an accredited laboratory for testing and analysis in order to ensure that any evidence gained is not later challenged in court.⁵⁴

Analysis of forensic material

36.71 The Inquiry understands that Australian forensic laboratories currently analyse only the non-coding section of the DNA molecule, for the sole purpose of creating a DNA profile.

36.72 Advances in forensic science suggest two potential developments in forensic analysis. First, scientists have suggested that non-coding DNA may contain some information relevant to health.⁵⁵ Second, it might be possible in future to obtain some information about physical, and possibly behavioural, traits from the coding section of DNA.⁵⁶

36.73 The United Kingdom's Forensic Science Service (FSS) is conducting research directed toward identifying commonplace characteristics from bodily samples — such as sex, race, skin/hair/eye colour, stature, weight, age and facial characteristics, and perhaps even behavioural traits — so that in future crime scene

52 National Association of Testing Authorities Australia, *ISO/IEC 17025 Application Document: Supplementary Requirements for Accreditation in the Field of Forensic Science* (2000), National Association of Testing Authorities, Australia.

53 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 3.68. The Inquiry understands that the forensic laboratory operated by the Northern Territory police service currently is not accredited, but is working toward obtaining NATA accreditation in the field of forensic science: Northern Territory Police Service, *Consultation*, Darwin, 18 March 2002.

54 M Parsell (National Association of Testing Authorities Australia (NATA)), *Telephone Communication*, 25 July 2002.

55 D Concar, *Fingerprint Fear*, New Scientist, <<http://www.newscientist.com/news/news.jsp?id=ns9999694>>, 2 May 2001, cited in Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

56 See R van Oorschot and others, 'Beyond DNA Databases: Physical Identification Using DNA' (Paper presented at DNA Evidence: Prosecuting Under the Microscope International Conference, Adelaide, 10 September 2001).

samples could be analysed to create a 'genetic photo-fit' of the offender for use in criminal investigations.⁵⁷

36.74 The FSS is also working on analysis of markers inherited from father to son on the Y chromosome. This information could be used in sexual assault cases in which the offender's DNA has been contaminated with that of the female victim; it has also been suggested that this analysis might provide information about possible surnames and geographic origin. In addition, the FSS provides a race identification service that gives at best a hundreds-to-one level of discrimination, and a 'red hair service' that detects about 85% of redheads.⁵⁸

36.75 The Inquiry has heard concerns about whether stored forensic material might be the subject of future analysis to obtain physical or behavioural information, predictive health information or other information unrelated to criminal investigations.⁵⁹ It has been suggested that the Australian community has accepted the forensic use of DNA on the understanding that only non-coding sections would be analysed. If coding DNA were analysed in future, this would have important privacy and other implications, and would require a fundamental review of the whole system.⁶⁰

Supply of forensic material

36.76 A second concern relates to the security of information contained in stored forensic material. In theory, a person could seek to obtain stored forensic material to conduct an 'off database' match with another sample or profile; to 'plant' the material at a crime scene to implicate an innocent person in an offence; or to substitute a stored sample with a crime scene sample to implicate an innocent person in an offence.

36.77 The relative ease of obtaining genetic samples directly from a person's body or personal effects renders the latter two concerns unlikely. The Inquiry considers that s 23YO(3) generally protects against the inappropriate disclosure of forensic material obtained from suspects, offenders and volunteers. However, the permitted disclosure 'for the purposes of the investigation of any offence or

57 Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002), London, para 9.40.

58 Ibid, para 9.41–9.42.

59 Eg, Australian police associations have raised privacy concerns in response to suggestions that members of particular police services should provide their own DNA samples to be placed on a database for the purpose of elimination from crime scene samples. The concern expressed was that, once obtained, the samples might be used in future for other purposes such as predictive health or other testing: G Warner, 'Greens Join Fight against Police DNA Testing Plan', *The Mercury* (Hobart), 13 February 2002; C Jackman, 'Police Fears on Push for DNA Bank', *The Sunday Herald Sun* (Melbourne), 24 February 2002, 30.

60 Advisory Committee members, *Advisory Committee meeting*, 29 November 2001.

offences generally' could, in some circumstances, permit disclosure for a broad range of purposes, such as 'off database' matching.

Secondary uses of forensic material

36.78 The Inquiry has heard concerns that forensic material collected and stored under Part 1D of the *Crimes Act* could in future be made available for human research. For example, in relation to forensic information obtained from Aboriginal people, the Inquiry heard:

These DNA databases could provide a general 'snapshot' of genetic information about Aboriginal people. This would be possible because while Indigenous people comprise about 2.1% of the total Australian population, they are 20% of the Australian prison population ... The Indigenous genetic profile would ... provide considerable saving for researchers in terms of clinical trials.⁶¹

36.79 This would only be permitted if the research fell within one of the permitted grounds for disclosure or use of forensic material under Part 1D,⁶² and subject to applicable laws and guidelines relating to the conduct of human research as discussed in Part D of this Paper.

Submissions and consultations

36.80 IP 26 asked whether existing laws and accreditation requirements adequately protect the confidentiality of genetic information held in forensic laboratories under Part 1D of the *Crimes Act*.⁶³

36.81 The Attorney-General's Department noted that the legislative and accreditation requirements protecting the confidentiality of genetic information held in forensic laboratories under Part 1D include the criminal offences in Part 1D, the *Privacy Act* and the NATA accreditation requirements. The Department submitted that the IPPs, and potentially the National Privacy Principles (NPPs) currently would apply to these genetic samples.⁶⁴

36.82 The Victoria Police submitted that the current NATA forensic science laboratory accreditation process ensures that adequate security is maintained. In addition:

61 Aboriginal and Torres Strait Islander Social Justice Commissioner – Human Rights and Equal Opportunity Commission, *Submission G160*, 13 May 2002.

62 Eg, for the purposes of the investigation of offences generally: *Crimes Act 1914* (Cth) s 23YO(3)(f).

63 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 13–6.

64 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

The current statutory oversight of forensic laboratories through statutory reporting, accreditation processes and the investigation of breaches by the Ombudsman's Office provides adequate protection of genetic information. Under the Commonwealth *Crimes Act* 1914, laboratories are required to protect the confidentiality of forensic material and to have formal operating procedures in place.

Furthermore, the degree of separation of the labs from operational policing areas, their staffing by professional civilian scientists and the location of the database containing the profiles at the labs all reduce the risk of inappropriate access to profiles, particularly by police personnel.⁶⁵

36.83 The HGSA commented:

Storage of genetic information requires stringent oversight and management, supported by clear guidelines, mechanisms of enforcement, transparent practices and enforceable penalties for breaches. The [Issues Paper] notes ... that to date there has been little apparent mishandling of DNA samples in criminal investigations; however because potential abuses become more likely with increased availability of DNA technologies in mainstream community contexts, adequate protective legislation is required.⁶⁶

36.84 The Office of the Federal Privacy Commissioner (OFPC) expressed concern about the relative vagueness or inconsistency in legislative obligations across Australian jurisdictions regarding retention and destruction or de-identification of forensic samples and data. The submission suggested that this leaves room for inconsistency in data handling, with significant potential for negative effects on privacy.

With regard to data retention, in the context of forensic DNA testing for identification purposes, most significant are the rules for the retention and destruction of the DNA sample itself — as presumably the only data sought in relation to the sample is that needed for identity purposes. Destroying the sample at an appropriate time then prevents its further unwarranted use.⁶⁷

36.85 Privacy NSW also noted that the scope of the question should be extended to cover Australian state and territory forensic procedures legislation, as NCIDD will depend on material analysed by state-based laboratories.⁶⁸

36.86 Finally, the Inquiry received a confidential submission arguing that confidence in the integrity of the criminal justice system would be enhanced if there were more independent handling of samples and DNA testing and analysis. The authors proposed that: forensic laboratories conducting DNA analysis should be independent of the police and fully NATA-accredited; DNA samples taken from a crime scene or otherwise obtained in the law enforcement context should be

65 Victoria Police, *Submission G086*, 21 January 2002.

66 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

67 Office of the Federal Privacy Commissioner, *Submission G143*, 22 March 2002.

68 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

sent directly to the independent laboratory for storage and testing; and all of these samples should be destroyed as soon as practicable after testing and analysis.⁶⁹

Options for reform

36.87 Where forensic material is stored on a long-term basis, the sensitivity of the information stored within the samples inevitably leads to concerns for the security of that information.

36.88 While s 23YO generally protects against the inappropriate disclosure of stored forensic material, it might not protect against future research or other uses conducted within the context of law enforcement. There are several ways to provide greater privacy protection for forensic material held under Part 1D of the *Crimes Act*.

Destruction of forensic material

36.89 One option is to require the destruction of forensic material after a DNA profile has been created.⁷⁰ Possible reasons for the long-term retention of forensic material are to allow for retesting if allegations of errors in the analytical process are made; or for re-analysis if, in future, more sophisticated analysis techniques become available.⁷¹ For example, forensic scientists might wish to re-analyse stored samples to include additional loci in DNA profiles stored on DNA databases; alternatively, scientists might wish to conduct a wholly new form of analysis on the samples, when better technology emerges.

36.90 The advantage of destruction is that it minimises public concerns regarding the potential misuse of forensic material. If forensic scientists wish to re-analyse samples using more sophisticated technology, they must request the person's consent, or seek an order for a new forensic procedure. However, the disadvantage of this approach is the significant time and cost implications of obtaining new samples for analysis.

Independent storage of forensic material

36.91 A second option is to permit the retention of forensic material after analysis, but provide for independent storage of that material to provide security against any allegations of future misuse.

69 Confidential Submission G169CON, 11 June 2002.

70 Except in relation to crime scenes samples, which are dealt with below.

71 Legislative Council Legislation Committee, *Forensic Procedures and DNA Profiling: The Committee's Investigations in Western Australia, Victoria, South Australia, the United Kingdom, Germany and the United States of America*, Report No 48 (1999), Parliament of Western Australia, Perth, para 9.2.

36.92 The Inquiry understands that the NSW government is considering the establishment of a State Institute of Forensic Sciences (SIFS) to oversee the organisation and management of forensic sciences and the use of technology in criminal investigations and prosecutions. This is a joint proposal of the Police Service, the Attorney-General and the Department of Health.⁷² It is understood that this proposal includes an independent storage facility for exhibits.

36.93 The advantage of this approach is that it could minimise public concerns regarding potential misuse of stored forensic material; however, this would depend on the nature of the body holding the information — that is, its real and perceived integrity and independence — and its systems for maintaining confidentiality and information security.

Improve existing protections

36.94 A third option is to permit the retention of forensic material after analysis but improve the privacy protections applying to that material. For example, Part 1D could be amended to limit analysis of genetic samples to the non-coding section of the DNA molecule. Several submissions supported this approach.⁷³

36.95 Existing privacy protection might be improved by extending coverage of the *Privacy Act* to genetic samples. For example, if the IPPs applied to bodily samples, the storage and security of the samples would be regulated under IPP 4. The laboratory holding the sample would be required to ensure it is protected by such security safeguards as are reasonable to protect against loss, unauthorised access, use, modification or disclosure, and against other misuse.

36.96 Finally, existing protections could be improved by extending the NATA accreditation framework to all forensic laboratories analysing and storing forensic material in the context of criminal investigations.

Inquiry's views

36.97 The Inquiry recognises the potential value of retaining forensic material for re-analysis as technology advances. It also recognises the vast amount of predictive health and other information that may be obtained from the genetic samples.

72 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 3.52.

73 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002; New South Wales Health Department, *Submission G092*, 25 January 2002.

36.98 There are good policy reasons for the indefinite retention of crime scene samples (see below for more detail). However, leaving crime scene samples to one side, the Inquiry considers that it is important that volunteers, suspects and offenders should be protected from perceived or real threats to their genetic privacy through future analysis, or misuse, of their forensic material. An appropriate balance between the public interest in solving crime, and the public interest in protecting individual privacy, could be struck by permitting the retention of forensic material after analysis, but improving legislative provisions for the confidentiality and security of that information.

36.99 First, Part 1D should be amended to narrow the purposes for which forensic material may be analysed, by providing that samples (including crime scene samples) collected or otherwise obtained for use in the law enforcement context only may be subject to genetic testing and analysis with respect to the non-coding sections of the DNA, and only for the purposes of creating a DNA profile, quality assurance or equipment validation.⁷⁴

36.100 Second, in Chapter 7, the Inquiry proposes that the *Privacy Act* should be amended to include genetic samples in the legislative definitions of ‘personal information’ and ‘record’. In the context of criminal investigations, these proposed amendments would extend coverage of the IPPs to genetic samples held by the AFP laboratory, and the NPPs to genetic samples held by private sector laboratories (if applicable). No further proposal is required.

36.101 Third, legislation should require that genetic samples can only be analysed for law enforcement purposes by a laboratory that has NATA accreditation in the field of forensic science. This would ensure standardised forensic laboratory practice across Australia for the effective operation of NCIDD, and would be consistent with the Inquiry’s proposals in other areas of laboratory practice. The proposal formalises what the Inquiry understands is current industry practice.

Proposal 36–8. Forensic procedures legislation should provide that samples (including crime scene samples) collected or otherwise obtained for use in the law enforcement context may be subject to genetic testing and analysis only with respect to the non-coding sections of the DNA, and only for the purposes of creating a DNA profile, quality assurance or equipment validation.

⁷⁴ By limiting the analysis of genetic samples in this way, the Inquiry does not wish to limit other forms of forensic testing that might be appropriate. For example, a forensic scientist might wish to analyse a crime scene sample to identify the presence of poison or disease in the person’s blood.

Proposal 36–9. Forensic procedures legislation should provide that forensic analysis of genetic samples must be conducted only by laboratories accredited by NATA in the field of forensic science.

Crime scene samples

36.102 Part 1D of the *Crimes Act* does not regulate the collection, use or destruction of forensic material found at a crime scene. Police administrative procedures and NATA accreditation criteria for crime scene examination outline procedures for the chain of custody of crime scene material, analysis, and storage of those samples. DNA profiles created from the samples are stored on the crime scene index of the DNA database system.

36.103 IP 26 asked whether Part 1D of the *Crimes Act* should regulate the collection and destruction of crime scene material.⁷⁵ Generally, submissions agreed that crime scene samples should be retained indefinitely for the purpose of post-conviction review.⁷⁶ The Victoria Police also noted the value of retaining crime scene samples for identifying serial offenders, and resolving long-term investigations.⁷⁷

36.104 Chapter 38 outlines the importance of retaining crime scene samples indefinitely for use in post-conviction review processes. To ensure opportunities for post-conviction analysis are not lost through inadvertent destruction of crime scene material, the Inquiry considers that Part 1D of the *Crimes Act* should require the permanent retention of the forensic material found at crime scenes. This would not, however, extend to a victim's sample or profile, which is discussed above.

Proposal 36–10. Forensic procedures legislation should require the permanent retention of forensic material found at crime scenes to ensure the preservation of crime scene material for post-conviction analysis.

⁷⁵ Australian Law Reform Commission, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, Question 13–8.

⁷⁶ Centre for Law and Genetics, *Submission G048*, 14 January 2002; Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Australian Privacy Charter Council, *Submission G120*, 18 March 2002.

⁷⁷ Victoria Police, *Submission G086*, 21 January 2002.

