Contents

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) © 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

(ii) the scientific and medical applications of human genetic information which are, or could be, of benefit to the Australian community; and

(iii) evidence of, and the potential for, the inappropriate use or application of human genetic information; and

(iv) the range of Australian ethical opinion as to which, if any, uses and applications of human genetic information are ethically acceptable; and

(v) the global dimensions of issues relating to research, regulation and the protection of interests; and

(vi) any relevant existing or proposed international law and obligations; and

(vii) any relevant constitutional issues; and

(viii) any relevant existing or proposed Commonwealth legislation; and

(ix) the implications of the recent decision by Australian health ministers to develop a national health information network; and

(x) developments in other jurisdictions, including legislative and other regulatory action; and

(xi) 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

Participants

Australian Law Reform Commission

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

President

Professor David Weisbrot

Members

Justice Ian Coleman (part-time Commissioner)

Mr Ian Davis (Commissioner)

Mr Brian Opeskin (Commissioner)

Justice John von Doussa (part-time Commissioner)

Australian Health Ethics Committee

Chair

Dr Kerry Breen

Deputy Chair

Associate Professor Colin Thomson

Advisory Committee to the Joint Inquiry

Dr Kristine Barlow-Stewart, Director, Genetics Education Program of NSW
Ms Tassin Barnard, National Manager, Risk, AXA Australia
Dr Alexandra Barratt, Department of Public Health and Community Medicine, University of Sydney
Mr John Basten QC, Sydney Bar
Professor Don Chalmers, Dean of Law, University of Tasmania, and immediate past Chair of AHEC
Mr Malcolm Crompton, Federal Privacy Commissioner

Dr Christopher Cordner, Department of Philosophy, University of Melbourne, and Member of AHEC
The Hon Justice Arthur Emmett, Federal Court of Australia
Ms Barbara Flick, Consultant on indigenous health issues
Associate Professor Eric Haan, Director, SA Clinical Genetics Services
Professor John Hopper, Director, Centre for Genetic Epidemiology, University of Melbourne
Dr Suzanne Jamieson, Department of Work and Organisational Studies, University of Sydney
Ms Kate Moore, Consultant and former Executive Director of the Consumer's Health Forum
Dr Trevor Mudge, Vice President, Australian Medical Association
Professor Marcia Neave, President, Victorian Law Reform Commission
Mr Chris Puplick, President, Anti-Discrimination Board of NSW & NSW Privacy Commissioner
Dr Tim Smyth, Phillips Fox Lawyers
Ms Melissa Sweet, Journalist, Sweet Communications
Professor Ron Trent, Chair of the Department of Molecular and Clinical Genetics, Royal Prince Alfred Hospital, and Chair of the NHMRC's Gene Therapy Research Advisory Panel
Reverend Bill Uren, Ethicist, Mater Hospital, Brisbane, and Member of AHEC
Graham Whittaker, Chief Actuary, American International Assurance Co (Australia) Ltd
Professor Bob Williamson FRS, Director, Murdoch Childrens Research Institute, Royal Children's Hospital, Melbourne

Working Group on Law Enforcement and Evidence

Ms Margaret Cunneen, NSW Crown Prosecutor
Mr Doug Humphreys, Director of Criminal Law Branch, NSW Legal Aid Commission
Mr Stephen Odgers SC, Sydney Bar
Dr James Robertson, Director of Forensic Services, Australian Federal Police
Mr Alastair Ross, Director, National Institute of Forensic Science Australia
Ms Linzi Wilson-Wilde, Forensic DNA Specialist, NSW Police Service

(Other members subject to confirmation.)

AHEC Officers

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Ms Helen Willimott (from April 2001)

ALRC Officers

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Associate Professor Phillip Tahmindjis, Faculty of Law, Queensland University of Technology
Professor Don Chalmers, Dean of Law, University of Tasmania, and immediate past Chair of AHEC

List of questions

Chapter 2: Background and emerging issues

2–1 Should genetic information be treated as being so unique or more powerful than other forms of health information that it requires special legal protection or other exceptional measures? If so, in which contexts should this apply, and how should this special status be accommodated in practice?

2–2 Should there be a more uniform, national approach to the protection of human genetic information?

2–3 Should a standing body be established to advise government on issues related to human genetics and the ongoing development of the regulatory framework governing human genetics? If so, how should it be comprised?

Chapter 3: Ethical considerations

3–1 Is it acceptable to leave ethical concerns relating to the collection, use and disclosure of genetic samples and information to be regulated largely by the personal and professional ethics of health practitioners, researchers and others? Or should certain ethical concerns be given recognition, or greater recognition, in law?

Chapter 4: Privacy

4–1 Is the framework provided for privacy protection in the federal *Privacy Act* adequate to protect genetic information? If not, why not, and how might the existing framework be improved?

4–2 Does the higher level of protection afforded to 'sensitive information' (including health information) under the *Privacy Act* adequately cover all forms of genetic information?

4–3 Are there any potential privacy problems that arise in the practical application of the *Privacy Act* and the National Privacy Principles to:

- the collection of genetic samples and information?

- the use and disclosure of genetic samples and information?
- access by individuals to genetic samples and information relating to them?
- the de-identification of genetic samples and information?
- other aspects of genetic information privacy?

4–4 What particular issues arise from the application of privacy law to the protection of human genetic samples and information? For example:

- Is the familial nature of genetic information adequately recognised in privacy principles applying to the collection and disclosure of genetic information?
- Are the interests of individuals who prefer 'not to know' about genetic information relating to them adequately protected?

4–5 Does the federal *Privacy Act* provide an adequate framework for national regulation of health information privacy and, if not, why not?

4–6 Should there be uniformity or greater harmonisation of federal, state and territory laws concerning the privacy protection of human genetic information?

4–7 Would any deficiencies identified in the privacy protection of genetic information best be addressed through:

- amendments to the existing privacy laws; or
- the enactment of privacy legislation specifically dealing with all forms health information privacy legislation; or
- the enactment of privacy legislation specifically dealing with only genetic information?

Chapter 5: Discrimination

5–1 Should there be uniformity or greater harmonisation of federal, state and territory laws concerning discrimination in relation to human genetic information?

5–2 Do the various federal anti-discrimination laws adequately protect against unfair discrimination on the grounds of genetic status, or is there a need to amend the laws to clarify their application to genetic information? Alternatively, would it be better to enact legislation dealing specifically with genetic discrimination?

Chapter 6: Medical and other human research

6–1 Are commercialisation arrangements posing any additional or different pressures on researchers and the system of ethical review of human research? If so:

- what is the nature of these pressures and their practical implications?
- how should these matters be addressed by the regulatory framework?

6–2 Should the system of ethical review of research involving humans be subject to different mechanisms of accountability? For example:

- should there be more comprehensive reporting requirements applicable to researchers and to Human Research Ethics Committees (HRECs)?
- should there be more emphasis on the obligations of HRECs to monitor the ongoing conduct of research?
- what sanctions, if any, should be applicable to breaches of ethical requirements?

6–3 With respect to research involving humans, are the current guidelines on privacy in the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*, together with the guidelines under s 95 and s 95A of the *Privacy Act 1988* (Cth), adequate for the purpose of protecting the privacy of genetic information?

6–4 The NHMRC National Statement provides that HRECs may 'sometimes' waive consent after taking into account a number of factors, such as the extent to which it is 'impossible or difficult or intrusive' to obtain consent. Are these waiver principles operating satisfactorily in practice, or are other safeguards required?

Chapter 7: Human genetic databases

7–1 In the specific context of human genetic databases, do federal, state and territory laws provide an adequate framework for protecting the privacy of human genetic samples and information? If not, why not, and how might the existing framework be improved?

7–2 With respect to genetic information held in human genetic databases, are the current guidelines in the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*, together with the guidelines under s 95 and s 95A of the *Privacy Act 1988* (Cth), adequate to protect privacy?

7–3 In practice, what privacy concerns are raised by the use or potential use for research purposes of samples stored in the archives of pathology laboratories or in human tissue banks? For example:

- Is there any evidence that samples stored in the archives of pathology laboratories or in human tissue banks are being used for research without the consent of the individuals concerned or without proper oversight by HRECs?
- Should there be additional sanctions against the unauthorised use of samples in this way?

7–4 Should the Human Tissue Acts be amended to regulate the collection and use of human tissue samples for genetic research and, if so, in what way? For example, should the Human Tissue Acts require researchers to obtain patient consent as a precondition to using human tissue samples originally removed for therapeutic purposes?

7–5 Should individuals have a form of property right (which need not amount to full 'ownership') in their own genetic material, in order to be able to better protect the privacy of this material? If so, how should such a right be defined and recognised?

Chapter 8: Medical practitioners

8–1 Is there a need to educate health professionals better about ethical principles involved in genetic testing and information? Should medical practitioners be required to undergo specific training before being able to order genetic testing or interpret the results for patients?

8–2 Should the public availability of genetic testing be regulated so that it may be conducted only on the request of a medical practitioner and by an accredited laboratory?