The DNA database system

Regulation of the DNA database system

Crimes Act provisions

36.105 Part 1D of the *Crimes Act* contains provisions for a DNA database system. A ‘DNA database system’ is defined as a database containing the following indexes of DNA profiles: a crime scene index; a missing persons index; an unknown deceased persons index; a serious offenders index; a volunteers (unlimited purposes) index; a volunteers (limited purposes) index; a suspects index; and information that may be used to identify the person from whose forensic material each DNA profile was derived. The system also contains a statistical index; and any other index prescribed by the regulations.⁷⁸

36.106 Section 23YDAE(2) provides an exhaustive list of the purposes for which a person may access information stored on the DNA database system, and a person is guilty of an offence if he or she accesses information on the system otherwise than in accordance with the provided list.⁷⁹ One of the permitted purposes for accessing information stored in the DNA database system is for forensic comparison permitted under s 23YDAF, which contains a table of permitted index matching. A person is guilty of an offence if he or she recklessly causes index matching that is not permitted by Part 1D.⁸⁰

36.107 As noted above, s 23YO(1) provides that a person is guilty of an offence if he or she has access to information stored on the DNA database system, and intentionally or recklessly causes the disclosure of the information other than as provided. The section provides an exhaustive list of purposes for which a person may disclose information stored on the DNA database system.⁸¹

36.108 Finally, it is an offence if a person recklessly causes the recording or retention of identifying information about a person obtained under Part 1D in a DNA database system after the forensic material is required to be destroyed.⁸²

⁷⁸ *Crimes Act 1914* (Cth) s 23YDAC.

⁷⁹ *Ibid*, s 23YDAE(1). This section does not apply to information that cannot be used to discover the identity of any person.

⁸⁰ *Ibid*, s 23YDAF(2). However, it is not an offence if the matching is solely for the purpose of administering the DNA database system: s 23YDAF(3).

⁸¹ *Ibid*, s 23YO(2).

⁸² *Ibid*, s 23YDAG(1). In addition, the ‘responsible person’ is guilty of an offence if he or she does not ensure any identifying information is removed from the system after the end of the identifying period for volunteers, or after becoming aware that a serious offender has been pardoned or acquitted, or the conviction has been quashed. The ‘responsible person’ means the person responsible for the care, control and management of the system: ss 23WA(1), 23YDAG(2), (3).

Other privacy protections

36.109 It is not clear whether DNA profiles are covered by the *Privacy Act* definitions of ‘personal information’ and ‘record’ — at least where they relate to an individual whose identity reasonably can be ascertained from the profile.⁸³ If profiles are ‘personal information’, the IPPs would apply to DNA profiles held by AFP forensic laboratories and stored on the NCIDD system.⁸⁴ In that case, it would generally be necessary for the AFP and CrimTrac to comply with the IPPs regarding the storage and security, use and disclosure of, and access to, the DNA profiles, and such compliance may be subject to review by the federal Privacy Commissioner.⁸⁵

36.110 In addition, as noted above, the NATA accreditation requirements for forensic science include provisions addressing the information security of forensic material received and analysed by the laboratory. In practice, the confidentiality of information held in computerised files could be protected by the use of security clearance, passwords, and audit trails.

Index matching

36.111 As of May 2002, CrimTrac had not conducted any inter-jurisdictional information sharing on the national DNA database system. CrimTrac has advised the Inquiry that it will not conduct inter-jurisdictional index matching until it finalises agreements with the participating jurisdictions. CrimTrac will enter into an agreement with each participating jurisdiction, which will include copies of the inter-jurisdictional matching agreements between each participating jurisdiction and the permitted database matching protocols.

36.112 The Commonwealth Attorney-General’s Department has advised the Inquiry that the protocols will reflect the legislative provisions of each participating jurisdiction, and inter-jurisdictional matching will be conducted on the ‘least’ permissive terms.

36.113 The DNA database system contains several indexes of DNA profiles that may be matched against each other only in accordance with the index-matching table contained in s 23DAF. The Inquiry has heard concerns that the provisions for index matching on the DNA database system may be unduly permissive, contrary

83 *Privacy Act 1988* (Cth) s 6(1).

84 The Inquiry is not aware of any private sector laboratories conducting forensic DNA analysis in the context of law enforcement, and has not considered the application of the NPPs in this section.

85 However, the IPPs contain exceptions in relation to law enforcement, and in some circumstances these may apply.

to the information privacy rights of those providing forensic material in the context of a criminal investigation.⁸⁶

36.114 For example, the index matching rules allow for unlimited index matching between the suspects index and the crime scene index, allowing for the generation of ‘cold hits’ between a suspect’s profile and any outstanding offences in the crime scene index. If a suspect consents, or is compelled, to undergo a forensic procedure in relation to the investigation of a particular offence, his or her DNA profile may be matched against all profiles on the crime scene index until the profile is ‘destroyed’ or moved to the serious offenders index, depending on the outcome of the investigation and proceedings.

36.115 In its 1999 discussion paper, MCCOC suggested that unrestricted comparisons between the suspects index and the crime scene index should not be permitted.

The suspects profile can be matched against anything on the crime scene index but unlike the serious offenders index, should not be available for unrestricted comparison as part of a pool of suspects that can be matched with profiles from any index. For example, it is not intended that the whole index of suspects could be compared with all crime scene profiles. To do so would go far beyond the purpose for which the forensic material was obtained in the first place and may expose suspects to random searchings by police anywhere in the country who are quite separate from the particular investigation and who are just fishing for matches on the crime scene index.⁸⁷

Although MCCOC did not provide any supporting explanation, the final draft of the Model Bill represented a change in approach, permitting unrestricted comparisons.⁸⁸

36.116 The rationale for the current approach appears to be to maximise the resolution of unsolved crimes by increasing the potential for ‘cold hits’ between suspect and crime scene profiles. While recognising the public interest in the resolution of crime, the Inquiry notes that this form of index matching is in fact a secondary use of suspects’ forensic material, unrelated to the purpose for which it was collected.

36.117 For example, a person may be one of a number of persons upon whom some level of suspicion has fallen in relation to an offence. The suspect might readily submit to a forensic procedure for the purpose of elimination from

⁸⁶ Index matching of profiles regarding victims and the relatives of missing persons has been discussed above.

⁸⁷ Model Criminal Code Officers Committee, *Report: Model Forensic Procedures Bill and the Proposed National DNA Database* (1999), Standing Committee of Attorneys-General, Canberra, 93. See also Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 6.13.

⁸⁸ See Model Criminal Code Officers Committee, *Final Draft: Model Forensic Procedures Bill and the Proposed National DNA Database* (2000), Standing Committee of Attorneys-General, Canberra, cl 82.

suspicion in relation to that offence. Despite being eliminated as a suspect, however, the person's DNA profile would remain on the suspects index of the DNA database system for a period of 12 months, during which time it could be subject to unlimited matching against the crime scene index.

36.118 The Inquiry notes that this matching rule is consistent with the Model Bill, and the Inquiry does not propose to question this policy at this time. However, it is important to maintain public confidence in the use of DNA profiling in criminal investigations and in the NCIDD system. Therefore, the Inquiry proposes that a suspect's forensic material and profile should be destroyed as soon as practicable after he or she has been eliminated from suspicion, or police investigators have decided not to proceed with a prosecution in relation to that investigation.

Proposal 36–11. Forensic procedures legislation should provide that forensic material taken from a suspect, and any information obtained from its analysis, must be destroyed as soon as practicable after the person has been eliminated from suspicion, or police investigators have decided not to proceed with a prosecution in relation to that investigation.

'Off database' matching

36.119 Part 1D of the *Crimes Act* regulates the use of, and access to, information stored on a DNA database system as defined in s 23YDAC. Part 1D does not, however, expressly prohibit certain 'off database' matching of forensic material or DNA profiles. Therefore, it might be possible for police investigators to conduct DNA matching without recourse to the DNA database system, for example through a manual comparison of DNA profiles.

36.120 Alternatively, police investigators could obtain information from DNA databases that fall outside the legislative definition of a DNA database system. For example, the Commonwealth and each State and Territory currently operate their own DNA databases for criminal investigation purposes, some of which might not accord exactly with the legislative definition. Alternatively, it is possible that unofficial databases might be established.

36.121 Dr Jeremy Gans has raised concerns in relation to the New South Wales forensic procedures legislation regarding the lack of regulation of access to, and matching of, profiles and samples kept on a database falling outside the legislative definition, or kept off a database altogether:

[I]t is presently legal for criminal investigators to obtain DNA profiles if they do not intend to place the resulting profile on the database. There is no reason for such a loophole. On the contrary, it would be better for the purposes of accountability and regulation (including destruction) if all profiles were stored *exclusively* on the database ... The matching of DNA profiles by criminal investigators off the database should be expressly banned. At present such matching is completely unregulated, because [s 23YDAF] is limited to matching between profiles on an index of the DNA database system.⁸⁹

36.122 The NSW Standing Committee considered this concern in relation to the New South Wales forensic procedures legislation and noted that the legislation could be clarified, either by prohibiting any database that does not fit the description of a DNA database system; or by redefining the term to include all databases, however formulated. The Committee recommended the former option, suggesting that this would prevent the proliferation of databases.⁹⁰

36.123 The NSW Standing Committee also recommended a more comprehensive approach to database restrictions, including prohibition of the collection of DNA samples other than pursuant to the Act; analysis of samples taken or retained in breach of the Act; profiling of non-database purposes; establishment of any database not fitting the definition of a DNA database system; unauthorised access to the database; unauthorised matching and non-database matching; and non-database storage of profiles.⁹¹

36.124 If jurisdictions participating in NCIDD continue to operate separate jurisdictional databases that do not comply with the definition of a DNA database system, these databases could fall outside the regulatory framework. The consequence will be the persistence of parallel systems with different regulatory frameworks and safeguards, contrary to the intention of creating an integrated national DNA database system.

Proposal 36–12. Forensic procedures legislation should be amended to prohibit the establishment or maintenance of any DNA database that does not fit within the legislative definition of a DNA database system.

89 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 6.29, quoting the submission of Dr Jeremy Gans.

90 Ibid, para 6.36.

91 Ibid, rec 46.

Independent oversight of the DNA database system

CrimTrac agency

36.125 CrimTrac is an executive agency of the Commonwealth government, established as a national law enforcement information system for Australia's police services — one of its main responsibilities is operation of NCIDD. CrimTrac is underpinned by an inter-governmental agreement, signed by all Australian police ministers.⁹²

36.126 The Australian Police Ministers' Council is responsible for defining CrimTrac's strategic directions and key policies, setting new initiatives, and appointing members to CrimTrac's Board of Management. The Board comprises nominees of the Commonwealth, States and Territories (as voting members) and several specialist advisers (as non-voting members). As at July 2002, the Commonwealth nominee was a senior officer of the Attorney-General's Department; State and Territory nominees included the Police Commissioners of Tasmania, Western Australia, Victoria and New South Wales.⁹³

Oversight of the CrimTrac agency

36.127 As a federal agency, CrimTrac must comply with the *Privacy Act*, including the IPPs. The federal Privacy Commissioner has the power to investigate complaints made by individuals who believe that an agency has breached an IPP in relation to personal information that relates to the individual.⁹⁴ The Commissioner can also audit an agency's compliance with the IPPs.⁹⁵

36.128 In addition, the Commonwealth Ombudsman has the power to investigate complaints about the administrative actions and decisions of Commonwealth departments and authorities. The Ombudsman also can initiate investigations on his or her own motion.⁹⁶

36.129 As noted above, Part 1D of the *Crimes Act* provides that the Attorney-General must cause an independent review of the operation of the Part as soon as possible after June 2002. The review includes nominees of both the Commonwealth Ombudsman and the Privacy Commissioner.⁹⁷

92 Agreement for the Establishment and Operation of 'CrimTrac', A National Law Enforcement Information System for Australia's Police Services, 13 July 2000, <http://www.crimtrac.gov.au/misc/ct_agreement.PDF>, 24 July 2002.

93 CrimTrac, *CrimTrac: About Us*, <<http://www.crimtrac.gov.au/aboutus.htm>>, 29 July 2002.

94 *Privacy Act 1988* (Cth) ss 27(1)(a).

95 *Ibid.*, s 27(1)(h).

96 See *Ombudsman Act 1976* (Cth) s 5(1).

97 *Crimes Act 1914* (Cth) s 23YV.

36.130 In summary, both the federal Privacy Commissioner and the Commonwealth Ombudsman provide independent oversight of CrimTrac in its administration of NCIDD. However, neither body has any direct power to oversee the national operation of the database system, and in particular the activities of the States and Territories participating in NCIDD.

Concerns about independent oversight

36.131 In considering the Crimes Amendment (Forensic Procedures) Bill 2001 (which was based on the Model Bill provisions), the Senate Legal and Constitutional Legislation Committee (Senate Committee) commented on the limited provision for independent monitoring of the database, the privacy aspects of the legislation, and the laboratories which process the samples for the database.

36.132 The Senate Committee recommended that the federal Privacy Commissioner's role should be expanded beyond monitoring CrimTrac's administration of the national DNA database system, to include: oversight of the processes governing the retention of material on the DNA database; provisions for the destruction of such material; oversight of the functioning of the new DNA database within the laboratory; and the operation of the database under the Bill.⁹⁸

36.133 During the second reading debate for the Forensic Procedures Bill, the Minister for Justice and Customs, Senator Chris Ellison, stated:

Some serious issues have been raised in relation to the oversight of the national DNA database system. In addition to extending the legislation to include the Privacy Commission and the statutory review of Commonwealth forensic procedures, I have written to state and territory ministers with a view to getting agreement on cooperation between Commonwealth, state and territory bodies to ensure there is effective oversight of not only the operation of a DNA system within each jurisdiction but also the overall operation of the national system. This is best achieved by including formal independent monitoring mechanisms in the CrimTrac agreement with the states.⁹⁹

36.134 The Commonwealth Attorney-General's Department submitted that:

Since that time, the Minister has also raised the issue at the Australasian Police Ministers' Council (APMC), which considered (at its November 2001 meeting) an interim report of the CrimTrac Board on what cooperative arrangements between oversight bodies were necessary for the coordinated and effective handling of complaints and general monitoring of the use of the CrimTrac systems. A final report is due to be presented to the next APMC meeting.¹⁰⁰

98 Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, rec 4.

99 Cited in Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

100 Ibid.

Submissions and consultations

36.135 The authors of a confidential submission proposed a new framework for operating a national DNA database system, putting this at arm's length from the police:

All DNA profiles should be computerised and held on a national or international DNA Database that is independent of police and preferably managed through a judicial agency. Police should be able to use a simple court procedure to allow a search of a DNA profile from a scene of crime sample for matches from the database, but would not hold the database themselves. If the protocol of application through a court process is not adhered to, the DNA evidence should not be admissible in court.¹⁰¹

36.136 The Inquiry received a detailed submission on these issues from the Office of the Federal Privacy Commissioner (OFPC), stating:

There is a need to ensure a proper, external oversight of the national DNA database. This is likely to be required whenever a powerful new law enforcement system is introduced ... Indeed, continued public acceptance of the database surely rests on guarantees of accountability, and assurances that the database will be effectively and securely managed — with such management open to independent, third party scrutiny. Such oversight (involving regular monitoring, auditing and reporting by independent authorities) will provide an effective accountability measure, which in turn can prevent, detect or rectify systemic non-compliance with database regulations.¹⁰²

36.137 The OFPC commented that this approach is not new to law enforcement, and cited the example of Part VIII of the *Telecommunications (Interception) Act 1979* (Cth), which provides for the Commonwealth Ombudsman to inspect the records of federal police at least twice a year to ensure compliance with legislative requirements for the retention and destruction of interception records:

The similarities in privacy intrusiveness between the investigative tools for telecommunications interception and the taking of forensic DNA samples, indicates that as independent oversight operates successfully for the former, it is surely similarly appropriate for the latter ...

There are risks in any multi-faceted system involving many agencies, regulators and jurisdictions for accountability processes to become piecemeal and ineffective, not providing the individual with a clear understanding of how complaints, audits and investigations are handled and by whom. It is inevitable, for instance, that a complaint will arise from a series of events that occur across more than one jurisdiction; this will quickly test the efficacy of the system.

101 Confidential Submission G169CON, 11 June 2002.

102 Office of the Federal Privacy Commissioner, Submission G143, 22 March 2002.

In the context of a national DNA database, there is a need for all relevant agencies and their investigation bodies to cooperate to ensure effective complaint handling, and coordinated, effective audit and investigation processes. The system, overall, needs to rest upon adequate accountability and transparency.¹⁰³

36.138 The OFPC concluded:

It is essential to achieve a cooperative approach on these issues. It remains possible, through collaboration between Commonwealth and State/Territory Ombudsmen, Police Authorities and the Privacy Commissioner, to settle on an approach to oversight that coordinates complaint handling, and ensures effective powers and processes for audits and 'own motion investigations'. This can provide the necessary, free and confidential mechanism that will give the public confidence that complaints are investigated appropriately, that the database is adequately audited and that necessary investigation is undertaken ... It is critical, however, that the work is seen through to resolution, and that such a system is delivered. Progress to date has been very slow and it needs to be accelerated ...¹⁰⁴

Inquiry's views

36.139 In addition to independent oversight of CrimTrac's administration of NCIDD, the Inquiry considers that independent oversight of the national DNA database system itself is fundamental to the maintenance of public confidence in NCIDD, and in the use of DNA profiling in criminal investigations generally.

36.140 Independent oversight of the national database system involves monitoring of the separate Commonwealth, state and territory forensic procedures regimes; and the operation of the national DNA database system as a whole — particularly the interaction of the various forensic procedure regimes participating in NCIDD.¹⁰⁵

36.141 As noted above, the Minister for Justice and Customs has suggested that the best way to ensure independent monitoring of the system is through the CrimTrac agreement with each participating jurisdiction. The agreements would provide for co-operation and co-ordination between Commonwealth, state and territory bodies to ensure effective oversight of both the operation of a DNA system within each jurisdiction, and the overall operation of the national system.

36.142 The Inquiry agrees that this would represent a significant improvement. However, the Inquiry is inclined, at this stage, to go further in order to ensure the high level of public confidence in the national DNA database system that is required for its effective operation. Accordingly, legislative provision should be

¹⁰³ Ibid.

¹⁰⁴ Ibid.

¹⁰⁵ Office of the Federal Privacy Commissioner, *OFPC Background Information for Review of Part 1D of the Forensic Procedures Provisions (Crimes Act 1914)*, OFPC, <<http://www.ag.gov.au/clrc/part1D/>>, 24 July 2002.

made for the provision of independent, co-ordinated and nationally consistent monitoring of the operation of the entire database system, and in particular the interaction of the various forensic procedures regimes operating in each jurisdiction that participates in NCIDD. This would provide greater transparency and co-ordination in relation to the national system, and therefore greater accountability.

Proposal 36–13. Forensic procedures legislation should be amended to provide for independent, co-ordinated and nationally consistent monitoring of the operation of the entire national DNA database, and in particular the interaction of the forensic procedures regimes operating in each jurisdiction that participates in the national DNA database system.

Destruction of forensic material and DNA profiles

Legislative requirements

36.143 The destruction requirements for forensic material and DNA profiles are contained in various parts of Part 1D of the *Crimes Act*, depending on the context in which the information was collected. Forensic material obtained from a suspect must be destroyed if:

- an interim order for the carrying out of a forensic procedure is disallowed;¹⁰⁶
- 12 months have elapsed since the forensic material was taken and proceedings have not been instituted against the suspect, or have been discontinued, and no warrant for apprehension has been issued;¹⁰⁷
- the suspect is convicted but no conviction is recorded; or
- the suspect is acquitted and no appeal is lodged against the acquittal or, if an appeal is lodged, and the acquittal is confirmed or the appeal is withdrawn.¹⁰⁸

36.144 Forensic material obtained from a serious offender must be destroyed as soon as practicable after his or her conviction is quashed.¹⁰⁹

¹⁰⁶ *Crimes Act 1914* (Cth) s 23YC(1).

¹⁰⁷ *Ibid*, s 23YD(2); unless the period has been extended by a magistrate under s 23YD(5).

¹⁰⁸ *Ibid*, s 23YD(3).

¹⁰⁹ *Ibid*, s 23YDAA.

36.145 If a volunteer (or parent or guardian) expressly withdraws consent to the retention of the forensic material taken or of information obtained from the analysis of that material, subject to a magistrate's order under s 23XWV, the forensic material and information must be destroyed as soon as practicable after the consent is withdrawn.¹¹⁰ In addition, to the extent that it is relevant, the volunteer (or parent or guardian) must also be informed that information placed on the DNA database system will be retained for such period as the Commissioner and the volunteer agree, and must then be removed from the system.¹¹¹

36.146 Where a magistrate finds that forensic evidence is inadmissible under s 23XX, any forensic material taken from the person by that forensic procedure must be destroyed.¹¹²

36.147 Part 1D of the *Crimes Act* provides for de-identification of forensic material and DNA profiles, rather than physical destruction. Section 23WA(5) provides that

a person *destroys* forensic material taken from another person by a forensic procedure, the results of the analysis of the material or other information gained from it if the person destroys any means of identifying the forensic material or information with the person from whom it was taken or to whom it relates.

36.148 MCCOC explained the reason for this position in its discussion paper:

Forensic scientists advise that once samples have been subjected to the various processes of analysis in a forensic laboratory it would be extremely difficult to trace all remnants of the samples and destroy them. The same also goes for all the different records of the DNA profile. However, they point out that the material is often labelled with a numerical Code which if destroyed makes it impossible to identify the sample.¹¹³

36.149 As discussed above, a person is guilty of an offence if he or she knowingly or recklessly causes any identifying information to be recorded or retained on the system after the forensic material is required to be destroyed.¹¹⁴ However, with some exceptions, Part 1D does not assign responsibility for notifying the person charged with destroying forensic material of the appropriate destruction date.

110 Ibid, s 23XWU(2). A volunteer (or parent or guardian) must be informed that he or she may at any time withdraw consent to the retention of the forensic material taken, or of information obtained from analysis of that material: s 23XWR(1)(f).

111 Ibid, s 23XWR(2)(d).

112 *Crimes Act 1914* (Cth) s 23YDAB.

113 Model Criminal Code Officers Committee, *Report: Model Forensic Procedures Bill and the Proposed National DNA Database* (1999), Standing Committee of Attorneys-General, Canberra, 83.

114 *Crimes Act 1914* (Cth) s 23YDAG(1). See also ss 23YDAG(2), (3).

36.150 CrimTrac considers the management of destruction dates the responsibility of the jurisdiction uploading information on the database. CrimTrac requires that the laboratory uploading a DNA profile must include a destruction date for the profile. However, problems may arise in practice in ensuring that notice is given to the responsible person that identifying information should be destroyed.

36.151 Information that is shared with another jurisdiction under s 23YUD of the *Crimes Act* must not be recorded or maintained in any database of information that may be used to discover the identity of a person or to obtain information about an identifiable person at any time after Part 1D or a corresponding law of a participating jurisdiction requires the forensic material to be destroyed.¹¹⁵

Submissions and consultations

36.152 IP 26 asked whether the storage and destruction provisions of Part 1D in relation to forensic material and profiles adequately protect individual privacy. If not, it asked how these safeguards might be improved.¹¹⁶

36.153 Several submissions asserted that ‘destruction’ under Part 1D should be defined as physical destruction, rather than de-identification of material or information. These submissions argued that de-identification might not sufficiently protect the privacy of the person from whom they were obtained, by allowing for future re-identification of information; therefore physical destruction was the most secure option.¹¹⁷

36.154 The Legal Aid Commission of New South Wales submitted that:

DNA samples and profiles should be destroyed rather than de-identified, and procedures should be put in place to ensure that all samples and profiles are destroyed as soon as possible. De-identification is not sufficient because of widely held fear about the possibility that the person’s identity may somehow be reassigned to the sample, and concerns about why the samples are being kept. Many people have strong concerns about government authorities having access to their genetic information, and are entitled to the assurance that the genetic material and any profiles or analysis obtained from the material will be destroyed once they are of no further forensic use.¹¹⁸

115 Ibid, s 23YUD(2).

116 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 13–4.

117 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002; Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002; Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002; Centre for Law and Genetics, *Submission G048*, 14 January 2002.

118 Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

36.155 The Androgen Insensitivity Syndrome (AIS) Support Group suggested that if tissue samples were de-identified only, they would then be available for use for other purposes, such as research:

In our view this definition of destruction amounts to a deception by omission and samples subject to destruction should be physically destroyed. Physical destruction is the only way [to] alleviate the temptation to later use human tissue samples for purposes not originally consented to.¹¹⁹

36.156 By contrast, the Commonwealth Attorney-General's Department submitted that the definition of destruction reflects the practicalities involved in analysing forensic samples; that it is extremely difficult to trace all remnants of the samples after analysis and destroy them. The submission noted that the same applies to all of the various records of the DNA profile.

The suggestion that forensic material could be re-identified in the future is an important issue but there are strong incentives to ensure proper destruction occurs. For example, the failure to adequately destroy these identifying links may constitute an offence ... Further, any evidence obtained and subsequently relied upon from a failure to properly destroy the identifying links will be inadmissible evidence ... Even where the profile is on the system, it will not be possible, in practice, for anyone other than authorised officers from the respective jurisdiction from which the DNA profile has been provided to identify the profile.¹²⁰

36.157 The Victoria Police suggested that evidence laws already provided an effective safeguard against inappropriate retention:

De-identification, rather than destruction, of forensic profiles is safeguarded by the inadmissibility of any evidence flowing from the use of a profile that should have been de-identified and the professional ethics and standards of the laboratories ... Therefore, while profiles *could* be retained indefinitely or even recreated, there would be no advantage in doing so, as the use of such a profile would jeopardise any future prosecution and, for the laboratory, risk losing their professional accreditation.¹²¹

Inquiry's views

36.158 As discussed above, MCCOC explained that it defined destruction in terms of de-identification upon advice from forensic scientists that once samples have been subjected to analysis, it would be extremely difficult to trace all remnants of the samples and destroy them; the same reasoning applied to the records of the DNA profile. MCCOC was advised that the destruction of the numerical code attached to a sample would make it impossible to identify it.

119 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

120 IP 26 outlined the information held by CrimTrac: Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 13.27.

121 Victoria Police, *Submission G086*, 21 January 2002.

36.159 This issue involves two competing considerations. On the one hand, there is the need to maintain public confidence in the use of DNA profiling generally, and in particular the protection of personal privacy rights to the extent practicable. On the other hand, there are concerns about the practical difficulty of ensuring that all remnants of a sample or profile have been located and destroyed.

36.160 The Inquiry has a preliminary view that the balance should be tipped in favour of physical destruction of forensic material and information obtained from it, in order to maintain information security and public confidence in the use of DNA profiling for criminal investigations. The Inquiry considers that good laboratory practices should allow for location of all remnants of a sample after analysis, and the destruction of these remnants; and good record keeping should allow for location of all references to the DNA profile and other identifying information. However, as the Inquiry has received some advice that in practice it would be too onerous to physically destroy all traces of a sample, and all records of a DNA profile, the Inquiry does not consider that it is in a position to formulate a proposal. The Inquiry would like more evidence on the practical implications of physical destruction, and invites submissions on this point.

36.161 In any case, to ensure the effectiveness of the system in practice, Part 1D or the regulations should specify the designated person responsible for notifying the forensic laboratory of the destruction date for forensic material, and CrimTrac of the destruction date for identifying information held on the DNA database system; and a process for a person to obtain written confirmation of the destruction of his or her forensic material and DNA profile.

36.162 In addition, although Part 1D requires a constable to advise a volunteer (or parent or guardian) that the person can agree to the retention period for information placed on the DNA database system, this does not appear to apply in relation to forensic material. This anomaly may have resulted from a drafting error or oversight, which should be rectified so that the volunteer (or parent or guardian) may specify the retention period for both the forensic material and the information obtained as a result of its analysis at the time the forensic procedure is carried out. This agreement should be formally recorded in a standard consent form.

Proposal 36–14. Forensic procedures legislation should be amended to:

- specify the person responsible for notifying the forensic laboratory, and CrimTrac, of the destruction date of forensic material and any information obtained from it;

- establish a process for persons to obtain confirmation that their forensic material, and any information obtained from it, has been destroyed; and
- provide (in regulations) a standard consent form for use at the time the forensic procedure is carried out to enable a volunteer (or parent or guardian) to specify the retention period for both the forensic material and any information obtained from it.

Question 36–1. Should the definition of ‘destruction’ in Part 1D be changed to provide for physical destruction of forensic material and information obtained from its analysis? Do the practical difficulties in tracing and physically destroying all remnants of a sample, and all records of the profile, justify confining privacy protection to de-identification rather than physical destruction?

37. Criminal Proceedings

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The use of DNA evidence in criminal proceedings

Evidence in criminal trials

37.1 The preceding chapters considered the use of DNA analysis by law enforcement authorities in the course of criminal investigations. Following such investigations, DNA evidence may be used in criminal proceedings by either the prosecution or the defence.

37.2 The prosecution may seek to introduce DNA evidence of a match between a bodily sample found at a crime scene (or on or in the victim), and a sample taken from the defendant, to suggest the likelihood that the defendant committed the offence or was at least present at the crime scene. The prosecution gives weight to evidence of such a match by offering statistical evidence of the relative probability that the sample taken from the crime scene could have come from any person other than the defendant.

Admissibility of DNA evidence

37.3 DNA evidence is a form of expert opinion evidence. Opinion evidence is admissible if it is wholly or substantially based on a person's specialised knowledge, which is established by the witness' training, study and/or experience.¹ DNA evidence that is relevant to a fact in issue is admissible in criminal proceedings unless it is barred under an exclusionary rule, or by judicial discretion.²

37.4 The *Crimes Act 1914* (Cth) (*Crimes Act*) contains exclusionary rules in relation to DNA evidence obtained as a result of a forensic procedure conducted under Part 1D. The *Evidence Act 1995* (Cth) (*Evidence Act*) contains exclusionary rules in relation to DNA evidence obtained under the *Crimes Act* and in other ways. See below for more detail.