8–3 Do medical practitioners require more guidance on the rights of individuals to obtain access to genetic information held in medical records (for example, on the application of National Privacy Principle 6 of the federal *Privacy Act*)?

8–4 What practical implications does the corporatisation of medical practice have in relation to patients' abilities to control the collection, storage, use and disclosure of information about them? For example, how are the duties of medical practitioners under the federal *Privacy Act* affected where personal ownership of medical records is replaced by ownership by a corporation (of which the medical practitioner may be a director and shareholder)?

8–5 In relation to the way medical practitioners handle genetic information and samples, does the existing ethical and legal regulatory framework provide adequate protection? If not, why not, and how might the existing framework be improved?

8–6 Should the content of the duty of confidentiality, reflected in ethical codes applying to the medical profession, be revised to take account of the specific characteristics of the genetic information?

Chapter 9: Health administration

9–1 In the specific context of population screening programs, do federal, state and territory privacy laws provide an adequate framework for protecting the privacy of genetic samples and information? If not, why not, and how might the existing framework be improved?

9–2 In the specific context of genetic registers, do federal, state and territory privacy laws provide an adequate framework for protecting the privacy of genetic samples and information? If not, why not, and how might the existing framework be improved?

9–3 What are the implications of moves towards a national system of linked electronic health records for the national regulation of health and genetic information privacy? Do these developments suggest a need for a single regulatory framework for health information privacy?

9–4 Does effective protection of health information privacy, including genetic information, require the use of a wider range of sanctions for breach (for example, enhanced criminal or administrative penalties)?

Chapter 10: Employment

10–1 Do federal anti-discrimination and workplace relations laws adequately protect a person with a predisposition to a genetic illness, but no symptoms, from unfair discrimination in the employment context?

10–2 How should a genetic predisposition be considered in relation to an individual's ability to fulfil the 'inherent requirements' of a particular position?

10–3 Where employers are permitted to conduct genetic testing, what measures should be put in place to establish the reliability, accuracy and proper interpretation of any genetic testing before making decisions based on that information?

10–4 Should employees in positions involving significant safety risks to the public and/or other employees (eg airline pilots and professional drivers) be required to undertake genetic testing? If so, how should this testing be regulated?

10–5 Should an employer have access to an employee or job applicant's genetic information for occupational health and safety reasons (such as to determine which employees have a genetic susceptibility to a disease that may triggered by specific environmental factors or substances present in the workplace)? If so, how should access to, and use of, such information be regulated?

10–6 Are there any other circumstances in which it would be justifiable for the genetic information of an employee or job applicant to be required by, or made available to, an employer?

10–7 In relation to privacy protection for employees under the federal *Privacy Act*, with respect to genetic information:

- Are Commonwealth public sector employees adequately protected?
- Are private sector employees adequately protected, in light of the 'employee records' exemption?

- Is there a need for uniform privacy regulation across public and private sector employment?

Chapter 11: Insurance

11–1 Is the information that agents and brokers currently receive from insurers adequate for them to advise insurance applicants effectively about the implications of genetic information? If not, what improvements could be made to the provision of such information?

11–2 How and to what extent should insurers be required to provide applicants with information and data that supports unfavourable underwriting judgments based on genetic information?

11–3 Should the standard medical authority provided for all types of health information continue to be used in relation to highly sensitive information, including genetic information? Alternatively, should an enhanced level of consent be required from the applicant in relation to genetic information to ensure that it is only collected when necessary?

11–4 In the specific context of insurance, do the new private sector privacy laws and arrangements provide an adequate framework for the protection of genetic information?

11–5 To what extent would it be appropriate for insurers to request for underwriting purposes:

- information about family medical history?
- the results of any existing genetic tests or analysis in relation to the applicant?
- that the applicant undergo genetic testing?
- the results of any existing genetic tests or analysis from members of the applicant's family?

11–6 In the specific context of insurance, do existing anti-discrimination laws provide an adequate framework for protection against discrimination based on genetic information?

11–7 How should insurers and government address the need to ensure the scientific reliability and actuarial relevance of genetic information used for underwriting purposes?

11–8 Is there any evidence that the potential use of genetic information by insurance companies is deterring individuals from taking genetic tests for clinical diagnosis or volunteering for genetic research? If so, how should these issues be addressed?

11–9 Does existing family medical history information requested from applicants in the majority of personal insurance proposals provide a sufficient level of information for risk rating, such that genetic test information might be excluded altogether from insurance underwriting?

11–10 If genetic information were to be excluded from underwriting, to what extent would this threaten the viability of the market for personal insurance?

11–11 Would the equitable treatment of all applicants for insurance 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?

11–12 Are there practical and cost effective mechanisms that could be introduced in the mutually rated personal insurance market to enhance access and equity for persons who might otherwise be disadvantaged because of genetic status? For example:

- providing a basic level of cover through community rating, with mutuality used for policies seeking coverage above this level?
- 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?

Chapter 12: Other services and contexts

12–1 Do existing anti-discrimination laws provide adequate protection against unfair or improper use of genetic information in the context of:

- the provision of government services, including access to education and health services?

- immigration processes?
- determining Aboriginal or other communal identity?
- participation in sport?
- or any other activities, services or entitlements?

To the extent any deficiencies may be identified, how should these be remedied?

12–2 Are there any other contexts in which the current or potential use of genetic information may raise ethical concerns, or have implications for unfair discrimination or personal privacy?

Chapter 13: Law enforcement

13–1 To what extent do the tests set out in Part 1D of the *Crimes Act 1914* (Cth), under which a decision-maker may authorise a forensic procedure in the absence of the consent of a suspect or a serious offender, adequately balance the public interest in law enforcement with protecting the privacy rights of those individuals?

13–2 Do the existing legal safeguards adequately protect the rights of vulnerable persons in relation to informed consent, and from unfair discrimination based on their vulnerable status? If not, how might these safeguards be improved?

13–3 In relation to volunteers, do the provisions of Part 1D of the *Crimes Act 1914* (Cth) adequately protect the principles of 'informed consent', individual privacy and protection from racial and other unfair discrimination? If not, how might these safeguards be improved?

13–4 Do the storage and destruction provisions of Part 1D of the *Crimes Act 1914* (Cth), in relation to forensic material and profiles, adequately protect individual privacy? If not, how might these safeguards provisions be improved?

13–5 Should the sharing of forensic material and DNA profiles across jurisdictions be regulated by legislation, or by ministerial agreements? Is a national, uniform approach required in this area to protect the privacy of an individual's genetic information?

13–6 Do existing laws and accreditation requirements adequately protect the confidentiality of genetic information held in forensic laboratories under Part 1D of the *Crimes Act 1914* (Cth)? If not, how might these safeguards be improved?

13–7 Is there a need for a national policy regarding access to 'Guthrie cards' for law enforcement purposes? If so, what should be the major elements of the policy, and should such a policy be cast in the form of legislation?

13–8 In relation to forensic material found at crime scenes, should Part 1D of the *Crimes Act 1914* (Cth) be amended to regulate its collection and destruction?

Chapter 14: Evidence

14–1 What measures should be undertaken to ensure that juries are better informed about DNA science in order to understand and evaluate DNA evidence?

14–2 In relation to the admissibility of unlawfully or improperly obtained DNA evidence in criminal prosecutions, are the exclusionary rules set out in the *Evidence Act 1995* (Cth) and Part 1D of the *Crimes Act 1914* (Cth) sufficient to discourage improper practices in obtaining such evidence?

14–3 Should forensic material, or information obtained from it, be admissible in Commonwealth criminal proceedings where it otherwise might have been excluded as having been improperly or illegally obtained, because of the operation of s 23YP(2)-(3) of the *Crimes Act 1914* (Cth)?

14–4 In light of the capacity for DNA evidence to 'establish innocence', should Part 1D of the *Crimes Act 1914* (Cth) be amended to provide a legislative framework for post-conviction review in relation to DNA evidence?

14–5 As a practical matter, do defendants currently have sufficient access to independent DNA testing and analysis services and expert advice?

14–6 Should genetic testing to establish paternity be regulated so that it may be conducted only by accredited laboratories, or only under the supervision of the courts, in order to meet concerns regarding informed consent, counselling and quality control?

14–7 Given the familial and the predictive nature of genetic information, should the procedural and evidentiary rules about discovery of medical and education records be reviewed? (For example, should a defendant in

negligence proceedings be entitled to require that a plaintiff undergo genetic testing — or should a defendant be entitled to discover records relating to a plaintiff's family members — in order to disprove causation or minimise damages for injury?)

1. Introduction to the inquiry

Contents

An ALRC-AHEC joint inquiry

1.1 In August 2000, the Attorney-General of Australia, the Hon Daryl Williams AM QC MP, and the Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, first 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] In February 2001, the same Ministers announced that terms of reference had been settled and signed, signalling the formal start of the joint inquiry.[2]

1.2 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.[3] The Commission has worked on medico-legal issues before, most notably in relation to alcohol, drugs and driving;[4] human tissue transplants[5] and informed consent to medical procedures.[6] However, it was considered that the addition of the specialist expertise of AHEC would be valuable to the success of the inquiry.