37.5 IP 26 gave an overview of the various disputed issues in relation to DNA evidence in criminal proceedings to date.³ One particular area of dispute was in relation to the reliability of the DNA testing kit, Profiler Plus, currently used by all Australian forensic laboratories regularly involved in criminal casework.⁴

37.6 In 2001, defence counsel in several criminal trials objected to the admission of DNA analysis results obtained from the Profiler Plus kit. Counsel argued that because the manufacturer would not publicly disclose the primer sequences used in the kit, or the developmental validation data used in validating it, it was impossible to scientifically validate the test kit to determine its reliability. In *R v Karger*, the court held that the evidence was admissible on the basis that the Profiler Plus test kit is recognised and accepted by the relevant scientific community as reliable.⁵ This decision has been followed in a number of subsequent proceedings.⁶

37.7 As DNA technology has developed, a number of the disputed issues in relation to DNA evidence have been resolved. Currently, disputes are generally limited to the integrity of the evidence; the application of statistics and population genetics to the results achieved; and the ability of juries to understand the evidence to be able to give it proper consideration.

1 *Evidence Act 1995* (Cth) s 79.

2 *Ibid*, s 56. In relation to the exclusionary rules and discretions, see ss 135, 137, 138. See below for more detail.

3 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 14.14–14.40.

4 J Gans and G Urbas, 'DNA Identification in the Criminal Justice System' (2002) 226 *Australian Institute of Criminology: Trends & Issues* 1, 2.

5 *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001).

6 See eg *R v Gallagher* (Unreported, NSW Supreme Court, Barr J, 4 May 2001); *R v Kami & Kami* (Unreported, NSW District Court, Shadbolt J, 14 May 2001).

Integrity of DNA evidence

37.8 The reliability of DNA evidence depends on a number of factors, including the quality of the sample analysed, laboratory technique in the analysis of the sample, and interpretation of results.

Quality of the sample

37.9 While polymerase chain reaction (PCR) based testing is relatively insensitive to degradation, the extent to which degradation affects the test partly depends on the size of the DNA sample.⁷

37.10 The analysis of poor quality DNA samples may lead to uncertain results requiring substantial interpretation by the forensic scientist, and the potential for human error or varying opinions in the interpretation of the results. For example, where a DNA sample contains a mixture of several persons' samples, and the forensic scientist does not detect this, the resulting DNA profile may be incorrect.⁸ This might lead to a false positive result.

37.11 A recent Victorian Court of Appeal case highlighted the difference between evidence produced from a DNA sample that is:

- so pure and unadulterated that clear typings can be obtained at a large number of DNA sites giving rise to statistical improbabilities running into the millions or even billions; and
- so adulterated and so old, and the testing process of amplification so powerful, that the typings produced are affected by complications which preclude an expert from giving an opinion as to the statistical probabilities.

37.12 The Court warned:

One of [DNA proofing's] advantages is that those who are expert in the interpretation of the 'typings' produced by the testing can express their opinions — both as to the 'match' of the sample with the defendant's profile and the statistical probability of others in the community having the same 'match' — in a simple and apparently authoritative manner to the jury. However there are cases where the simplicity with which the opinion is expressed cannot be permitted to obscure the difficulties which have been encountered in the testing process. As in this case, those difficulties will include the poverty of the sample, its mixture with the bodily fluids of others, the age of the sample, the effect of the re-amplification process or the reliability of results and

7 D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 505–506.

8 While some kinds of samples are expected to be mixtures, this is not always the case. The chance of detecting a mixture by finding extra alleles at a locus depends on the proportion of DNA from each contributor and the chance that the contributors have different genotypes at one or more loci: *Ibid*, 508.

whether — because of or in spite of the encountering of these difficulties — any statistical probability can be pronounced as to the likelihood of other members of the community producing the same ‘match’.⁹

37.13 In that case, the prosecution experts could not give a rational explanation for aberrations in the readings at a large number of sites. They acknowledged that the analysis system was one previously unknown to them, and that as a result they had been unable to conduct a statistical calculation on the results. The Court concluded that it would have been virtually impossible for a jury to make a conclusion from this part of the DNA evidence.¹⁰

Contamination

37.14 Contamination may occur at any stage of the collection, transport or analysis of a DNA sample. A DNA sample may be contaminated with other human DNA in a number of ways, for example:

- the crime scene sample may contain a mixture of fluids or tissues from different persons due to the nature of the crime;
- the crime scene sample may be contaminated during sample handling at the crime scene or in the laboratory; or
- carry-over contamination may occur in PCR-based testing if the amplification products of one test are ‘carried over’ into the mix for a subsequent PCR test.¹¹

37.15 A case of apparent sample contamination occurred in New Zealand in 1999. The case involved the unexplained match between the DNA profile of an assault victim in Christchurch, and profiles created from DNA samples found at two separate homicide scenes in Wellington. DNA samples collected from each crime scene, including the assault, were analysed in the same forensic laboratory. Police were satisfied the assault victim had not been at either of the homicide scenes at any time.

37.16 An independent inquiry (Eichelbaum Inquiry) could not find any conclusive explanation for the false positive results. The inquiry identified a number of potential sources of contamination, including bench contamination, instrument contamination, failure to observe certain protocols, and deliberate contamination. It concluded that, on the balance of probabilities, the results were

9 *R v Juric* (Unreported, Supreme Court of Victoria, Court of Appeal, Winneke P; Charles and Chernov JJA, 29 May 2002), [20].

10 *Ibid*, [19].

11 D Kaye and G Sensabaugh Jr, ‘Reference Guide on DNA Evidence’ in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 514–515.

caused by accidental contamination of the crime scenes samples during an early stage of processing at the laboratory.¹²

Laboratory error

37.17 Laboratory errors may result in a false positive, false negative or an inconclusive result in profile matching. Laboratory staff could make errors in conducting a DNA analysis, or in interpreting or reporting the results of the analysis. This might result from a failure to comply with an established procedure, misjudgement by the analyst, or an accident.¹³ Alternatively, a false result might result from deliberate tampering with samples.

37.18 While protocols and precautions can be introduced to minimise the opportunity for error during analysis or interpretation, the potential for human error cannot be fully eliminated.

Improving processes

37.19 The Inquiry considers that the best way to ensure the integrity of DNA analysis and evidence is through protocols that minimise the opportunity for contamination, degradation or substitution of a DNA sample, and other forms of error in the analysis and reporting process.

37.20 Laboratory accreditation programs provide an important means of ensuring quality control and assurance in the DNA analysis process, by setting minimum standards and procedures, and providing external oversight of adherence to them. In Australia, the National Association of Testing Authorities, Australia (NATA) operates a national system of laboratory accreditation for forensic science (see Chapter 36 for more detail).

37.21 In Chapter 36, the Inquiry proposed that forensic procedures legislation should provide that forensic analysis of genetic samples must be conducted only by laboratories accredited by NATA in the field of forensic science. The Inquiry considers that Proposal 36–9 is equally important as a means of protecting the integrity of DNA analysis and results. However, laboratory accreditation alone cannot guarantee the integrity of DNA evidence in every circumstance.¹⁴

12 Rt Hon Sir Thomas Eichelbaum and Sir John Scott, *Report on DNA Anomalies* (1999), Auckland. The report commented that while there was no direct evidence of contamination, they had eliminated all other hypotheses: para 8.3.

13 D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 510.

14 For example, the Eichelbaum Inquiry noted that the New Zealand laboratory at which the sample contamination most likely occurred was accredited by the American Society of Crime Laboratories Directors (ASCLD) and had met these audit requirements. The inquiry recommended a number of changes to laboratory procedures to minimise the risk of future problems: Rt Hon Sir Thomas Eichelbaum and Sir John Scott, *Report on DNA Anomalies* (1999), Auckland, para 8.10.

Presentation of DNA evidence

Statistical interpretation of evidence

37.22 A match between the DNA profile obtained from a crime scene sample and a defendant's profile does not prove that the defendant is the offender. There may be several alternative explanations for a DNA match, including the possibility that the sample was innocently left at the crime scene before or after the offence; the possibility of error or tampering; the possibility that the sample originated from a close relative of the suspect; or the possibility that it originated from an unrelated person who, by coincidence, has the same DNA profile as the suspect.¹⁵

37.23 As a DNA profile contains only a very small section of a person's DNA, it is possible that two persons might have the same DNA profile, by coincidence. There have been no known cases of match coincidence in Australia, but two cases have been reported overseas.

37.24 One case involved a British man who was charged with burglary in 1999 as a result of a coincidental match between the DNA sample found at a crime scene and his profile, which was stored on the United Kingdom's national DNA database. The profiles matched at six loci along the DNA molecule, but there was no match upon subsequent comparison at ten loci. The coincidence had a probability of one in 37 million.¹⁶ The Eichelbaum Inquiry, discussed above, considered the second case of coincidence, which in that case appeared to result from contamination of samples.

37.25 Forensic scientists must interpret the evidential value of a match. Scientists present their statistical calculations in one of two ways. First, the 'match probability' is the probability that a randomly selected, unknown, unrelated person would have the same DNA profile as the suspect.¹⁷ The forensic scientist needs some knowledge of the frequency with which the alleles occur within a population, and population databases are used for this calculation. As Ian Evett and others have commented:

There appears to be a fairly widespread misconception that there is a real 'statistical probability' to be assigned to a profile but this is not the case. There is an infinite range of ways of carrying out the calculation that underlies the figure given. The

15 D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 520.

16 L Lee, 'England Man to Sue Police Over DNA Mistake', *Newsbytes* (Minneapolis), 18 February 2000. The man had an alibi, lived 200 miles from the crime scene, was suffering Parkinson's disease and could not drive. There was no other evidence linking him to the crime.

17 National Research Council Committee on DNA Forensic Science, *The Evaluation of Forensic DNA Evidence* (1996) National Academy Press, Washington, 127; I Evett, 'DNA Profiling: A Discussion of Issues Relating to the Reporting of Very Small Match Probabilities' (2000) *Criminal Law Review* 341, 346.

method chosen in the individual case must be seen to be as much a matter of opinion as one given in other areas of forensic science. The match probability is 'personal'. It is based on what the scientist considers to be the most appropriate calculation given the circumstances of the case.¹⁸

37.26 It has been argued that match probabilities may be unfairly prejudicial in certain circumstances, such as where there is a chance that the suspect and offender are identical twins, siblings, or otherwise closely related; or if they belong to the same ethnic community. Therefore, where an innocent suspect and the offender are members of the same family, or even ethnic community, this could result in a higher than random probability that their DNA profiles will match.¹⁹

37.27 In addition, false positives might occur as a result of contamination or other laboratory error, misinterpretation of results, or tampering. The Inquiry understands there is some dispute as to whether and how to incorporate the possibility of error into the calculation of match probabilities.²⁰

37.28 The second form of calculation is the 'likelihood ratio' (LR). This is the ratio of the probability of a match if the DNA in the evidence sample and that from the suspect came from the same person, to the probability of a match if they came from different persons. For example, a likelihood ratio can be expressed as 'an LR of 1,000'. This means the probability that the profiles are the same is 1,000 times as great if the samples came from the same person as if they came from different persons.²¹

Jury comprehension of DNA evidence

37.29 The early Australian authorities supported the exclusion of DNA evidence on the basis that the probative value of the evidence was, in the circumstances, outweighed by its prejudicial tendencies. However, subsequent cases have considered conflicting expert testimony about the reliability of specific DNA testing methods as a matter for the jury to determine, subject to appropriate judicial direction.²² Deborah Kellie has commented:

18 I Evett, 'DNA Profiling: A Discussion of Issues Relating to the Reporting of Very Small Match Probabilities' (2000) *Criminal Law Review* 341, 346.

19 See eg D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 526–527. See also Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 3.36.

20 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 3.34.

21 National Research Council Committee on DNA Forensic Science, *The Evaluation of Forensic DNA Evidence* (1996) National Academy Press, Washington, 127–129. A third method of statistical calculation is Bayes' Theorem, which is widely used in parentage testing but not in criminal trials: Ibid, 130–133.

22 B Saul, 'Genetic Policing: Forensic DNA Testing in New South Wales' (2001) 13(1) *Current Issues in Criminal Justice* 74, 96.

The case law shows that the concern about admissibility of DNA evidence in Australia has been with the jury's competence to assess the evidence, particularly where there are competing experts, rather than with counsels' competence at leading evidence and cross examination.²³

37.30 In order to properly evaluate DNA evidence, the jury must have sufficient understanding of DNA analysis and the statistical calculations used to determine its probative value. In most cases, it is the role of the expert scientific witness to explain the science and technology of DNA analysis, the interpretation of the results, and their significance to the jury.²⁴ However, the prosecution and defence counsel must also have sufficient understanding to examine or cross-examine the expert witnesses appropriately. The trial judge must have sufficient understanding to properly direct the jury in its evaluation of the evidence.

37.31 Concerns about the ability of juries to properly understand and evaluate DNA evidence have arisen in two main contexts, discussed below.

Small match probabilities

37.32 As discussed above, expert evidence about matching DNA usually involves explaining how the forensic laboratory ascertained that the defendant's DNA profile matched the profile obtained from the crime scene sample, and an estimate of the random match probability.

37.33 There are a number of criticisms of this practice. It is often suggested that jurors, as ordinary members of the community, generally do not understand probabilities, and infinitesimal match probabilities (eg 'one in 90 billion') will so dazzle jurors that they will not be able to evaluate the evidence fairly and critically.²⁵

37.34 Evett and others have commented that probabilities of the order of one in trillions, following from calculations based on 10 locus profiles, require independence assumptions that cannot be evaluated by statistical experiment in the light of the size of existing databases. They suggested that very tiny numbers (for example, 'one in trillions') are not necessarily incorrect as a technical matter of mathematics, but are without any real meaning and lack credibility in the context of criminal proceedings.²⁶

23 D Kellie, 'Justice in the Age of Technology: DNA and the Criminal Trial' (2001) 25(4) *Alternative Law Journal* 173, 175.

24 The Hon Justice E Mullighan, 'Presenting DNA Evidence' (Paper presented at DNA Evidence: Prosecuting Under the Microscope International Conference, Adelaide, 11 September 2001), 4–6.

25 For example, see D Kaye and G Sensabaugh Jr, 'Reference Guide on DNA Evidence' in Federal Judicial Center (ed), *Reference Manual on Scientific Evidence* (2000) Washington DC, 485, 537–538.

26 I Evett, 'DNA Profiling: A Discussion of Issues Relating to the Reporting of Very Small Match Probabilities' (2000) *Criminal Law Review* 341, 347.