1.3 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.[7] The Minister for Health and Aged Care 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.[8] Some of AHEC's recent work has included the *National Statement on Ethical Conduct in Research Involving Humans*,[9] *Guidelines for Genetic Registers and*

1 Attorney-General and Minister for Health and Aged Care, Joint News Release, 'Gene Technology', 9 August 2000.
2 Attorney-General and Minister for Health and Aged Care, Joint News Release, 'Genetic Privacy', 7 February 2001.
3 The functions of the ALRC are set out in *Australian Law Reform Commission Act 1996* (Cth) s 21.
4 Australian Law Reform Commission, *Alcohol, Drugs and Driving*, Report 4 (1976), ALRC, Sydney.
5 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), Australian Government Printing Service, Canberra.
6 Australian Law Reform Commission, *Informed Decision-Making in Medical Procedures*, Report 50 (1989), ALRC, Sydney.
7 The functions of AHEC are set out in the *National Health and Medical Research Council Act 1992* (Cth) s 35.
8 Ibid, s 36.
9 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

Associated Genetic Material,[10] and an information paper *Ethical Aspects of Human Genetic Testing*.[11]

Advisory committees

1.4 It is standard operating procedure for the ALRC to establish a broad-based, expert Advisory Committee to assist with the development of its inquiries.

1.5 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; law; and privacy and anti-discrimination. A separate Working Group on Law Enforcement and Evidence also has been established, with experts on forensic medicine, DNA profiling, policing and trial practice. As always, attention has been paid to achieving a measure of gender, geographical and interest group balance.

1.6 The Advisory Committee and the Working Group each will meet several times during the course of the inquiry, 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 recommendations of the inquiry remains with the Commissioners of the ALRC and the members of AHEC.

Defining the scope of our inquiry

The terms of reference

1.7 The terms of reference for the joint inquiry 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'.

1.8 The terms of reference also acknowledge the breadth of contexts in which the use of genetic information may be relevant, and of potential concern, including in 'employment; health, including medical research, pharmaceuticals and health administration; insurance and superannuation; intellectual property; and law enforcement'.

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

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

1.9 The 'action' part of the terms of reference specifically asks the ALRC and AHEC to inquire into and report on:

> (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.

1.10 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'.

1.11 As suggested by the terms of reference and discussed further in Chapter 2, the specific drivers for the establishment of the inquiry were concerns about privacy and discrimination — especially in the contexts of employment and insurance — and these matters have been central to our research and consultation thus far.

1.12 It is accepted by the ALRC and AHEC that the inquiry also should cover existing or potential privacy, discrimination or ethical concerns about the use of human genetic information in a range of other contexts, including among other things medical research, patient care and health administration; the management of human genetic databases and tissue banks; law enforcement and evidence in court; and access to services and entitlements (for example, schools and nursing homes).

The organisation of this paper

Building blocks

1.13 The Issues Paper is organised around four basic 'building blocks', which are then applied to a number of specific contexts in which the use of human genetic information is, or may become, important.

Background matters and emerging issues in genetics

1.14 Chapter 2 describes some of the events that led to the establishment of the joint inquiry, including the Human Genome Project and various legislative initiatives and regulatory decisions in Australia. The chapter also provides a 'basic primer' on modern genetics and genetic testing, and considers the nature and role of 'genetic information'. Finally, the chapter looks at some basic approaches to regulating biotechnology and providing advice to governments about developments in human genetics.

Ethical considerations

1.15 Where the previous two chapters deal primarily with *legal* regulation, Chapter 3 considers the role of *ethics* — and specifically the sub-field of bioethics — in influencing medical and other human research and in protecting societal interests.

Privacy law

1.16 Chapter 4 examines the existing framework of Australian law protecting the privacy of genetic information, and makes special reference to medical records and other health information. These laws include the recent extension of federal 'light touch' privacy laws to the private sector (effective from 21 December 2001). The chapter seeks comment on possible deficiencies in the protection provided to genetic information specifically and possible approaches to reform. If deficiencies in privacy protection for genetic information are identified, a key question becomes whether these should be addressed through new regulation dealing specifically with genetic privacy, or accommodated within new health information or general information privacy regulation.

Anti-discrimination law

1.17 Chapter 5 covers existing anti-discrimination law and practice in Australia, with special reference to the possible application of disability discrimination law to the area of genetic information, as well competing or complementary regimes governing such areas as occupational health and safety.

Application to specific contexts

Medical and other human research

1.18 Chapter 6 examines ethical, privacy and related legal issues with respect to the use of genetic samples and information in the conduct of medical and other research involving humans. The chapter contains background information

describing the regulatory framework under which research is conducted in Australia, the processes that are required and the principles (especially ethical principles) that are to be followed. The chapter asks questions about how this framework, based on review of research proposals by Human Research Ethics Committees, operates in practice and whether the existing regulatory framework is adequate to protect genetic samples and information.

Human genetic databases

1.19 Chapter 7 looks at related issues involved in the collection, storage, use and disclosure of genetic samples and information held in human genetic databases, including in human tissue banks maintained by hospitals and public and private research organisations. This is an important area in which the interests of researchers — and ultimately the interests of society, since the research is aimed at achieving advances in medical diagnosis and treatment — must be balanced against the interests individuals may have in exercising control over their own genetic information.

Medical practitioners

1.20 Chapter 8 considers the role of medical practitioners in the protection of human genetic information. Medical practitioners provide advice on diagnostic and treatment options for genetic conditions, facilitate access to genetic testing, and provide advice and counselling on the implications and results of genetic tests. As health care providers, medical practitioners are important 'gatekeepers' of genetic information: they collect and store genetic information in health and medical records, and help to determine when and how genetic information is used or disclosed, and for what purposes. The chapter examines the existing regulatory framework that governs how medical practitioners handle genetic information. This framework includes the common law, legislation, guidelines and professional ethics.

Health administration

1.21 Chapter 9 looks at some systemic health administration issues raised by the collection, use and disclosure of genetic information and samples. These include health resource allocation issues raised by the increasing availability and potential use of genetic testing; population screening programs, such as newborn screening ('Guthrie cards'); and the development of electronic health record systems, including the proposed national health information network.

Employment

1.22 Chapter 10 considers the use of genetic information in employment, both in the workplace as well as in the process of applying for work. Generally, employers may seek access to an employee or job applicant's genetic information for the purpose of minimising risk in the workplace or to the public generally; to minimise their own business costs; or for occupational health and safety reasons. Indeed, there are strict common law and statutory obligations imposed on employers to maintain high standards of health and safety for all workers, as well as for customers and others. On the other hand, federal and state laws affirm the rights of individuals to be free from unfair direct or indirect discrimination in the workplace. Individuals also may be concerned about the privacy of their genetic information, and may desire assurance that employers will neither gain access to such information, nor pass it on to third parties, without their consent. There are difficult issues and balances to be struck in this area, particularly where genetic testing may reveal a susceptibility or predisposition to a medical condition, but the person concerned does not presently show any symptoms of that condition, and in fact may *never* develop the condition.

Insurance

1.23 Chapter 11 explores in some depth the potential use of genetic testing and information for the purposes of underwriting insurance policies. Insurance companies, especially life insurers, have collected and used family medical histories for well over a century. In recent times, however, the development of the potential to use information derived from DNA analysis has placed a greater spotlight on the collection and use of personal information by the insurance industry in Australia and overseas.

1.24 As noted in Chapter 2, one of the factors that led to the establishment of this joint inquiry was the scrutiny given by the Australian Competition and Consumer Commission (ACCC) to aspects of the genetic testing policy developed by the peak industry body in Australia, the Investment and Financial Services Association (IFSA).[12]

1.25 Among the specific issues canvassed in Chapter 11 are: how scientific reliability and the actuarial relevance of genetic information should be addressed by the insurance industry and government; the impact that the use of genetic information in insurance may have upon health and medical research; whether genetic information is necessary for underwriting insurance policies; and equity of access issues related to the use of genetic information.

12 Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999).

Other services

1.26 Chapter 12 considers a range of areas outside employment and insurance in which genetic information *might* be used to determine eligibility for, or the provision of, goods, services or entitlements. For example, should genetic information be used to determine eligibility for certain social security and training programs? Or used by hospitals to determine the allocation of scarce resources (such as organ transplants)? Or used as part of immigration screening for proof of a family relationship, or the good health of an intending immigrant? Or used to prove Aboriginal or Torres Strait Islander identity? Or used by school or nursing home authorities as a factor in determining admissions? Or used by sporting bodies to determine whether a person is fit to participate?

Law enforcement

1.27 Chapter 13 considers a number of issues of principle and practice in relation to the collection, storage and use of genetic information by law enforcement authorities, including in relation to the development of the National Criminal Investigation DNA Database operated by the federal agency CrimTrac.

Evidence

1.28 Chapter 14 then looks at the presentation and admissibility of DNA evidence in court, both in criminal matters as well as in civil proceedings (such as in relation to establishing paternity in a Family Court matter or determining causation or the award of damages in a personal injury suit).

Related matters not under investigation by this inquiry

1.29 Given the breadth of potentially important issues and concerns, the challenge for the inquiry has been to identify quickly the key matters with which to deal, taking into account our resources, other similar work being done in Australia (for example, by parliamentary committees), the tight timeframe for reporting, and anticipating the areas in which our ultimate recommendations may have the greatest likelihood of making a positive contribution to policy development in this country.

1.30 Thus, without minimising their importance, the ALRC and AHEC have determined that we could not sensibly or properly cover within the bounds of this inquiry a number of areas.

Genetically modified organisms

1.31 The federal government has had in place a voluntary system of regulation of genetically modified organisms (GMOs) since 1975, 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 action in the event of non-compliance. Industry, and increasingly the general community, had concerns about the lack of rules and standards, creating uncertainty in the market.

1.32 In 1998, the deficiencies of the voluntary system were recognised and legislation was developed collaboratively by the federal, state and territory governments after public consultation. 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, or using a GMO in the manufacture of another thing.

1.33 The Act establishes the Office of the Gene Technology Regulator, which has the primary role in regulating dealings with GMOs. The higher the risk factor involved in a particular dealing, the greater the level of regulation. Thus, while some dealings will be exempt from regulation, others (notifiable low risk dealings) must be notified to the Gene Technology Regulator, conducted in an accredited facility by an accredited organisation, and cannot be released into the environment. Any dealings of a higher risk, including any involving intentional release into the environment, can only be conducted under a license granted by the Gene Technology Regulator. Dealings conducted under licence that have proven to have no risk can be placed on the GMO Register. Any dealings on the GMO Register can be undertaken by any person or organisation without licence.

1.34 The Australian New Zealand Food Authority (ANZFA) maintains a list of genetically modified foods that are approved for use in Australia and New Zealand.[13] A food that is or contains a non-approved genetically modified food or ingredient is illegal. From 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'.

13 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.

1.35 There has been considerable public interest in Australia about genetically modified foods. However, given the recent move to place this area under formal regulation, and the fact that there is no direct connection with human genetic information, it is not a matter we can deal with further in this inquiry.

Access to assisted reproductive technology

1.36 Victoria, South Australia and Western Australia have legislation regulating access to in vitro fertilisation (IVF) — also known more generally as assisted reproductive technology (ART) — which, among other things, purports to limit access to women who are married or are in a de facto relationship with a man. The other States operate under guidelines established by the NHMRC that do not impose these restrictions.[14]

1.37 The question of access to assisted reproductive technology (ART) is currently before the High Court of Australia, on appeal from a decision by the Federal Court of Australia. In *McBain v State of Victoria*,[15] the Federal Court considered the validity of s 8(1) of Victoria's *Infertility Treatment Act 1995*, which provides that to be eligible to undergo infertility treatment a woman must either be married and living with her husband on a genuine domestic basis or be living with a man in a de facto relationship. Sundberg J held that this provision was in breach of the federal *Sex Discrimination Act 1984* (Cth) s 22, which makes it unlawful to refuse to provide services to another person on the ground of a person's marital status.

1.38 In 1996, in *Pearce v South Australian Health Commission*, the Full Court of the Supreme Court of South Australia considered a similar provision of that State's *Reproductive Technology Act 1988* (SA) s 13, which limited access to IVF procedures to a 'married couple' (including a man and woman in a de facto relationship of at least five years' duration). The Full Court came to the identical conclusion,[16] ruling that this provision was clearly inconsistent with s 22 of the federal *Sex Discrimination Act*, and constitutionally invalid.

1.39 Following *McBain*, the federal government announced its intention to amend the *Sex Discrimination Act* to remove IVF services from protection, but the amendment bill did not receive support from opposition parties. Although topical, this issue does not fall within the terms of reference for this inquiry, and in any event will soon receive clarification. At the time of writing, the High Court had heard argument in this matter, and had reserved judgment.

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14 National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology* (1996), NHMRC, Canberra.

15 *McBain v State of Victoria* (2000) 177 ALR 320.

16 *Pearce v South Australian Health Commission* (1996) 66 SASR 486.

1.40 Because of the potential to test IVF embryos for genetic conditions, the ALRC and AHEC considered briefly whether this general area should be part of this joint inquiry. However, it does not fall squarely within the terms of reference; the NHMRC already has announced its intention to review its guidelines in this area, and has called for public submissions;[17] and, as discussed above, the High Court will soon rule on the existing position. Consequently, this inquiry will not consider these issues further.

Human cloning and stem cell research

1.41 Guidelines developed by the NHMRC in 1996 generally prohibit research involving the destruction of human embryos, save in 'exceptional circumstances' in which there is a likelihood of a significant advance in medical knowledge or improvement of technologies or treatment.[18] A 1998 report by AHEC on *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*[19] was clear in its condemnation of the cloning of whole human beings (sometimes referred to as human reproductive cloning).[20] However, the report encouraged further discussion regarding the cloning of tissue or body parts for therapeutic use.

1.42 The *Gene Technology Act 2000* (Cth) includes a prohibition on the cloning of a whole human being.[21] This prohibition is intended as an interim measure until nationally consistent legislation is adopted by the States and Territories. Three States (Victoria, South Australia and Western Australia) already have legislation in place, while others rely on NHMRC Guidelines and ethics.

1.43 Denmark, Germany, Norway, Slovakia, Spain, Sweden, Switzerland and the United Kingdom, among other nations, have legislation in place explicitly or implicitly banning human reproductive cloning. The French and German governments recently issued a joint statement to the United Nations, urging the creation of a working group to draft a convention that would ban human cloning for reproductive purposes as 'an offence to human dignity'.[22] In the United States,

17 In September 2001, the NHMRC issued a notice of its intention to review these guidelines, under s 13 of the *NHMRC Act 1992* (Cth), to 'look at strengths and weaknesses of existing guidelines; recently emerged issues; regulation of existing and new practices, especially re embryo/stem cell research; the role of HRECs; any other relevant issues'.

18 National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology* (1996), NHMRC, Canberra.

19 Ibid.

20 See also M Soules, 'Human Reproductive Cloning: Not Ready for Prime Time' (2001) 76(2) *Fertility & Sterility* 232.

21 *Gene Technology Act 2000* (Cth) s 192B. The maximum penalty for breach is 2 000 penalty units or imprisonment for 10 years. The term 'cloning of a whole human being' is expressly defined to mean 'the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original': s 192B(2).

22 S Erlanger, 'France and Germany Jointly Seek a Ban on Cloning Humans', *The New York Times*, 22 August 2001.

the House of Representatives has supported a Bill that would prohibit reproductive and therapeutic cloning.[23]

1.44 In recent times, there has been considerable debate in Australia and overseas about the scientific and ethical merits of research involving 'embryonic stem cells'. Most stem cells are extracted from 'surplus' embryos produced as part of IVF programs, but which are no longer needed for those purposes. In the process of harvesting the central core (a cluster of about 100 cells) of the stem cells, however, such embryos (usually four-day-old embryos, called 'blastocysts') are destroyed. Greater ethical controversy attaches to the creation of embryos expressly for the purposes of harvesting stem cells, as has occurred recently in Australia[24] and the US.[25] However, there is also promising research emerging which suggests that stem cells may be retrievable from adult or placental tissue which, coupled with the informed consent of the donor, would have few, if any, ethical problems attached.[26]

1.45 The excitement about stem cell research is that, in theory at least, such cells can be manipulated in the laboratory to grow into any type of cell or tissue required — suggesting the possibility of 'a new era of regenerative medicine' based on stem cell therapy, with such serious diseases as juvenile onset (Type I) diabetes, Parkinson's disease, motor neurone disease, and Alzheimer's disease cured by 'replacement tissue grown to order'.[27] For example, researchers believe that they will be able to coax stem cells into growing into brain cells, heart cells,[28] nerve cells, muscle cells or insulin-producing tissue,[29] as may be required in the particular circumstances. Recent research also holds out the promise of using stem cells to grow red blood cells, white blood cells and platelets, for use in blood transfusions as well as to combat some kinds of leukaemia and bone diseases.[30]

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23 Human Cloning Prohibition Bill, 107th Congress, US House of Representatives Bill No. 2505.

24 D Smith and M Metherell, 'Embryo stem cell research bombshell' *The Sydney Morning Herald* 30 August 2001, 3.

25 See S Lanzendorf and others, 'The Use of Gametes Obtained From Anonymous Donors for the Production of Human Embryonic Stem Cell (ESC) Lines' (2000) 74(3) *Fertility & Sterility* 16; discussed in S Stolberg, 'Scientists Create Scores of Embryos to Harvest Cells: Medical Taboo is Broken', *The New York Times*, 11 July 2001; A Zitner, 'Embryos Created for Stem Cell Research', *The Los Angeles Times*, 11 July 2001.

26 See Committee on the Biological and Biomedical Applications of Stem Cell Research and others, *Stem Cells and the Future of Regenerative Medicine* (2001), National Academy Press, Washington DC, 13-20.