37.35 The Inquiry understands that the National Institute of Forensic Science (NIFS) and the Australian Institute of Judicial Administration are conducting a research project into jury comprehension of DNA evidence. This project should lead to more effective communication of DNA evidence and better understanding by juries.²⁷

Prosecutor's fallacy

37.36 The 'prosecutor's fallacy' is an error in relation to probabilities that usually favours the prosecution. The forensic scientist could make the error in presenting DNA evidence by misrepresenting its probative value. Alternatively, the evidence initially may be presented correctly but the judge or counsel inadvertently could commit the error in summing up. A third possibility is the jury could make an error in applying the evidence even though the evidence has been presented and summed up correctly.²⁸

37.37 Two different questions may be asked regarding evidence of a match between a defendant's profile and the profile obtained from a crime scene. First, what is the probability that the defendant's DNA profile matches the crime scene sample profile, given that he or she is innocent? Second, what is the probability that the defendant is innocent, given that his or her DNA profile matches the crime scene sample profile? The first question assumes the innocence of the defendant and asks about the chances of getting a match; the second assumes that the defendant's profile matches and asks about guilt or innocence. The 'prosecutor's fallacy' consists of giving the answer to the first question as the answer to the second.²⁹

37.38 In *R v Keir*, the NSW Court of Criminal Appeal considered whether the 'prosecutor's fallacy' had arisen during a criminal trial. The case involved the presumed murder of a woman in circumstances in which bone fragments were found buried under her house some years after her disappearance. DNA taken from the fragments was compared with her parents' DNA for the purpose of identification.³⁰

37.39 The expert witness gave evidence that it was 660,000 times more likely to obtain the DNA profile found in the bones if it came from a child of the missing woman's parents, rather than from a child of a random mating in the Australian population. However, in his directions, the trial judge (restating the prosecution's submissions) referred to the DNA evidence as providing a '660,000 to one' chance

27 National Institute of Forensic Science, *Consultation*, Melbourne, 5 September 2001.

28 D Balding and P Donnelly, 'The Prosecutor's Fallacy and DNA Evidence' (1994) *Criminal Law Review* 711, 711–712.

29 Ibid, 713, 716.

30 *R v Keir* (Unreported, NSW Court of Criminal Appeal, Giles JA; Greg James and McClellan JJ, 28 February 2002).

that the bones were those of the missing woman, and therefore a '660,000 to one' chance that alleged visual identifications of the woman after her disappearance were not correct.

37.40 The NSW Court of Criminal Appeal held that the Crown had fallen into the 'prosecutor's fallacy', and the trial judge had repeated the Crown's submissions. The Court noted that neither the defence counsel nor the trial judge had recognised the fallacy at trial.³¹

37.41 Even if the prosecution or the trial judge does not make this error, there is a danger that the jury will commit the fallacy in its consideration of the evidence. In *R v GK*, Mason P held that the evidence in question should have gone to the jury accompanied by appropriate directions emphasising the need to avoid the prosecutor's fallacy.³² In *R v Galli*, the Court held that although the direction about the prosecutor's fallacy might not be necessary in all cases where DNA evidence is admitted, a warning about impermissible reasoning would have been desirable in the circumstances.³³

Submissions and consultations

37.42 IP 26 asked what measures should be undertaken to ensure that juries are better informed about DNA science in order to understand and evaluate DNA evidence.³⁴ The Commonwealth Attorney-General's Department submitted:

Criticisms of DNA evidence are an understandable reaction to the widely held, but inaccurate, view that DNA matching can always conclusively determine guilt or innocence. In truth, the value of DNA evidence varies from case to case ... In some cases, DNA evidence will be of little value. In others, it may show a high probability that DNA found at a crime scene is the suspect's DNA.³⁵

37.43 The Human Genetics Society of Australasia (HGSA) submitted that it is important that jurors and those in the legal profession have information about the validity and interpretation of DNA evidence. They suggested:

A pre-trial information/teaching session outlining the issues involved may be given to jurors. Members of the legal profession who need to be more aware of the values of DNA evidence should undertake more substantive training ... One option may be to utilise an independent expert agreed to by both the defence and the prosecution to

31 Ibid.

32 *R v GK* (Unreported, NSW Court of Criminal Appeal, Mason P; Sully and Dowd JJ, 16 October 2001), [59].

33 *R v Galli* (Unreported, NSW Court of Criminal Appeal, Spigelman CJ; Sully and Adams JJ, 12 December 2001), cited in *R v Keir* (Unreported, NSW Court of Criminal Appeal, Giles JA; Greg James and McClellan JJ, 28 February 2002), [39].

34 Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, Question 14–1.

35 Commonwealth Attorney-General's Department, *Submission G158*, 7 May 2002.

provide an opinion to the judge on the DNA evidence pretrial, and if the evidence is to be admissible to appear as an adviser in court for the prosecution or defence if required ... As the cost should be borne by the Crown ... there would be equitable access to DNA technology for the defendant.³⁶

37.44 The Victoria Police submitted that Australian cases examining the admissibility of DNA evidence have developed tests to ensure that the evidence presented is relevant and of probative value:

[C]ourts can exercise control over both sides in a trial through the introduction of a practice rule that requires the development of an agreed statement of facts at *voir dire* to be presented to the jury, rather than leave the jury to wade through the science and jargon of DNA ... The amount of education on DNA that juries should receive is a complex issue. Too much education may give undue weight to the scientific evidence being presented, when it may only be one form of evidence in a trial. It may also inundate and confuse the jury with technical and complex information. Conversely, insufficient training prevents a jury from understanding the importance of the evidence being presented.³⁷

37.45 The Victoria Police suggested a multi-level approach, where scientists provide police, lawyers and magistrates with training in DNA evidence, the correct interpretations and the terminology used; and the most simple and effective means of communicating to a jury what the DNA evidence means and the interpretations that could be made. The submission noted that overseas institutions had developed education packages for police, lawyers, magistrates and the public.³⁸

37.46 The Androgen Insensitivity Syndrome (AIS) Support Group submitted:

Short of introducing special tribunals to hear and decide matters related to scientific evidence and an abolition of the principle of a person being tried by 12 of their peers for at least that part of the trial process, the only other way of dealing with inadequate understanding of the limitations of genetic information used this way is greater community education. It is very unlikely that a jury, even one considered to be educated and instructed appropriately, will understand in such a short time the nature of genetic information and the weight it should be given in a tribunal of fact.³⁹

Improving the use of DNA evidence at trial

37.47 DNA technology is an evolving area of science. Different methods of DNA analysis and statistical calculation may be employed by forensic scientists who will then be required to give evidence about these methods and results in criminal proceedings.

36 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

37 Victoria Police, *Submission G086*, 21 January 2002.

38 Ibid.

39 Androgen Insensitivity Syndrome Support Group Australia, *Submission G106*, 26 February 2002.

37.48 The Inquiry considers that a number of proposals may be necessary to ensure that DNA evidence is used in criminal proceedings in a way that is fair, and upholds the ethical standards expected in the use of genetic information. These proposals relate primarily to the presentation of the evidence, and the level of understanding of DNA science and evidence by each participant in criminal proceedings.

Education

37.49 The way in which DNA evidence is presented in criminal proceedings can be fundamental to the outcome of the proceedings, due to the scientific nature of the evidence, and the characteristically large numbers used to estimate the probative value of a DNA match.

37.50 The Inquiry considers there is a need for greater education in DNA science and evidence among the scientific profession, the legal profession and judiciary. For example, in *R v Keir*, the ‘prosecutor’s fallacy’ was committed by the prosecution, and was repeated by the trial judge, but was not corrected by the defence counsel. If the conviction had not been appealed, the mistake might not have become known and might have been continued in future criminal proceedings.

37.51 In the *Managing Justice* report, the Australian Law Reform Commission called for enhanced professional development and continuing education schemes in order to improve the efficiency and effectiveness of the justice system. In particular, the Commission called for greater emphasis on programs for trial lawyers and judges, to familiarise them with DNA science, technology and evidence.⁴⁰

37.52 In the United States, an organisation known as the Einstein Institute for Science, Health and the Courts (EINSHAC) provides education to judges, courts and court-related personnel in relation to a number of scientific and technical areas, including genetic evidence.⁴¹ A small number of Australian judges have already participated in EINSHAC programs, and this connection will be further strengthened by a round of meetings scheduled to be held in Australia in 2003.

Direction to juries

37.53 In the absence of direct empirical evidence about jury understanding of DNA evidence, it is unclear to what extent this is an issue in criminal proceedings. There are several potential ways to inform juries about the nature of DNA evidence

40 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), ALRC, Sydney.

41 Einstein Institute for Science Health and the Courts, *Website*, <<http://www.einshac.org>>, 24 September 2001.

to ensure they are able to properly evaluate the probative value of the evidence. For example, juries could be given written guidance in the form of booklets, explaining DNA evidence generally, for reference during the trial.⁴²

37.54 The Inquiry also has considered the need for a standard judicial direction to juries for use where a party to criminal proceedings seeks to rely on DNA evidence. For example, s 165 of the *Evidence Act* provides for judicial warnings to the jury in relation to evidence of a kind that may be unreliable, including identification evidence. Where a party requests the judge to do so, unless there are good reasons not to do so, the judge must warn the jury that the evidence may be unreliable; inform the jury of matters that may cause it to be unreliable; and warn the jury of the need for caution in determining whether to accept the evidence and the weight to be given to it.

37.55 On one view, there is no need to change the present position under the *Evidence Act*, in which case defence counsel would need to request a judicial warning under s 165 where they consider that, in the circumstances of a particular case, the DNA evidence is unreliable. Under this approach, jury directions regarding DNA evidence would continue to be dealt with on an ad hoc basis. Where defence counsel failed to request the direction, or where the judge, through error, determined the evidence might not be unreliable, the direction would not be given.

37.56 Another option is to propose that a standard jury direction in relation to DNA evidence should be inserted into the *Evidence Act*. The standard direction would provide that the trial judge must direct the jury on the need for caution in evaluating DNA evidence and the statistical calculations relating to that evidence; for example, juries could be warned about the potential unreliability of DNA evidence, the need to avoid the ‘prosecutor’s fallacy’, and the need to evaluate the evidence in the light of all the other evidence admitted in the proceedings.

37.57 The Inquiry prefers the latter approach because it ensures consistency in the judicial approach to DNA evidence in criminal proceedings. DNA evidence is a form of scientific evidence that may, without proper direction, be given more probative weight by a jury than is warranted.

37.58 While defence counsel has the opportunity to test the probative value of evidence through cross examination of an expert witness, the Inquiry is concerned the jury might nonetheless be ‘dazzled’ by the statistics presented to them, and might fail to consider the DNA evidence in the context of all the other evidence admitted. In addition, a judicial warning about impermissible reasoning would help

⁴² The Hon Justice E Mullighan, ‘Presenting DNA Evidence’ (Paper presented at DNA Evidence: Prosecuting Under the Microscope International Conference, Adelaide, 11 September 2001), 5–6.

guard against the jury introducing the ‘prosecutor’s fallacy’ even though the evidence was presented and summed up correctly.

Managing DNA evidence

37.59 The Inquiry recognises that there is ongoing debate within the field of forensic science about the appropriate means of calculating and presenting DNA evidence. The Inquiry considers that some form of independent standard setting should be provided regarding the use of DNA evidence in criminal proceedings.

37.60 The NSW government has proposed the establishment of a State Institute of Forensic Sciences (SIFS) to oversee the organisation and management of forensic sciences and the use of technology in criminal investigations and prosecutions. This is a joint proposal of the NSW Police Service, the Attorney-General and the Department of Health. In its review of the NSW forensic procedures legislation, the NSW Legislative Council Standing Committee on Law and Justice (NSW Standing Committee) considered that this would be an appropriate body to further assess the most effective means of accurately presenting this form of evidence in proceedings.⁴³

37.61 The Inquiry agrees with this approach and proposes that a body with expertise in forensic science and court proceedings should provide ongoing guidance to forensic scientists and legal practitioners regarding reliable methods of DNA analysis, statistical calculation, and presentation of evidence in criminal proceedings.

37.62 The Inquiry recognises that an existing body, the National Institute of Forensic Science (NIFS), already fulfils functions similar to this proposal. The core functions of NIFS are to sponsor and support research in forensic science; advise on and assist with the development and co-ordination of forensic science services; gather and exchange forensic information, including through the establishment of a national forensic reference service; support, co-ordinate and conduct training programs in forensic science; and conduct relevant quality assurance programs. An additional function is to raise the profile of forensic science.⁴⁴ In the light of its current functions, the Inquiry considers that NIFS would be an appropriate body to take on this role.

43 Legislative Council Standing Committee on Law and Justice, *Review of the Crimes (Forensic Procedures) Act 2000*, Report No 18 (2002), Parliament of NSW, Sydney, para 3.52–3.53.

44 NIFS was established as a national common police service, under an agreement signed by the Australasian Police Ministers’ Council in 1991. NIFS reports to the Australasian Police Ministers’ Council. Its board of control comprises three Commissioners of Police, three forensic laboratory directors and the current chair is the Chief Justice of Victoria: *National Institute of Forensic Science website*, <http://www.nifs.com.au/NIFS/NIFS_frame.html?about.asp&1>, 18 July 2002.

Proposal 37–1. The National Judicial College of Australia and the Law Council of Australia (through its constituent professional associations) should ensure the availability of continuing legal education programs for judges and legal practitioners, respectively, in relation to DNA evidence.

Proposal 37–2. A standard jury direction should be inserted into the *Evidence Act 1995* (Cth) for use where DNA evidence has been admitted in criminal proceedings. The direction should outline the warning that trial judge should give the jury regarding the need for caution in evaluating DNA evidence and the statistical calculations relating to that evidence.

Proposal 37–3. The National Institute of Forensic Science should provide ongoing guidance to forensic scientists and legal practitioners regarding reliable methods of DNA analysis, statistical calculation, and presentation of evidence in criminal proceedings.

Access to independent analysis

37.63 Where the prosecution seeks to rely on DNA evidence in a criminal prosecution, the Inquiry understands the usual procedure is for the prosecution to give defence counsel access to the crime scene samples, and the DNA analysis results, as part of pre-trial disclosure. This is consistent with the recommendation of the Consultative Committee on Police Powers of Investigation:

[t]hat in any case where a sufficient crime scene sample is available to permit independent analysis on behalf of the accused person, the accused person has a right to access to a sufficient portion of such sample as to allow analysis to occur.⁴⁵

37.64 Where a DNA sample is obtained from a person under Part 1D of the *Crimes Act*, the AFP must make part of the material available to the person as soon as practicable after the procedure has been carried out.⁴⁶ If material taken from a person is analysed in the investigation of the offence, the AFP must ensure a copy of the analysis results are made available to the person.⁴⁷

⁴⁵ Consultative Committee on Police Powers of Investigation, *Body Samples and Examinations* (1989), Victoria, Melbourne, 245.

⁴⁶ *Crimes Act 1914* (Cth) s 23XU. However, if there is insufficient material to be analysed both in the investigation of the offence and on behalf of the person, and the material does not need to be analysed immediately after the sample is taken, the person can request that a person be present while the material is analysed, or to be present personally during the analysis: *Crimes Act 1914* (Cth) s 23XUA.

⁴⁷ *Crimes Act 1914* (Cth) s 23XW.