27 S Stolberg, 'Patent Laws May Determine Shape of Stem Cell Research', *The New York Times*, 17 August 2001.

28 I Kehat, 'Human embryonic stem cells can differentiate into myocytes with structural and functional properties in cardiomyocytes' (2001) 108(3) *Journal of Clinical Investigation*, 407, 414; reported in 'Team Turns Human Stem Cells into Heart Cells', *The Canberra Times*, 2 August 2001.

29 S Assady, 'Insulin Production by Human Embryonic Stem Cells' (2001) (50) *Diabetes* 1691, 1697; see also 'Insulin From Stem Cells Promises Treatment for Diabetes', *The Canberra Times*, 1 August 2001.

30 R Eccleston, 'Doctors Get Blood Out of Stem Cells', *The Australian*, 5 September 2001.

1.46 As has been widely reported, in August 2001, US President George W Bush ordered that US federal government funding of stem cell research may proceed only where the research is conducted on existing 'stem cell lines' (colonies of self-perpetuating stem cells),[31] to guarantee that no further human embryos will be destroyed as part of the research.

1.47 With the strong public/private distinction that operates across much of the regulatory sphere, publicly financed research is heavily regulated in the US, while there are few formal restraints operating in relation to entirely privately financed research (for example, research sponsored by large pharmaceutical companies).

1.48 Earlier this year the British House of Commons voted, by more than a two-to-one margin, to permit research on existing stem cell lines and the harvesting of new stem cells for authorised research purposes and, most controversially, to allow therapeutic cloning techniques to be used to create embryos for these purposes.[32]

1.49 The Australian House of Representatives Standing Committee on Legal and Constitutional Affairs spent two years reviewing AHEC's 1998 report on cloning, presenting its own report to the federal Parliament on 20 September 2001.[33] Reflecting the strong representation it had received from experts and the community throughout the inquiry, the Committee unanimously called for a national legislative ban on cloning for reproductive purposes. It also unanimously supported continued research involving adult and placental stem cells. However, the Committee, experts and the community were divided over the use of embryos in cloning research for the derivation of stem cells.

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31 The NIH maintains a very useful website on stem cell research, with a listing of all of the existing stem cell lines, including those maintained in Australia: see <http://www.nih.gov/news/stemcell/index.htm>. There is some controversy about whether all of these lines are usable: see G Kolata, 'Researchers Say Embryos in Labs are not Available', *The New York Times*, 26 August 2001. The US National Academy of Sciences recently has released a report calling for the development of new stem cell lines. See Committee on the Biological and Biomedical Applications of Stem Cell Research and others, *Stem Cells and the Future of Regenerative Medicine* (2001), National Academy Press, Washington DC. See also D Smith, 'Clone Age', *The Sydney Morning Herald*, 15 September 2001, 55.

32 See the debate on the Human Fertilisation and Embryology (Research Purposes) Regulations, made under the *Human Fertilisation and Embryology Act* 1990 (UK), in the House of Commons, 19 December 2000. In the UK, research projects involving human embryos or stem cells require the express approval of the Human Fertilisation and Embryology Authority. Research only could be done for one of five purposes: advances in the treatment of infertility; increasing knowledge about congenital diseases; increasing knowledge about the causes of miscarriage; developing more effective contraception techniques; or developing methods for detecting gene and chromosome abnormalities before implantation. The new regulations extend that regime to include basic research into stem cells and research into the understanding and treatment of serious disease. The vote was 366-174 in favour. See <http://www.parliament.the-stationery-office.co.uk/pa/cm200001/cmhansrd/vo001219/debtext/01219-21.htm>.

33 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.

1.50 In contrast to the British House of Commons, all members of the Australian Committee supported a ban on the deliberate creation of embryos for experimentation. The newer technique of creating embryos by somatic cell nuclear transfer, which does not involve fertilisation of an egg by a sperm, raised additional issues. The Committee called for a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years, after which time the issues should be re-examined by AHEC.

1.51 A majority of the Committee supported research, in defined limited circumstances, on embryos surplus to assisted reproductive technology programs (such as IVF). They also supported research on existing stem cell lines and any stem cell lines newly created from surplus embryos within defined circumstances. The remaining members of the Committee would restrict research to existing human embryonic stem cell lines, provided that these stem cells cannot develop into an embryo.

1.52 The Committee members recognised that the ultimate decision to legislate in relation to cloning and stem cell research would be made by the various parliaments of the Commonwealth, States and Territories. Regardless of whether embryonic stem cell research was to be permitted, permitted subject to restriction, or banned, the Committee agreed upon a regulatory framework including the following features:

- A national uniform legislative approach.
- A ban on cloning for producing children.
- A ban on the deliberate creation of embryos for research purposes (subject to a moratorium on somatic cell nuclear transfer).
- A single system of regulation for privately and publicly funded research.
- A national licensing body established to regulate human cloning and research using cloning techniques.
- The licensing of individual researchers for each research project that involves the use of an embryo.
- The imposition of a criminal penalty and the withdrawal of the licence to undertake research in the area for any attempt to undertake reproductive cloning.
- A ban on the import and export of embryos; however, the import and export of embryonic stem cells would be permitted within a prescribed framework.

1.53 On 8 June 2001, the Council of Australian Governments (COAG) decided to adopt a national approach to human cloning, stem cell research and related matters, so the Standing Committee's report will need to be considered by all state and territory governments as well as the federal government. (See Chapter 2, regarding national approaches to advice and regulation.)

1.54 In light of this comprehensive recent report — and the fact that AHEC already has commenced its review of the 1996 guidelines on Assisted Reproductive Technology, which will include guidelines on the use of embryonic stem cells[34] — the ALRC and AHEC will not be covering the same territory in this inquiry.

Gene therapy

1.55 The idea behind gene therapy is to identify point mutations in the genome responsible for illness, and then synthesise and apply corrective genes to rectify the defect.[35] Gene therapy is still experimental, and certainly not far enough advanced for routine use in clinical situations.[36] However, this may change in future due to promising research in Australia and elsewhere on the targeted delivery of gene therapy utilising artificial genes, rather than using retroviruses as a vector. To the extent that there is some activity, this is overseen by the Gene and Related Therapies Research Advisory Panel (GTRAP), an advisory body established by the NHMRC.[37] As a consequence, the joint inquiry will not focus on issues of gene therapy.

Prenatal and pre-implantation testing

1.56 Prenatal testing is performed to determine whether the embryo or foetus will be affected by a serious medical condition either at birth or afterwards. The test may be for an inherited genetic disorder (such as cystic fibrosis, Tay-Sachs disease or β-thalassaemia), in which case a foetal DNA sample is obtained from foetal cells in the amniotic fluid (amniocentesis) or the developing placenta (chorionic villus sampling, or CVS). Testing may be for a genetic disorder that is not hereditary, such as Down syndrome, where a chromosome count (karyotype) is performed on foetal cells; or it may be for a sporadic disorder such as spina bifida, using high-resolution ultrasound.

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34 See above regarding the NHMRC's September 2001 notice of its intention to review these guidelines under the *National Health and Medical Research Council Act 1992* (Cth) s 13.

35 The limited gene therapy experimentation currently underway involves somatic gene therapy, which entails modification of the DNA of cells other than germ line cells. (Only the results of germ line gene therapy could be passed on to subsequent generations, but such experimentation is not authorised in most countries.)

36 Dutch Ministry for Health Welfare and Sport, *The Applications of Genetics in the Health Care Sector* (2001), 19.

37 GTRAP is chaired by Professor Ron Trent, who is also a member of the Advisory Committee of this joint inquiry.

1.57 Tests may be triggered either because of a general risk factor (such as maternal age for Down syndrome), a previous family history (as for cystic fibrosis), or as a result of an indicative population screening test (such as elevated serum alpha-fetoprotein, which may indicate spina bifida). Although most tests are performed using CVS or amniocentesis between the 10th and 16th weeks of pregnancy, some DNA tests are now being conducted on embryos prior to implantation in the womb following IVF.

1.58 In some circumstances, tests for specific hereditary disorders or features are conducted, as in the recent case of genetic screening undertaken in the US by Australian parents, seeking to select a child who would not develop chronic granulomatous disease (CGD) and who could be a bone marrow donor for their ailing 5-year-old son.[38]

1.59 There is already anecdotal evidence of the use of prenatal and pre-implantation testing for the purposes of sex selection, although formal requests for medically assisted sex selection are not common in Australia.[39] A number of commentators have raised concerns that the increased knowledge obtained from the Human Genome Project and related research, and the improved technology for pre-natal and pre-implantation testing of embryos, will lead to an increase in 'selection' at the prenatal stage.[40]

1.60 English sociologist of health and disability rights campaigner, Dr Tom Shakespeare, has expressed concern about the advent of 'consumer eugenics', with a presumption that all forms of disability should be searched out and destroyed. Shakespeare has stated that:

> While I support a woman's right to choose, I regret situations where pregnancies are terminated because of inaccurate or prejudiced information about what it is like to be disabled.[41]

1.61 Similarly, the Hon Justice Michael Kirby of the High Court of Australia has raised concerns that if genes are found that are associated with features or traits such as homosexuality, schizophrenia, baldness or blue eyes, these may be tested

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38 D Paget, 'Technology to Select Baby', *The Daily Telegraph* (Sydney), 10 July 2001.

39 J Savulescu, 'Sex Selection: The Case For' (1999) 171 *Medical Journal of Australia* 373. See also P Lui and G Rose, 'Social Aspects of Over 800 Couples Coming Forward for Gender Selection of Their Children' (1995) 10 *Human Reproduction* 968. For a consideration of the ethics of preconception techniques for sex selection, see Ethics Committee of the American Society for Reproductive Medicine, 'Preconception Gender Selection for Non-medical Reasons' (2001) 75(5) *Fertility & Sterility* 861.

40 Public attitudes towards prenatal genetic testing were surveyed recently by the Millward Brown research group on behalf of Biotechnology Australia. The study indicated an increase (from 22% to 29%) over the past two years in the proportion of adult Australians who believe this practice is 'morally acceptable'; however, support is strongly influenced by whether prospective parents would use such tests results to inform and prepare themselves, rather than to terminate the pregnancy. See Millward Brown Australia, *Biotechnology Public Awareness Survey Final Report*, Biotechnology Australia, <http://www.biotechnology.gov.au/MBsurveyresults.pdf>, 1 July 2001, 27.

41 T Shakespeare, *The Danger of Disability Prejudice*, <www.genecrc.org.site/hi/hi3z.htm>, 1 September 2001.

for and used as a basis for selection and/or termination of embryos and foetuses.[42] With such decisions affected by social and cultural forces, public opinion and economic considerations, it may be difficult to draw the line about where selection is ethical or unethical.

1.62 Of course, this presupposes that such genes exist and can be isolated. One leading genome researcher considers that the limited availability of testing would suggest that there is unlikely to be a problem in the short term, estimating that about only one per cent of abortions are carried out for genetic reasons.[43] As discussed further in Chapter 2, most genetic conditions and features are a result of the interaction of a number of genes, usually in combination with environmental factors.

1.63 Prenatal testing is not formally regulated beyond standard ethical constraints applied to the medical practitioners ordering and conducting the testing. In some cases, testing is carried out in conjunction with extensive counselling, such as with CVS and amniocentesis. However, it appears that, in a large number of practices, other tests (such as nuchal translucency, maternal serum or ultrasound screening) are being performed without counselling for parents regarding the likely consequences or their options for dealing with the results.[44] In some States and Territories there are laws relating to handling and destruction of embryos used in ART and/or research experimentation.

1.64 There is little doubt that advances in genetic research and testing technology over time will provide prospective parents with a much greater amount of information about the foetus, creating certain pressures to make decisions based on this information. Such choices usually reflect a complex interaction of personal ethics, religious views, professional advice, social mores, and particular circumstances. The lawfulness or otherwise of the termination of a pregnancy is regulated by the law relating to abortion, as it exists in each State and Territory, but is typically linked to the need to preserve the life, health or well-being of the mother.

1.65 The ALRC and AHEC consider that, given the existing state of the science and the nature of the terms of reference, this aspect of prenatal testing is not one that forms part of this inquiry.[45]

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42 See eg M Kirby (2001).

43 'Kirby Urges Laws to Protect Unborn With Disabilities', *The Canberra Times*, 26 June 2001, quoting Professor John Mattick.

44 Initial consultations with experts suggest that the percentage who do not get counselling is about 50%.

45 However, in some circumstances, prenatal genetic testing will have continuing ethical and practical implications that should be picked up in other parts of this inquiry. For example, if prenatal testing indicates the presence of an adult-onset disorder, there will be issues after birth about the duty of care to inform the child/adult about the disorder, and the effect upon the person's autonomy and his or her ability to secure work and insurance coverage.

Intellectual property rights

1.66 The preamble to the terms of reference asks the ALRC and AHEC to *have regard to*, among a number other things, 'emerging issues about the control of, ownership of, and intellectual property rights in relation to human genetic samples and information'. The recent publicity surrounding the success of the Human Genome Project has also highlighted some of the issues surrounding the commercialisation of the knowledge gained through such applied research. In particular, concerns have been expressed that patent monopolies and the costs associated with licensing fees for the use of genetic testing technology may reduce access to such.[46]

1.67 In Australia, the legal position requires analysis of domestic law (especially under the *Patents Act 1990* (Cth)),[47] as well as international obligations arising out of the World Trade Organization *Trade-related Aspects of Intellectual Property Rights Agreement* (TRIPS), signed by Australia and incorporated into domestic law in 1994.[48]

1.68 There is an emerging literature questioning the continued application of traditional patent law (granting monopoly rights for 20 years over 'inventions') to the rapidly changing new genetic technology, and calling for the development of laws geared more finely to this dynamic area of research. It is often repeated in the media that 'the human genome has now been patented three times over', and there certainly has been a dramatic increase in patent applications overseas and a steady increase in Australia.[49] There also are questions about what constitutes 'novelty' and an 'inventive step' in the context of DNA research.[50] Perhaps the weakest claims are over simple documentation of DNA sequences and gene functions;[51] stronger claims involve the development of synthetic related processes, such as the Polymerase Chain Reaction (PCR) method of genetic testing.

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46 See eg G Chin, 'Is Gene Patenting in the Interests of Public Health?' (1999) *ALSA Academic Journal* 1, 6.

47 Section 51(xviii) of the Constitution expressly gives the Commonwealth power to make laws with respect to 'Copyrights, patents of inventions and designs, and trade marks'.

48 The TRIPS Agreement was annexed to the Marrakesh Agreement establishing the World Trade Organization (WTO): *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). Australian patent law had been reviewed and restructured in 1990, resulting in the *Patents Act 1990* (Cth). As a result, few amendments were necessary to bring the system into conformity with the TRIPS, and the *Patents (World Trade Organization Amendments) Act 1994* (Cth) implemented the required changes. Similarly, all other pieces of intellectual property legislation were amended to bring the TRIPS Agreement into domestic law. Under TRIPS, Australia has a duty to enforce a minimum standard of intellectual property law; failure to do so would render Australia liable to sanctions imposed by the WTO.

49 A survey by GeneWatch UK reports over 34,500 applications a month being made in the UK for exclusive development rights over natural processes in the human body; in Australia, the number of patent applications relating to genetic science increased from 1,248 in 1995 to 2,857 in 1999: see D Smith, 'Who owns your DNA?', *Sydney Morning Herald* 14 March 2001, 15.

50 Some jurisdictions do not even require an 'inventive step', accepting mere 'discovery' as a basis for granting a patent.

51 D Smith, 'Who owns your DNA?', *Sydney Morning Herald*, 14 March 2001.

1.69 Patents may be granted for DNA and genes that have been identified and copied from their natural source and then manufactured synthetically with an industrial use. IP Australia[52] documents that patentable items can include:

- DNA, RNA, genes and viruses;
- mutation or genetic engineering;
- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;
- DNA coding sequence for a gene;
- protein expressed by the gene;
- anti-sense DNA;
- general recombinant DNA methods; and
- genes and gene sequences that have been separated from the human body and manufactured synthetically for re-introduction into the human body for therapeutic purposes.[53]

1.70 The UK House of Lords Select Committee on Science and Technology Report on Human Genetic Databases recommended that gene patents should be granted only when a significant gene function has been established.[54] The Select Committee also recommended that patenting practices in the field of genetics should be closely monitored to ensure that there is a proper balance maintained between protecting inventors' interests, facilitating commercial development of ideas and allowing research to flourish.[55]

1.71 There are many opponents to the concept of patenting a gene, which they believe should be the common heritage of mankind. The American College of Medical Genetics has a firm position that genes and their mutations are naturally occurring substances that should not be patented.[56] The Human Genome Organisation (HUGO) opposes the patentability of DNA sequences of unknown

52 IP Australia is the Commonwealth body that grants and administers rights in patents, trademarks, and designs.

53 IP Australia, *Australian Patents for: Micro-Organisms; Cell Lines; Hybridomas; Related Biological Materials and Their Use; and Genetically Manipulated Organisms*, IP Australia, <http://www.ipaustralia.gov.au/library/PDFS/patents/biotech.pdf>, 22 February 2001.

54 House of Lords — Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2000-01), The Stationery Office Limited, London, 45.

55 Ibid.

56 American College of Medical Genetics, *Position Statement on Gene Patents and Accessibility of Gene Testing*, American College of Medical Genetics, <http://www.faseb.org/genetics/acmg/pol-34.htm>, 3 April 2001.

function or utility.[57] European Directive 98/44 on the protection of biotechnological inventions, currently being considered by member states for transposition into national legislation, stipulates that discovery of a human genome sequence alone cannot be patented; rather, what should be patentable is the process that utilises that sequence with a view to specific applications.[58] There is presently controversy in the US over a patent granted to a foundation of the University of Wisconsin, which covers embryonic stem cells (both the method of isolating the cells and the cells themselves) and threatens to inhibit promising research (see above).[59]

1.72 The Royal College of Pathologists of Australasia has submitted that arrangements involving exclusive or restricted licensing would likely result in: reduced patient access to testing; increased costs of testing; an increasing divide between those who can afford tests and those who cannot; patent holders essentially dictating standards of care for testing; a reduction in the vital element of peer review in test performance; the creation of unacceptable conflicts of interest; and a restriction of future research activity.[60]

1.73 In May 2001, the Human Genetics Society of Australasia (HGSA) ratified a position paper[61] expressing 'great concern' over the patenting of gene and gene sequences, and calling for broadly based consultations in Australia and New Zealand as a matter of urgency to develop a legal framework that 'achieves an appropriate balance between the legitimate requirement for intellectual property protection and the benefits that flow to the community as a result of intervention'. The HGSA notes that Article 27.3(a) of TRIPS provides that member states may exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals', and similarly Article 53(a) of the European Patent Convention permits the exclusion of products or processes where public policy or public morality so requires.