37.65 However, there is no legislative requirement at the federal level that the prosecution must provide all or any part of a crime scene sample to a defendant. This could have significant implications in relation to DNA evidence. The Queensland case of *R v Button* provides an example of the potential consequences where the prosecution fails to analyse a crime scene sample prior to trial.⁴⁸ In that case, the Queensland Court of Appeal held that this failure led to a miscarriage of justice. If the sample had been analysed before the trial, the defendant would have been excluded as a suspect in the investigation. Instead, the sample was not analysed and the defendant was convicted of the offence. Williams JA commented:

What is of major concern to this Court is the fact that the evidence was not available at the trial ... What is disturbing is that the investigating authorities had also taken possession of bedding from the bed on which the offence occurred, and delivered those exhibits to the John Tonge Centre. No testing of that bedding was carried out prior to trial. The explanation given was that it would not be of material assistance in identifying the appellant as the perpetrator of the crime.⁴⁹

37.66 Williams JA emphasised the two-fold purpose of DNA testing, being to identify the perpetrator of a crime, and to exclude a possible offender as the perpetrator.⁵⁰

37.67 The Inquiry considers that in any criminal proceedings in which the prosecution relies on DNA evidence, it is important that the defence be given notice of, and access to, all genetic material collected from the crime scene. In addition, the defence should have sufficient access to retesting and independent expert advice, and be in a position to evaluate the probative value of the evidence and cross-examine the prosecution's expert witness effectively.

37.68 Where defence counsel is not given access to all probative evidence; has insufficient knowledge of DNA to properly evaluate the weight of the evidence; or does not have the funds to obtain independent advice on the evidence, this will undermine the defendant's chance of obtaining a fair trial.

37.69 A number of submissions raised concerns about the impact of the cost of DNA testing and expert advice on the defendants' access to independent analysis of the evidence. The NSWLAC submitted:

The cost of DNA testing and expert evidence is a concern to this Commission. An increasing emphasis on DNA evidence adds to the cost of criminal trials in circumstances where the Commission's budget is already overstretched. The Commission is a significant participant in the criminal justice system. However, increases in funding to law enforcement agencies are not accompanied by increased

48 *R v Button* (Unreported, Queensland Court of Appeal, Williams JA, White and Holmes JJ, 10 April 2001).

49 *Ibid.*

50 *Ibid.*

Commission funding. An increasing emphasis on expensive DNA evidence in criminal trials will have an impact on the services the Commission can provide to its clients.⁵¹

37.70 The Victoria Police noted that access to independent laboratories is usually dependent upon sufficient access to funds, and the availability of properly accredited independent laboratories.⁵² The HGSA submitted that defendants should have a legislative right of access to independent DNA analysis and expert witnesses as part of their defence in a criminal trial.

The cost of using DNA evidence may be high. In some cases, access to independent expert witnesses may involve the use of overseas experts. Allowance should be made for equitable access to DNA analysis and expert witnesses for both defence and prosecution. The right of the defendant to have access to this, as part of their defence in a criminal trial, should be enshrined in legislation and legal aid funding should be reviewed in light of this proposal.⁵³

37.71 The Inquiry recognises the fundamental importance of access to independent DNA analysis and advice to ensure that a defendant receives a fair trial. This is particularly important where analysis of a crime scene sample may provide material evidence that would assist the defence in rebutting the prosecution case.

37.72 As discussed above, Part 1D of the *Crimes Act* currently requires the AFP to provide suspects, serious offenders and volunteers with a portion of any DNA sample taken from them by way of a forensic procedure (where there is sufficient material to share), and a copy of the analysis of that sample. The Inquiry considers that as a matter of procedural fairness, similar provisions should apply in relation to crime scene samples. The prosecution should have a legislative duty to provide the defendant with reasonable pre-trial notice of all DNA samples collected at a crime scene in order to have an opportunity to have this evidence independently analysed.

Proposal 37–4. Forensic procedures legislation should be amended to provide that the prosecution has a duty to provide defendants with reasonable pre-trial notice of all DNA samples collected at a crime scene in order to give defendants an opportunity to have this evidence independently analysed.

51 Legal Aid Commission of New South Wales, *Submission G087*, 21 January 2002.

52 Victoria Police, *Submission G086*, 21 January 2002.

53 Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

Admissibility of unlawfully obtained DNA evidence

37.73 Under the *Crimes Act*, evidence obtained from a forensic procedure is inadmissible if there has been a breach of, or failure to comply with, the provisions of Part 1D in relation to the forensic procedure or in relation to recording or use of information on the DNA database system. However, the court has a discretion to admit the evidence if it is satisfied on the balance of probabilities of matters that justify its admission in spite of the non-compliance; or if the person who is the subject of the forensic evidence does not object to its admission.⁵⁴ Section 23XX(5) provides a list of matters that the court may consider in making this decision. The probative value of the evidence will not itself justify the admission of the evidence.⁵⁵

37.74 If the judge admits the evidence, he or she must inform the jury of the breach or failure to comply with the legislation, and give whatever warning about the evidence the judge thinks appropriate in the circumstances.⁵⁶ Evidence obtained as a result of a forensic procedure is not admissible in proceedings if it is required to be destroyed under Part 1D.⁵⁷

37.75 In addition, the *Evidence Act* regulates the admissibility of evidence generally, including DNA evidence obtained under the *Crimes Act* provisions, and evidence obtained from a crime scene sample, or otherwise (for example, from a person's cigarette butt, used tissue or used glass).

37.76 Under the *Evidence Act*, the court must exclude evidence led by the prosecution if its probative value is outweighed by the danger of unfair prejudice to the defendant.⁵⁸ The court must exclude evidence that has been improperly or unlawfully obtained unless the desirability of admitting the evidence outweighs the undesirability of admitting evidence obtained in this way.⁵⁹ Finally, the court has a discretion to exclude evidence where it considers the probative value is substantially outweighed by the danger that the evidence might be unfairly prejudicial, misleading or confusing, or might result in an undue waste of time.⁶⁰

37.77 The highly probative value of DNA evidence means that trial judges will need to take care when considering the balance between the probative versus the prejudicial value of the evidence (and, where the evidence is admitted, in directing juries). For example, while an expert witness might present a random match probability in the order of 'one in one billion', this might not take into account the

54 *Crimes Act 1914* (Cth) s 23XX.

55 *Ibid*, s 23XX(6).

56 *Ibid*, s 23XX(7).

57 *Ibid*, s 23XY.

58 *Evidence Act 1995* (Cth) s 137.

59 *Ibid*, s 138.

60 *Ibid*, s 135.

possibility of a false positive resulting from contamination, tampering or laboratory error.

‘Behavioural genetics’

37.78 IP 26 noted that some scientists are currently undertaking research into whether there is a genetic component to various traits relating to an individual’s behaviour and personality, including intelligence, aggression, antisocial behaviour, anxiety, alcoholism and addiction. Research into behavioural genetics has raised concerns of a renewed interest in the notion of ‘genetic behavioural determinism’.

37.79 If these deterministic theories become widely accepted, defendants in criminal proceedings might seek to rely on these theories to prove that they should not be held responsible for their behaviour. For example, a defendant might admit striking the victim, but argue that his or her responsibility was diminished or eliminated because of a genetic predisposition to aggression and violence. These arguments have been raised in a number of criminal trials to date, without success.⁶¹

37.80 Privacy NSW submitted that, from a privacy perspective, a great deal of caution is called for before sanctioning an approach to the production of evidence which requires individuals to submit themselves to any form of mandatory genetic testing:

It might be argued that until more is known about the behavioural expression of genetic traits we should not be in too much of a hurry to create a potentially inflexible legislative structure. However, as parties to proceedings are already beginning to put these issues forward it is likely to be only a matter of time before courts start developing a more or less systematic response. Can we rely on the ability of the courts to discriminate between contentious and sound scientific evidence? ... Are courts likely to be sensitive to issues of privacy in determining requirements to produce genetic evidence? The weak development of privacy in the Australian common law has been a perennial theme ...⁶²

37.81 The Inquiry notes that the courts have taken a cautious approach to admitting arguments or evidence based on genetic behavioural determinism. The science in this area is still at an early stage of development, and no doubt in future there will be strong arguments about the extent of genetic determinism versus environmental influences and interactions, and about criminal responsibility and free will.

61 Eg, *Nelio Avelino DaSilva Serra v R* (Unreported, Court of Criminal Appeal of Northern Territory, Kearney, Angel and Priestley JJ, 24 February 1997).

62 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

37.82 The Inquiry is not in a position to add anything to this early discussion, much less to propose any changes to the law. The standing body proposed in Chapter 3, the Human Genetics Commission of Australia, will have a role to play in moderating community debate about these important issues in future.

38. Post-Conviction Use of Genetic Information

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Introduction

38.1 DNA evidence has become a powerful tool in exonerating convicted offenders. Depending on the circumstances of the offence, where DNA analysis excludes the convicted offender as the source of a DNA sample found at the crime scene, sufficient doubt of guilt may be established to overturn the conviction.

38.2 For example, in a sexual assault case involving only one offender whose DNA sample was found on or in the body of the victim, DNA analysis that excludes the convicted offender as the source of that DNA would provide substantial doubt about guilt. However, where the suspect has admitted that sexual contact took place, but claims that it was consensual, the presence or absence of DNA will be of little value.

38.3 By 30 June 2002, 108 convicted offenders had been exonerated in the United States as a result of post-conviction DNA analysis; a number of these had been on 'death row'.¹ The first Australian post-conviction exoneration occurred in April 2001, when a man's conviction for rape was quashed after DNA analysis of seminal fluid stains on the bed sheets found at the crime scene excluded him as the perpetrator. The evidence had not been tested before the trial.²

¹ *Innocence Project Website*, Benjamin N Cardozo School of Law, <<http://www.innocenceproject.org/>>, 30 June 2002.

² *R v Button* (Unreported, Queensland Court of Appeal, Williams JA, White and Holmes JJ, 10 April 2001). See also D Kellie, 'Justice in the Age of Technology: DNA and the Criminal Trial' (2001) 25(4) *Alternative Law Journal* 173, 174.

Evidence in post-conviction review

38.4 A person might seek to access the original crime scene sample for analysis to overturn his or her conviction where:

- the person was convicted before DNA technology became available;
- more sophisticated DNA technology since has become available;
- the prosecution omitted to test and analyse, or to introduce as DNA evidence at trial, a sample found at the crime scene for the purpose of the trial; or
- the defence failed to question the nature/quality/probity/presentation of the DNA evidence.

Avenues for obtaining a review of conviction

38.5 Every jurisdiction provides statutory avenues for appeal against conviction. In New South Wales, appeals against conviction at trial may be lodged on a timely basis with the NSW Court of Criminal Appeal (CCA); one ground for appeal is on the emergence of significant ‘fresh evidence’. Theoretically, there may be a further appeal to the High Court of Australia; however, in practice, appellants rarely are granted special leave to appeal on the basis of fresh evidence, and there are constitutional constraints on the capacity of the High Court to consider such evidence.³

38.6 In addition, Part 13A of the *Crimes Act 1900* (NSW) provides a framework for prisoners to petition the Governor for a review of a conviction, or a pardon. Upon receiving a petition, the Governor may direct that an inquiry be conducted. Alternatively, the Minister may refer the case to the CCA to be dealt with as an appeal, or may request the CCA to give an opinion on any point arising in the case. Applications for an inquiry may also be made direct to the Supreme Court, and the Court may direct that an inquiry be held on its own motion. The conviction may be quashed after a pardon is granted.⁴

3 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 (Cth) and Related Legislation*, Report 92 (2001), ALRC, Sydney, para 17.13–17.17.

4 See *Crimes Act 1900* (NSW) ss 474A–P.

38.7 The University of Technology, Sydney, and Griffith University each have established Innocence Projects, with the intention that law students may assist prisoners in gaining access to post-conviction review on the basis of DNA (and other) evidence.⁵

Access to crime scene samples

38.8 The collection, use and retention of crime scene exhibits and DNA samples in each Australian jurisdiction are generally regulated by police guidelines, rather than legislation.

38.9 Generally, crime scene exhibits are held by the police officer in charge of the investigation. DNA samples are usually stored at the forensic laboratory at which they are analysed. While DNA samples are currently stored long term, where the offence took place prior to the development of DNA technology, there can be no guarantee that the crime scene exhibit (which might include a bodily sample from which DNA can be extracted) has been retained. Prisoners can apply to the Office of the Director of Public Prosecutions (DPP) in the relevant jurisdiction, or to the relevant police service, for access to a crime scene exhibit or sample.

38.10 If an initial request for access to a crime scene sample is unsuccessful, a prisoner could seek access to the sample through a court order. Where the prisoner has lodged an appeal against conviction, the court may order production of the crime scene sample in relation to those proceedings. Where the prisoner has exhausted all avenues of appeal, the prisoner might be able to rely on some form of administrative law proceedings to obtain a court order for the production of the sample. In some circumstances — for example where the sample was collected before the introduction of DNA technology, or through error — the crime scene sample will not have been preserved.

38.11 The NSW Police Minister has established an alternative means for prisoners to obtain access to crime scene samples for DNA analysis, through an administrative body known as the Innocence Panel.⁶ Panel members include a District Court judge, the NSW Privacy Commissioner, the Director of Public Prosecutions, the NSW Police Commissioner, a Public Defender, an academic specialist in the area, and representatives of the NSW Legal Aid Commission and the Victims' Advisory Board.

5 These projects are based on the Innocence Project founded in 1992 by Professor Barry Scheck and Peter Neufeld at the Benjamin N Cardozo School of Law, Yeshiva University, New York.

6 Parliament of New South Wales, *Parliamentary Debates*, Legislative Assembly, 16 August 2000, 8253 (Mr Paul Whelan MP).

38.12 Once established, prisoners who believe that DNA evidence may prove their innocence will be able to apply to the Innocence Panel for a post-conviction comparison of their DNA with the crime scene sample. If an application is approved, the Panel will locate the crime scene sample (provided it is still in existence), and arrange the DNA analysis for a nominal fee. The analysis results could then be used as ‘fresh evidence’ in an appeal against conviction.

38.13 The Inquiry received a submission from Privacy NSW commenting:

As a member of the NSW Innocence Panel ... I feel obliged to comment on a potential weakness of such schemes. The body which reviews the availability of genetic evidence needs to be sufficiently independent from the original prosecution to have some credibility. However, unless it is adequately resourced the conclusions of an independent panel will have limited value and can scarcely replace those of the original investigators and prosecutors. There is a risk of raising expectations among convicted persons and their supporters which cannot be satisfied.⁷

38.14 The Panel was established in October 2001, but the Inquiry was advised in June 2002 that due to delays in establishing operating protocols, the Panel had not yet commenced processing applications.

Submissions and consultations

38.15 Dr Gregor Urbas outlined particular obstacles that might confront an appellant seeking to have a conviction overturned on the basis of DNA evidence, including:

- a sometimes narrow reading by appellate courts of the jurisdiction conferred under the ‘common form’ appeal statutes, with a reluctance to ‘usurp the function of the jury’;
- the requirements that any new evidence brought before the court of appeal be ‘fresh and cogent’, with the added difficulty that the High Court does not have power to receive fresh evidence in a criminal appeal; and
- the costs and difficulties of obtaining access to forensic material and having such material independently examined.⁸

38.16 Privacy NSW submitted:

Post-conviction review is a second best mechanism for ensuring that genetic evidence receives appropriate consideration. Of more importance is to expedite facilities for adequate appraisal and consideration of evidence by defence and appropriate appeal

⁷ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

⁸ G Urbas, *Submission G131*, 19 March 2002.

channels. The time limits on criminal appeals may be too short to allow proper investigation of the failure to disclose genetic evidence.⁹

38.17 The Victorian Police submitted that post-conviction review of DNA evidence should be a counterpart to the provisions that enable police to establish guilt through forensic evidence. The submission noted that overseas models and research regarding post-conviction review suggest the need for criteria to evaluate requests for testing, such as the availability of physical evidence for re-testing; the role of physical evidence in the case against the person; the probative value of re-testing; and the defence that was used at trial. The submission suggested that post-conviction review should not be considered as an alternative to the normal appeal process.¹⁰

38.18 The Victoria Police also commented on the implications of post-conviction DNA testing on policies for the retention and storage of exhibits, appeal periods, and the impact on victims. The submission noted that overseas examples indicate that it is essential that police and laboratories be funded to handle the increased need to store and analyse exhibits, and there be a requirement to specify or limit which exhibits are retained.¹¹

38.19 Finally, Dr Urbas raised privacy and ethical concerns regarding the need to obtain consent to the testing or retesting of a crime scene sample taken from a victim or a victim's relative.