1.74 The HGSA also expressed serious concern about the consequences of patenting genetic tests and treatments for patients, with monopolies or exclusive licence agreements leading to increased cost and decreased access, as well as a diminution in professional expertise and the incentives for technological improvement that come with competition.[62]

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57 Human Genome Organisation (HUGO), *Statement on Patenting of DNA Sequence*, (2000) <http://www.hugo-international.org/hugo/patent2000.html>.

58 See the 'Genetics and the Future of Europe' website: *Genetics and the Future of Europe*, <http://europa.eu.int/comm/research/quality-of-life/genetics.html>, .

59 S Stolberg, 'Patent Laws May Determine Shape of Stem Cell Research', *The New York Times*, 17 August 2001. It is believed that the United States is the only nation to have issued a patent on human embryonic stem cells, but the University of Wisconsin foundation also has applied for patents in Europe.

60 The Royal College of Pathologists of Australasia, *Submission G4*, 5 April 2001.

61 Human Genetics Society of Australasia (HGSA), *HGSA Position Paper on the Patenting of Genes*, <http://www.hgsa.com.au/policy/patgen.html>, 1 May 2001.

62 Ibid, part 3.

1.75 The issue emerged again in dramatic fashion recently in relation to media reports that Myriad Genetics, an American-based biopharmaceutical company, has claimed patent rights over tests regularly used in Australia to detect a genetic predisposition to breast cancer (BRCA1 and BRCA2). [63] Public hospital laboratories in Australia are not presently paying patent royalties for such testing — and to do so would increase the cost from the current $2,000 to about $4,700 for the same service offered by Myriad.

1.76 Continued access by Australian patients to these tests (which are very complicated and involve a large number of mutations) would seem to depend upon both the determination of patent rights, and — by way of analogy to the position regarding pharmaceuticals under the Pharmaceutical Benefits Scheme (PBS) — the extent to which the Australian government can use its purchasing power to negotiate favourable prices or is willing to provide substantial subsidies out of the public purse for such tests.

1.77 At present, however, the Medicare Benefits Schedule includes only *two* DNA/genetic tests — those for haemochromatosis and Factor V Leiden. With limited Commonwealth responsibility, then, DNA testing is very much an issue for the States and Territories, insofar as most tests are arranged through public hospitals. To the extent that each State handles DNA testing somewhat differently, there are inevitable discrepancies and anomalies in terms of access, costs and so on. This also could encourage the emergence of a public/private split, in which genetic tests would be available outside the public hospital system for those who can afford them. Some of the American experience in this regard suggests that apart from important issues of access and equity, this scenario can lead to unnecessary and unreasonable testing.

1.78 Although the ALRC and AHEC accept the critical and growing importance of issues relating to gene patenting, our view is that the research work and considerations involved (a) are substantially different in nature to those (ethics, privacy and discrimination) which form the central part of the current inquiry; and (b) would require substantial additional time and resources to do justice to the complex issues.

1.79 Accordingly, the ALRC and AHEC wrote to the Attorney-General and the Minister for Health and Aged Care in October 2001 to suggest that the intellectual property issues raised by genetics become the subject of a fresh inquiry with its own terms of reference. We consider that this separation will not detrimentally affect the ability of our joint inquiry to make recommendations in relation to the core issues covered by the terms of reference.

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63 See S Ferris and A Doble (2001), 64–65; D Smith, 'Women to Pay for Cancer Gene Test', *The Age* (Melbourne), 14 March 2001; D Smith, 'Patent Battle Looms over Cancer Gene', *The Sydney Morning Herald*, 15 March 2001.

Some other useful sources of information

1.80 One of the main objectives of this Issues Paper is to promote community education and debate about the social, ethical and legal implications of developments in genetic research and technology. To this end, Chapter 2 and other parts of this paper provide some basic information about these matters. In recent years, a great deal of literature has emerged which is thought provoking and accessible to a general audience, but nevertheless is scientifically respectable. Without attempting to be exhaustive, a number of books and websites are listed below, which we believe will be of assistance to people who wish to learn more.

Books

L Andrews, *Future Perfect: Confronting Decisions About Genetics* (2001) Columbia University Press, New York.

R Dawkins, *The Selfish Gene* (2nd ed, 1976) Oxford University Press, Oxford.

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

D Hamer and P Copeland, *Living with Our Genes* (1999) Anchor Books, New York.

J Harris, *The Nurture Assumption* (1998) Bloomsbury, London.

R Hawley and C Mori, *The Human Genome: A User's Guide* (1999) Harcourt Academic Press, Burlington.

A Huxley, *Brave New World* (1932) Penguin Modern Classics, London.

R Lewontin, *The Triple Helix: Gene, Organism and Environment* (2000) Harvard University Press, Cambridge.

M Morange, *The Misunderstood Gene* (2001) Harvard University Press, Cambridge.

M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London.

R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, Sidcup.

A Wexler, *Mapping Fate* (1995) University of California Press, Los Angeles.

Websites

Australian Health Ethics Committee, <www.nhmrc.gov.au/issues/humanethics.htm>

Australian Law Reform Commission, <www.alrc.gov.au>

American Journal of Human Genetics, <www.journals.uchicago.edu/AJHG/journal/>

Biotechnology Australia, <www.biotechnology.gov.au/index.asp>

Canadian Biotechnology Advisory Committee (CBAC), <www.cbac-cccb.ca/english>

The Centre for Law and Genetics, <www.lawgenecentre.org>

Cooperative Research Centre for Discovery of Genes for Common Human Diseases, <www.genecrc.org>

European Community, Genetics and the Future of Europe, <http://europa.eu.int/comm/research/quality-of-life/genetics.html>

Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing*, Office of the Federal Privacy Commissioner, <www.privacy.gov.au/publications/pg2pubs.html#26>

Gene and Related Therapies Research Advisory Panel (GTRAP), <www.health.gov.au/nhmrc/research/gtrap.htm>

Genetics Education Program of NSW, <www.genetics.com.au>

The Genome Database, Hospital for Sick Children, Toronto, Canada, <www.gdb.org/>

House of Lords — Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities*, The Stationery Office, <www.parliament.the-stationery-office.co.uk/pa/ld200001/ldselect/ldsctech/57/5701.htm>

Human Genetics Commission (UK), <www.hgc.gov.uk>

Human Genetics Society of Australasia, <www.hgsa.com.au>

N Jones, *Genetic Information: Legal Issues Relating to Discrimination and Privacy*, US Congressional Research Service, <www.cnie.org/nle/st-55.html>

National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: an Information Paper*, NHMRC, <www.nhmrc.gov.au/publications/pdf/e39.pdf>

National Health Museum (US), *Access Excellence* <http://www.accessexcellence.org/AB/>

National Human Genome Research Institute (US), <www.nghri.nih.gov>

Nature ('genome gateway'), <www.nature.com/genomics/>

New York Times On the Web, <www.nytimes.com/pages/health/genetics/index.html>

Progress Educational Trust's *BioNews*, <www.progress.org.uk/News/Index.html>

Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* Parliament of Australia, <www.aph.gov.au/senate/committee/legcon_ctte/genetic/index.htm>

Community consultation processes

1.81 One of the most important features of ALRC inquiries is the commitment to widespread community consultation. The nature and extent of this engagement normally is determined by the subject matter of the reference. Areas that are (or are seen to be) narrow and technical tend to be of interest mainly to expert health and legal practitioners, industry associations and government agencies. Recent ALRC reviews of the *Marine Insurance Act 1909* (Cth) and the *Judiciary Act 1903* (Cth) may fall into this category. Other ALRC references, however — such as those relating to children and the law, Aboriginal customary law, multiculturalism and the law, and equality before the law — have involved a much greater level of interest and involvement from the general public and the mass media.

1.82 The present inquiry into the protection of human genetic information falls into the latter category, and the ALRC and AHEC are planning around this basis. The ALRC-AHEC media release in February 2001 responding to the issuing of the terms of reference expressly recognised that widespread public consultation would be a key feature of the genetic information inquiry and noted that, while it was essential that the inquiry familiarised 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.[64]

1.83 The media release, the ALRC's website, and a number of articles written about the initiation of the reference noted that expressions of interest and preliminary submissions could be lodged with the inquiry. Already, some hundreds of expressions of interest and several submissions have been received. The inquiry also has established contacts with other bodies that are undertaking parallel projects or research, such as the Human Genetics Commission in the UK, the OECD's Working Party on Information Security and Privacy, and the US Equal Employment and Opportunities Commission.