Where the forensic material sought to be tested or re-tested as part of a post-conviction review originates from victims or victims' relatives, there are serious ethical difficulties in turning such material over without the consent of those involved, or more problematic still, in requiring such persons to provide fresh DNA samples for testing ... it is difficult to see how a full inquiry could proceed without the willing co-operation of the victim's family, or failing that, the extension of coercive powers in regard to forensic procedures significantly beyond current limits.¹²

Options for reform

Specific legislation

38.20 Several States in the United States have implemented legislation providing for post-conviction access to DNA testing and review of conviction. Most of these States have followed the Illinois or New York legislative models.¹³

9 Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

10 Victoria Police, *Submission G086*, 21 January 2002.

11 Ibid.

12 G Urbas, *Submission G131*, 19 March 2002.

13 K Christian, "'And the DNA Shall Set You Free': Issues Surrounding Postconviction DNA Evidence and the Pursuit of Innocence" (2001) 62 *Ohio State Law Journal* 1195, 1200, 1208.

38.21 Illinois provides a number of conditions that must be satisfied for access to post-conviction DNA testing. The evidence must have been secured in relation to the trial; the identity of the offender must have been at issue during the trial; the evidence must have been subject to a proper chain of custody; the results must have the scientific potential to produce new evidence ‘materially relevant’ to the assertion of actual innocence; and the testing methods must be accepted within the scientific community. The New York model requires instead that the results must raise a ‘reasonable probability’ that the verdict or sentence would have been more favourable to the defendant. Illinois limits access to DNA testing to prisoners convicted before genetic testing was available at trial; New York limits access to prisoners convicted before 1996.¹⁴

38.22 The Innocence Protection Bill 2001 has been introduced into the United States Congress to permit inmates convicted of federal offences to petition a federal court for post-conviction DNA testing.¹⁵ The bill provides that federal courts must grant a defendant’s request for post-conviction DNA testing if:

- the DNA evidence relates to the federal crime for which the defendant was convicted;
- the evidence is still in existence and in a suitable condition for testing;
- the evidence must not have been previously tested, or new DNA testing procedures must exist that will resolve an issue not resolved by previous testing;
- the testing procedures must be scientifically valid; and
- the testing must yield ‘new, noncumulative, exculpatory evidence material to the claim’ of innocence. If the DNA testing produces exculpatory results, the federal courts must order a hearing and make appropriate orders.¹⁶

Administrative bodies

38.23 As discussed above, the NSW Innocence Panel is an administrative body established for the purpose of arranging analysis of crime scene samples for use in appeals against conviction.

14 Ibid, 1200–03.

15 The Bill was re-introduced into Congress in June 2002: *Innocence Project Website*, Benjamin N Cardozo School of Law, <<http://www.innocenceproject.org/>>, 30 June 2002.

16 K Christian, “‘And the DNA Shall Set You Free’: Issues Surrounding Postconviction DNA Evidence and the Pursuit of Innocence’ (2001) 62 *Ohio State Law Journal* 1195, 1229–30. The Bill encourages state compliance by conditioning federal grant money on compliance with the Bill’s provisions.

38.24 The United Kingdom's Criminal Cases Review Commission (CCRC) is another administrative model for post-conviction review. The CCRC is an independent body responsible for investigating suspected miscarriages of criminal justice in England, Wales and Northern Ireland. To be eligible for case review, a person must generally have exhausted the normal appeals process. The CCRC can carry out its own investigations or arrange for others to do so.

38.25 After investigation, the CCRC can refer cases to the appropriate appeal court, or to the Home Secretary where it feels a royal pardon should be considered. Generally, the CCRC may refer a conviction, verdict or finding to a court of appeal only if it considers that there is a 'real possibility' that the conviction, verdict or finding would not be upheld.¹⁷

38.26 For example, the CCRC referred a case to the Court of Appeal in 1999, involving a man who had been convicted of armed robbery, on the basis that DNA profiling of a shoe, which had been crucial evidence in the trial, supported the prisoner's explanation that he had been forced to change shoes with a man whom he alleged was one of the robbers. The profiling technique had not been available at the time of the trial, three years earlier. The Court of Appeal overturned the man's conviction.¹⁸

Inquiry's views

38.27 DNA testing has the potential to 'establish innocence' for a number of persons previously convicted, and including some still serving prison sentences. DNA testing also can confirm guilt — and this has occurred in some cases in the United States, removing doubt about the guilt of a prisoner around whom long-running campaigns had developed alleging a miscarriage of justice. The Inquiry considers it would be desirable to establish an independent body to consider allegations of miscarriages of justice due to the use of, or failure to use, DNA evidence in a criminal prosecution.

38.28 The long-term preservation of the crime scene sample is fundamental to a prisoner's access to post-conviction DNA analysis. In Chapter 36, the Inquiry proposed that forensic procedures legislation should be amended to require the permanent retention of crime scene samples.

38.29 At this stage, the Inquiry considers the body should operate in a similar fashion to the English CCRC. However, it should be established on a legislative footing, to ensure public confidence in its independence, and thus in the integrity of the criminal justice system as a whole.

¹⁷ Criminal Cases Review Commission, *Annual Report: 2000-01* (2001), CCRC, London.

¹⁸ Criminal Cases Review Commission, *Press Releases: Referrals to the Court of Appeal*, <http://www.ccrc.gov.uk/latestnews/latestnews_referrals.htm>, 17 July 2002.

38.30 The body should consider applications for post-conviction review based on DNA evidence, where the person provides prima facie evidence that there has been a miscarriage of justice in the sense that a verdict of guilty could not be allowed to stand, and therefore the verdict should be quashed or a new trial should be ordered. In practice, the body should have the power to investigate an alleged miscarriage of justice by obtaining access to the crime scene sample, arranging analysis of the sample against the prisoner's DNA sample, and referring appropriate cases to the relevant appeal court or to the Governor for a pardon.

Proposal 38–1. The Commonwealth should legislate to establish an independent body to consider applications for post-conviction review based on DNA evidence where the person provides prima facie evidence that there has been a miscarriage of justice.

Proposal 38–2. The Standing Committee of Attorneys-General should consider developing equivalent legislation and processes in the States and Territories.

39. Civil Proceedings

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Introduction

39.1 IP 26 gave an overview of the potential use of DNA evidence in civil proceedings in relation to proof of causation and assessment of damages in certain tort claims.¹ To date there has been limited use of genetic information in civil proceedings in Australia, with the exception of the use of DNA parentage testing in family law proceedings and in relation to succession (see Chapter 31). However, commentators have suggested that as the predictive quality of genetic tests gains greater acceptance in the scientific and medical communities, this information could increasingly be used.²

39.2 This chapter discusses the potential use of genetic information that discloses a person's inherited predisposition to, or presymptomatic status for, a disease or condition in the context of civil proceedings. In addition, the chapter discusses the potential use of genetic information in the context of workers' compensation claims and common law actions for work-related injuries.

¹ Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (2001), ALRC, Sydney, para 14.66–14.75.

² See eg G Marchant, 'Genetics and Toxic Torts' (2001) 31 *Seton Hall Law Review* 949; M Rothstein, 'Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation' (1996) 71 *Indiana Law Journal* 877; J Wriggins, 'Genetics, IQ, Determinism and Torts: the Example of Discovery in Lead Exposure Litigation' (1997) 77 *Boston University Law Review* 1025; R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313.

Applications of genetic information

39.3 Genetic information could be used as evidence in various tort actions, including actions for personal injury and other forms of negligence, medical negligence or product liability. Genetic information could also be used in the context of workers' compensation claims or common law actions for injuries or illnesses suffered by employees as a result of employer negligence.

Potential application in tort actions

39.4 The legal elements of a claim in negligence are that the defendant owed the plaintiff a duty of care; the defendant breached that duty; and the plaintiff suffered damage that was caused by the breach of the duty and was not too remote in law.³ Where negligence is established, the court usually awards damages to the plaintiff. Damages can include past and future loss, including future lost earnings, sustained by the plaintiff.⁴

39.5 One commentator has argued that, in the past, the tort system generally treated all persons as 'identical black boxes' in relation to their risk from exposure to hazardous substances and agents. While there have been some limited exceptions, such as the 'egg-shell skull' rule in relation to highly vulnerable plaintiffs (see below), generally there has been no basis for discerning individual risk factors from the risk posed to the general population.⁵

39.6 There are a number of ways in which genetic information and, in particular, genetic test results could potentially be applied in tort actions.

Causation

39.7 A defendant in a negligence action might seek to use genetic information to disprove the plaintiff's allegation that the defendant caused the plaintiff's injury. For example, where a plaintiff had a genetic predisposition to the same condition that he or she ultimately developed, the defendant could argue that it was the predisposition, rather than the defendant, that caused the injury. The strength of that argument may depend on the penetrance of the genes, that is, on the strength of the link between the genetic mutation and the occurrence of the disorder.

3 S Berns and G Masel, 'Torts: Negligence' in G Masel (ed), *The Laws of Australia* (1997) The Law Book Company Limited, Sydney, vol 33.2, [1].

4 M Noone, 'Torts: Damages' in Geoff Masel (ed), *The Laws of Australia* (1993), vol 33.10, [1]-[3].

5 G Marchant, 'Genetics and Toxic Torts' (2001) 31 *Seton Hall Law Review* 949.

Susceptible plaintiffs

39.8 A plaintiff could seek to rely on genetic tests that show that he or she has a higher susceptibility to a particular chemical agent than the ordinary person to establish that exposure to that chemical caused the particular illness or injury. Alternatively, defendants might argue that they have no duty to protect genetically ‘hyper-susceptible’ persons from harm or injury, in particular where the defendant can show that its product is safe for the ‘normal’ population. However, this is inconsistent with an established doctrine of tort law — the ‘eggshell skull’ rule. This rule provides that a defendant is liable for the full damages to an unusually susceptible or fragile plaintiff, even if the extent of those damages would not occur in a ‘normal’ person.⁶

Duty to warn susceptible persons

39.9 Generally, the manufacturer of a product has a duty to warn of potential hazards posed by that product. Failure to provide an adequate warning can result in civil liability. With increasing knowledge of susceptibilities to chemicals, pharmaceuticals and other products, it might become necessary to consider to what extent a manufacturer has a duty to warn persons with specific susceptibilities of potential hazards to them.⁷

Assumption of risk

39.10 As more genetic tests become available, defendants could seek to rely on the ‘voluntary assumption of risk’ or ‘contributory negligence’ defence. A defendant could argue that a plaintiff knew, or should have known, that he or she had a genetic susceptibility to a particular agent and therefore should have taken greater precautions to avoid exposure.⁸

39.11 However, it is unlikely that this argument would be successful in the workplace context because occupational health and safety statutes place a duty on employers (rather than employees) to eliminate or minimise hazards in the workplace. In practice, employees might be compelled by financial circumstances to accept risks that are considered unacceptable by the general community.

Genetic monitoring

39.12 Chapter 29 discusses the use of genetic monitoring as part of health surveillance of employees exposed to hazardous substances in the workplace. Genetic biomarkers of exposure and effect can identify changes in a person’s cells

6 Ibid, 953–956, 960–961, 963.

7 Ibid, 956–957.

8 Ibid, 965.

as a result of exposure to toxic substances. These genetic changes can provide a measure of exposure to the substance, or an early diagnostic measure of the development of the disease before the onset of symptoms.

39.13 Plaintiffs could potentially rely on biomarkers of exposure and effect as evidence of a plaintiff's exposure to a hazardous agent, and of the harm suffered as a result of exposure. Defendants could rely on the absence of these biomarkers within the plaintiff to argue against causation. However, the use of such biomarkers in court proceedings will be limited until they are fully validated scientifically.⁹

Assessment of damages

39.14 Defendants who have been found liable in tort could seek to have the amount of damages reduced on the basis that the plaintiff has a predisposition to, or is presymptomatic of, a condition that would diminish the plaintiff's quality of life or lead to a shorter life expectancy. For example, where a defendant is found liable but can establish that the plaintiff would have developed the injury at some future point regardless of the defendant's action, the defendant might seek to have the damages discounted to compensate the plaintiff only for the period for which the defendant's actions accelerated the development of the injury.¹⁰

39.15 The defendant might alternatively seek to identify a genetic predisposition, or presymptomatic status, for any disease that could shorten or diminish the quality of the plaintiff's life. For example, the defendant might seek to use genetic tests that reveal the plaintiff is presymptomatic of Huntington's disease to argue that, because the plaintiff would not be expected to live beyond middle age, the court should reduce the amount of damages accordingly.

The need for judicial education

39.16 Evidence based on genetic test results is a form of opinion evidence. Under the *Evidence Act 1995* (Cth), opinion evidence is admissible if it is wholly or substantially based on a person's specialised knowledge, which is established by the witness' training, study or experience.¹¹ DNA evidence that is relevant to a fact in issue is admissible in civil proceedings unless it is barred under an exclusionary rule, or by judicial discretion.¹²

9 Ibid, 976.

10 Ibid, 968. The difficulty with this argument is in establishing that a person with a mere predisposition to a multifactorial disease would ultimately have developed the disease.

11 *Evidence Act 1995* (Cth) s 79.

12 Ibid, ss 56, 135, 138.

39.17 Chapter 37 discusses the impact of DNA evidence on criminal proceedings. The Inquiry considers that a number of the concerns identified in that chapter will also be relevant in the context of civil proceedings. For example, in the light of the often highly scientific nature of genetic test results, judges will need to balance the probative value of genetic evidence against its potential prejudicial effect when considering whether to admit such evidence. Once the evidence is admitted, the expert scientific witness must explain the science and technology involved in the genetic test conducted, the interpretation of the results, and their significance to the arbiter of fact, whether judge or jury.¹³ In addition, each party's counsel must have sufficient understanding to examine or cross-examine the expert witnesses appropriately. Finally, the judge must have sufficient understanding to evaluate the evidence, or to direct the jury in its evaluation of the evidence.

39.18 Justice Ming Chin of the Supreme Court of California has commented on the potential implications where genetic evidence is admitted in court proceedings:

The use of genetic information in court raises new evidentiary challenges. DNA evidence is often complicated and laborious to present, and those without a scientific background — including most judges and jurors — often have difficulty understanding it. A courtroom is not an ideal forum for resolving conflicts between scientific theories, yet judges will constantly be asked to referee battles among lawyers and scientific experts over the acceptance of DNA evidence. The complexity and rapid development of genetic science will exacerbate the problem. Scientists need ongoing dialogue and continuous re-examination to test their theories. In courtrooms, decisions must be made at the close of the evidence. This reality creates a natural tension between science and the law.¹⁴

39.19 In the *Managing Justice* report, the Australian Law Reform Commission called for enhanced professional development and continuing education schemes in order to improve the efficiency and effectiveness of the justice system. In particular, the Commission called for greater emphasis on programs for trial lawyers and judges, to familiarise them with science, technology and evidence.¹⁵

39.20 In the United States, an organisation known as the Einstein Institute for Science, Health and the Courts (EINSHAC) provides education to judges, courts and court-related personnel in relation to a number of scientific and technical areas, including genetic evidence.¹⁶ According to its website:

13 The Hon Justice E Mullighan, 'Presenting DNA Evidence' (Paper presented at DNA Evidence: Prosecuting Under the Microscope International Conference, Adelaide, 11 September 2001), 4–6.

14 M Chin, 'Genetics and Law: A Challenge for Lawyers and Judges in the New Millennium' (2002) 18(65) *Notizie de Politeia* 103, 105.

15 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), ALRC, Sydney.

16 Einstein Institute for Science Health and the Courts, *Website*, <<http://www.einshac.org>>, 24 September 2001.

Our calling is to make science accessible to the instruments of justice. Our mission is to provide judges, courts and court-related personnel with knowledge tools related to criminal and civil justice proceedings involving evidence from the genetic sciences — genetics, molecular biology, biotechnology and molecular medicine — and from new discoveries and technologies in the environmental and neuro-sciences. In sum, we emphasize the science and impacts of ... technologies in judicial system proceedings.¹⁷

39.21 A small number of Australian judges have already participated in EINSAC programs, and this connection will be further strengthened by a round of meetings to be held in Australia in 2003.

Submissions and consultations

39.22 The Inquiry received only a small number of submissions in relation to the use of genetic information in civil proceedings. The Human Genetics Society of Australasia submitted:

There should be no occasion in civil law where there is a compulsion for DNA testing ... In the broad context the adversarial nature of civil proceedings should be reviewed.¹⁸

39.23 Privacy NSW submitted:

Distinct approaches may be required in relation to requiring the production of potential evidence which is already held and requiring parties to submit themselves to the process of creating new evidence. Where evidence already exists there is an understandable tendency for privacy to lose out to relevance. However recent legislation expanding the scope of privilege for confidential professional advice and counselling can be seen to reflect the felt need to impose limits on some of the more intrusive effects of the expanded use of the courts' subpoena powers, in an age where litigation has come to rely on the potential of advanced information processing.

Where evidence will only become available if a party submits to testing other factors need to be considered. Should genetic evidence collected without the knowledge of a party in the course of an independent medical examination be admissible? Should the party who is sought to be tested be involuntarily exposed to the knowledge which testing might disclose? Should courts be entitled to draw adverse inferences from a refusal to submit to voluntary testing?

This is an instance where safeguards relating to genetic information might best be addressed in the context of legislation relating to evidence, rather than in general privacy legislation.¹⁹

39.24 The Victoria Police submitted:

¹⁷ Ibid.

¹⁸ Human Genetics Society of Australasia, *Submission G050*, 14 January 2002.

¹⁹ Office of the NSW Privacy Commissioner, *Submission G118*, 18 March 2002.

Consideration should be given to establishing an expert panel to advise a court on issues relating to the impact of genetic information that reveals that a plaintiff has a predisposition to disease or similar affliction ... It would seem unreasonable, however to allow one party to demand that another party in a civil matter undergo DNA testing to reveal genetic dispositions when the results would reveal just that, a disposition towards a condition, not a guarantee. The probability of developing the condition may be further complicated by environmental factors and the possibility of medical advances in treatment in the future.²⁰

Inquiry's views

39.25 The Inquiry is not aware of Australian civil proceedings in which either party has sought to introduce predictive health information into evidence. Outlined above are a number of potential applications of genetic information in civil proceedings, in particular in relation to issues of causation and damages.

39.26 In Chapter 37, the Inquiry made several proposals addressing the need for greater education of judges and legal practitioners in relation to the use of DNA evidence in criminal proceedings. The Inquiry considers that these proposals are also important in the context of civil proceedings, where courts will increasingly be asked to consider evidence based on genetic test results.

39.27 The Inquiry proposes that the National Judicial College of Australia and the Law Council of Australia (through its constituent state and territory law societies and bar associations) should develop continuing legal education programs for judges and legal practitioners, respectively, in relation to the use of genetic information in civil proceedings. These bodies should provide ongoing guidance regarding genetic technology, reliability of genetic testing, interpretation of genetic test results, and presentation of evidence in civil proceedings.

Proposal 39–1. The National Judicial College of Australia and the Law Council of Australia should ensure the availability of continuing legal education programs for judges and legal practitioners, respectively, in relation to the use in civil proceedings of evidence based on genetic information.

20 Victoria Police, *Submission G086*, 21 January 2002.

Workers' compensation

Current law and practice

39.28 Workers' compensation legislation in each Australian jurisdiction requires employers to insure against their statutory and common law liability to compensate employees for work related injury and disease that results in incapacity or death.²¹

39.29 Workers' compensation is a system of accident compensation for employees who suffer or contract work-related injuries or disease; and for the dependants of those whose death is attributable to employment.²² These schemes provide employees with compensation on a 'no-fault' basis. Depending on the legislation, the worker might also be able to bring a common law damages action against the employer.²³

39.30 An employee may be required to submit to a medical examination by a person nominated by the employer or its compensation authority upon notifying the employer of an injury²⁴ or submitting a workers' compensation claim.²⁵ Each jurisdiction also allows for the medical examination of employees in the course of resolving compensation disputes.²⁶

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- 21 R Johnstone, *Occupational Health and Safety Law and Policy: Text and Materials* (1997) LBC Information Services, Sydney, 549. See *Safety, Rehabilitation and Compensation Act 1988* (Cth); *Seafarers Rehabilitation and Compensation Act 1992* (Cth); *Workers Compensation Act 1987* (NSW); *Workplace Injury Management and Workers Compensation Act 1998* (NSW); *Workers Rehabilitation and Compensation Act 1986* (SA); *Workers Rehabilitation and Compensation Act 1988* (Tas); *Accident Compensation Act 1985* (Vic); *Workers' Compensation Act 1951* (ACT); *Workers' Compensation and Rehabilitation Act 1981* (WA); *Work Health Act 1986* (NT); *WorkCover Queensland Act 1996* (Qld).
 - 22 T Paine, 'Labour Law: Workers' Compensation' in J Golden and D Grozier (eds), *The Laws of Australia* (2000) The Law Book Company Limited, Sydney, vol 26.5, [1].
 - 23 R Johnstone, *Occupational Health and Safety Law and Policy: Text and Materials* (1997) LBC Information Services, Sydney, 575.
 - 24 *Safety, Rehabilitation and Compensation Act 1988* (Cth); *Seafarers Rehabilitation and Compensation Act 1992* (Cth); *Workers' Compensation Act 1951* (ACT); *Workplace Injury Management and Workers Compensation Act 1998* (NSW); *Workers' Compensation and Rehabilitation Act 1981* (WA); *WorkCover Queensland Act 1996* (Qld). See T Paine, 'Labour Law: Workers' Compensation' in J Golden and D Grozier (eds), *The Laws of Australia* (2000) The Law Book Company Limited, Sydney, vol 26.5, [113].
 - 25 *Workers Rehabilitation and Compensation Act 1986* (SA); *Workers Rehabilitation and Compensation Act 1988* (Tas); *Accident Compensation Act 1985* (Vic); *Work Health Act 1986* (NT). See T Paine, 'Labour Law: Workers' Compensation' in J Golden and D Grozier (eds), *The Laws of Australia* (2000) The Law Book Company Limited, Sydney, vol 26.5, [113].
 - 26 See T Paine, 'Labour Law: Workers' Compensation' in J Golden and D Grozier (eds), *The Laws of Australia* (2000) The Law Book Company Limited, Sydney, vol 26.5, [240].

Issues and problems

39.31 Genetic information might be relevant to workers' compensation in several ways. First, employers might face pressure from their insurance companies to exclude susceptible employees from the workforce. This pressure could take the form of higher premiums for employers who employ individuals with certain genetic susceptibilities.

39.32 In New South Wales, Queensland, South Australia, Victoria and Western Australia, workers' compensation premiums are recommended by a central authority having regard to the employer's risk and industry classification, the number of employees, and their remuneration. Premiums may also be loaded or discounted having regard to considerations relating to a particular employer.²⁷ In New South Wales, a premium discount scheme provides an incentive to employers to implement programs to impose workplace safety and return to work strategies for injured workers.²⁸ Under the Commonwealth's Seacare scheme, the premium is left to the insurer to determine; in Tasmania there is no legislative provision governing the fixing of premiums; and in the Australian Capital Territory the premium is subject to some legislative limitations, but is otherwise left to insurers to determine.²⁹

39.33 The second context in which genetic information might be relevant to workers' compensation is that insurers might seek access to an injured employee's genetic information once he or she has lodged a workers' compensation claim. This information could be used to identify any relevant susceptibilities that might minimise the insurer's liability to pay compensation. For example, the United States Equal Employment Opportunity Commission (EEOC) instituted proceedings against the Burlington Northern and Santa Fe Railway Company in 2001 for allegedly genetically testing, or seeking to test, 36 of its employees without their consent, after they filed claims for work-related carpal tunnel syndrome injuries. The company was allegedly seeking to detect whether the employees had a genetic predisposition to that condition.³⁰

27 Ibid, [228].

28 Workcover NSW, *Outline of the NSW Workers Compensation Premium Scheme 2001/2002* (2001) NSW Government.

29 T Paine, 'Labour Law: Workers' Compensation' in J Golden and D Grozier (eds), *The Laws of Australia* (2000) The Law Book Company Limited, Sydney, vol 26.5, [228]. The Seacare scheme is regulated under the *Seafarers Rehabilitation and Compensation Act 1992* (Cth).

30 The EEOC reached a mediated settlement with the company in May 2002: *EEOC v. Burlington Northern Santa Fe Railroad*, [Civ No 01-4013 MWB (N.D. Iowa Apr. 23 2001) (Agreed Order)]. See also US Equal Employment Opportunity Commission, *Press Release: EEOC Petitions Court to Ban Genetic Testing of Railroad Workers in First EEOC Case Challenging Genetic Testing under Americans with Disabilities Act*, 9 February 2001.

39.34 Another possibility is that insurers might in future seek to access an injured employee's genetic test results, which may have been obtained from health surveillance conducted in a previous workplace. The insurer might seek to establish that the employee was exposed to hazardous substances in a previous workplace and, although the condition manifested at the current workplace, the previous employer should be partly or wholly liable for compensation.

Submissions and consultations

39.35 IP 26 did not address this issue in great detail, and the Inquiry has received few submissions on it. Several submissions opposed the collection of genetic information in the context of workers' compensation claims.³¹ The Australian Council of Trade Unions (ACTU) submitted that many employers see employees' use of sick leave or workers' compensation as an indication of their suitability for employment. One of the grounds for opposing employers' access to their employees' genetic information was that:

Employers could find themselves required by insurers to minimise risk by not employing people with predispositions to disabling conditions, or face higher workers' compensation premiums. Collection of genetic information could also affect general workplace salary continuance insurance arrangements which are currently offered to all employees in some workplaces ... If such testing and data collection became widespread, it could very well lead to the development of an "underclass", whose employers, assuming they were employed, would be unwilling to invest in their training and development, or to offer them long-term advancement opportunities.³²

39.36 Dr Paul Henman submitted:

A possible consideration of genetic information by employers relates to claims for workers compensation that may involve a genetic component. This is a more complex matter as a workplace injury may combine with a genetic predisposition to a specific injury. In this scenario, it would only be appropriate (if at all) for the employee's genetic information to be made available when a claim for worker's compensation is made. This will enable a court to assess the extent to which an injury results from a workplace activity or from a pre-existing condition.³³

39.37 The National Council of Women Australia submitted that employers should not need to collect genetic information for this purpose, provided they obtain a 'waiver' from an employee in the event of the development of disease.

Employers who ascertain that an employee's or applicant's personal genetic information is potentially a problem in terms of Workers' Compensation could add a waiver clause but still employ the person. This would be fair to both parties ... An

31 See Australian Council of Trade Unions, *Submission G037*, 14 January 2002; P Henman, *Submission G055*, 15 January 2002; New South Wales Nurses' Association, *Submission G090*, 21 January 2002.

32 Australian Council of Trade Unions, *Submission G037*, 14 January 2002.

33 P Henman, *Submission G055*, 15 January 2002.

employer should not have access to a job applicant's genetic information for occupational health and safety reasons because the concern on the part of the employer that his insurance premiums might rise if he has someone afflicted can be allayed by again putting in a waiver "if at the time any symptoms develop from the situation of the environment, it is established that the genetic test results prior to employment showed a predisposition, there is no insurance cover".³⁴

Inquiry's views







39.38 The Inquiry outlined its proposals for the use of genetic information in employment in Part H of this Paper. The Inquiry is not aware of any instances in which Australian employers or insurers have sought to obtain or use genetic information in the context of a workers' compensation claim, or a common law claim for work-related injury. However, as the scientific reliability and range of genetic tests increases, and the cost of testing decreases, there will be clear incentives for employers or insurers to seek access to this information.

39.39 As the Inquiry has so far received few submissions on this issue, the Inquiry invites comment on issues and concerns in relation to the use of genetic information for workers' compensation.

Question 39–1. Should employers or insurers have access to an employee's genetic information to determine the liability, or to assess compensation or damages, in relation to a workers' compensation claim or a common law claim for work-related injury?

34 National Council of Women Australia, *Submission G095*, 31 January 2002.

Appendix A

  	  
NSW NEWBORN SCREENING PROGRAMME	NSW NEWBORN SCREENING PROGRAMME
Baby's Last name	For Phenylketonuria, Hypothyroidism, Galactosaemia, Cystic Fibrosis etc (see pamphlet "Test to Protect Your Baby")
Mother's Full Name	
Baby's Date of Birth Sex M/F Birth Weightg Gestation weeks	Collect from ALL newborns after 72 hours (but not less than 48) or on discharge, if sooner. If child is discharged under 48 hours, arrangements must be made for specimen to be recollected after 72 hours.
Date of Sample Test less than 48 hr [] Feeds: Breast/Formula/Soy based/TNP/Others	1. Warm heel before blood collection. 2. Puncture clean dry heel with a sterile disposable lancet (Point <2.4mm). Wipe away first drop of blood. 3. Blood must soak right through paper filling all circles completely. Do NOT layer blood. Only fill spot from one side. 4. Allow spot to dry before mailing (4 hours). 5. Return completed card <u>without delay</u>
Hospital of Birth	To: NSW Newborn Screening Programme
Hospital/Sample Source Paediatrician/Doctor In Charge	
Relevant Clinical Information	
Initial Repeat Test [] Test []	COMPLETELY FILL EACH CIRCLE - BLOOD MUST SOAK RIGHT THROUGH PAPER
COMPLETE ALL DETAILS REQUESTED ABOVE. COMPLETELY FILL EACH CIRCLE- BLOOD MUST SOAK RIGHT THROUGH PAPER	S&S 903TM # W-981