1.84 This **Issues Paper** is the first document produced by the joint inquiry, and is intended to set out the main issues relevant to the inquiry, provide some background to these issues, and encourage informed public participation.

1.85 If there are passages in this paper which appear to imply tentative conclusions about the likely direction of work, this is unintended and not meant to inhibit full and open discussion of issues and policy choices before the program of research and consultation is completed. This is not merely a rhetorical device to suggest perceived impartiality — at this early stage, the members of the joint inquiry are genuinely open to all approaches.

1.86 A number of public meetings will be organised in November–December 2001 in capital cities, as well as in some selected rural and regional centres. Specific dates and venues will be published in advance — interested persons should monitor the ALRC's website at <www.alrc.gov.au> and watch for advertisements in local newspapers for further details. In addition to public hearings, there will be opportunity for people to provide private and confidential submissions to the joint inquiry, in recognition of the potentially delicate nature of the issues under investigation. Written submissions also will be encouraged from individuals and organisations, and meetings arranged with relevant stakeholders.

1.87 This will be followed by the publication of a **Discussion Paper** in the early part of 2002. The Discussion Paper will contain a more detailed and scholarly treatment of the issues, and will contain an indication of the inquiry's thinking in the form of proposals — specific reform options to which the community can respond. The ALRC and AHEC will then undertake a further round of national meetings and consultations to consider these proposals.

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

1.88 As community consultation documents, the Issues Paper and Discussion Paper may be obtained in hard copy free of charge from the ALRC. Both papers and the final Report also will be available for downloading free of charge from the ALRC's website.

1.89 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 ways forward. For the same reasons, the ALRC and AHEC understand that they cannot sit back and wait for thorough, well-crafted submissions to roll in — rather, it is necessary to maintain a very active program of direct consultation.

In order to be considered for use in the Discussion Paper, submissions (including those responding directly to this Issues Paper) must reach the ALRC by no later than Monday, 14 January 2002. Details about how to make a submission are set out on the inside cover.

1.90 The ALRC and AHEC strongly urge interested parties, and especially stakeholder groups and institutions, to make submissions (even in a preliminary or interim form) *prior* to the publication of the Discussion Paper. Once the basic pattern of proposals is set down it is hard for the inquiry to alter course radically — while it is quite possible for the inquiry to abandon or substantially modify proposals for which there is little support, it is more difficult for the inquiry to publicise and gauge support for novel approaches suggested to us during the later consultation process.

1.91 The **Report** of the joint inquiry, containing our final recommendations (with supporting reasoning), is due to be presented to the Attorney-General and the Minister for Health and Aged Care by 30 June 2002. Once tabled in Parliament the Report becomes a public document.

1.92 It is important to note that the final Report will not be a self-executing document — the inquiry only may provide advice and recommendations about the best way to proceed, but implementation is a matter for others.[65]

1.93 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

65 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.

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; education and training programs; better coordination of governmental (and intergovernmental) programs, and so on.

1.94 Similarly, although the inquiry's final Report will be presented to the Attorney-General and the Minister for Health and Aged Care, it is likely that some (or many) of the recommendations will be directed to government departments and agencies; the NHMRC; the Australian Health Ministers' Conference; the Standing Committee of Attorneys-General; 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, among others.

1.95 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 report will be out of date in a relatively short span of years. If there is no standing body established to advise governments on these matters, then the inquiry may have to be reconstituted in future to revisit the issues.

2. Background and emerging issues

Contents

Introduction: 'Mad science' or 'modern miracles'?

The future for genetic technology

2.1 As is now the case with many OECD countries, Australia has a policy, expressed in its *Innovation Statement*, placing great reliance for its economic future on genetic technology, particularly 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*)[66] has set down a comprehensive national ethical regulatory framework for the conduct of research in general and genetic research in particular.[67]

- *Biotechnology Australia* is a whole of government initiative[68] to coordinate efforts to develop biotechnology for the benefit of the Australian community.[69]

- 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.[70]

- A major review of health and medical research in Australia has been undertaken. The Wills Report[71] 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.[72] It recognises that this window of opportunity would close given the pace of change unless Australia acts promptly.

2.2 These initiatives recognise that the preconditions to economic growth in the genetic technology sector include access to research tools (including human biological material), security of investment and effective and appropriate regulation. This inquiry considers those matters, focusing on the appropriate use of genetic information.

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66 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 Learned Academies in 1999.

67 See Principles 16.1-16.23 and the section on Human Tissue (Principle 15).

68 Involving the Commonwealth Departments of Industry, Sciences and Resources; Environment and Heritage; Agriculture, Fisheries and Forestry; Health and Aged Care; and, Education, Training and Youth Affairs.

69 Commonwealth of Australia, *Australian Biotechnology: Progress and Achievements* (2000) 2.

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

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

72 Ibid, 1.

2.3 A central tenet of *Biotechnology Australia* is to ensure that 'consistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and environment'.[73] The Commonwealth Minister for Health and Aged Care, the Hon Dr Michael Wooldridge MP, has 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'.[74] 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.[75]

2.4 As discussed in Chapter 1, the Human Genome Project (HGP) and Celera Genomics jointly announced the first near-complete draft of the entire DNA sequence of the human genome in June 2000, and publication of material by Public Sequencing Consortium of the HGP followed in February 2001. The first draft of the human genome sequence is a starting point in the research effort to apply this knowledge into mainstream medical practice. It will provide information for other more applied sub-branches of human genetic research and technology, including such topics as gene identification, genetic variation, gene expression monitoring, microarray technology, bio-informatics, systems biology, protein structure and proteomics.

2.5 This research effort will continue apace in both the public and private sectors. The principal research tool is human biological material, in the forms of human genetic information or human tissue. The science is developing rapidly. It is equally important that the development of the science is accompanied by the development of secure and appropriate ethical and regulatory frameworks.

Social reactions to rapid change

2.6 It is a now a rare day when the news media fails to contain some coverage of an exciting development or a worrying controversy (or both) arising out of genetic research and technology.

2.7 The pace of scientific advancement in biotechnology and in other related fields creates a high level of social ambivalence about the potential benefits and detriments of change. On the one hand, there is very strong public support for

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73 See *Australian Biotechnology: Progress and Achievements* (2000), available at <http://www.biotechnology.gov.au/Industry_Research/National_Strategy/prop-biotech_prog_achiev.pdf>.

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

75 See *Australian Biotechnology: A National Strategy* (2000), available at <http://www.biotechnology.gov.au/Industry_Research/National_Strategy/prop-biotech_nat_strategy.pdf>.

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.

2.8 Some of the generalised concern here and overseas is heightened by the emotional blending together of a number of distinct scientific and medical problems and issues — and government and corporate responses to them — such as foot and mouth disease, mad cow disease, Creutzfeldt-Jakob Disease (CJD), genetically modified (GM) foods, human cloning, global warming, nuclear fallout from Chernobyl, concerns about nuclear energy generally, and so on.

2.9 In the United Kingdom, a public opinion survey commissioned recently by the Human Genetics Commission revealed that:

> In general there is a high level of public support for some uses of genetic information, for example: to improve the diagnosis of diseases and to better understand who is at a higher risk of common diseases, to develop treatments for genetic disorders, and to identify or eliminate possible offenders from police enquiries. However, this is balanced by concerns about how genetic information will be protected from inappropriate use, in particular concerns over the use of genetic information by insurance companies, employers or use by parents to choose their child's characteristics.[76]

2.10 The key findings of the survey were that:[77]

- Nine out of 10 people agree that genetic developments could and should be used to diagnose and bring cures for many diseases.

- About one-third of people are concerned that research on human genetics is tampering with nature, and is unethical. The level of concern is higher among women, ethnic and racial minorities, and those who say that religion or faith has an influence on the decisions they make.

- Three-quarters of people feel they have too little information on controls on biological developments, and most have little or no confidence that rules and regulations are keeping pace with new scientific developments.

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76 See MORI Social Research, *Public Attitudes to Human Genetic Information: People's Panel Quantitative Study Conducted for the Human Genetics Commission* (2000), <http://www.hgc.gov.uk/business_publications_morigeneticattitudes.pdf>.

77 Human Genetics Commission, 'Human Genetics Commission Publishes Results of Major Survey on Attitudes to Human Genetics', Press Notice 2001/0001 <http://www.hgc.gov.uk/business_press10htm>, 2 March 2001.

- Four out of five people believe that genetic information should not be used for setting insurance premiums.

- Almost all (94%) respondents think human genetic information should be used to identify and eliminate possible offenders from police enquiries, especially for serious offences. Young people are only half as likely as those over 65 to support such a course of action, and opinion is equally divided about whether samples should be kept in the event of acquittal.

2.11 The European Community also has undertaken extensive public opinion polling regarding biotechnology, most recently in 1999. The Eurobarometer report *The Europeans and Biotechnology*[78] involved a survey of over 16,000 adults in all member states. Key findings included that:

- Over 80 per cent of Europeans feel poorly informed about biotechnology,[79] but most said they were willing to take the time to learn.

- When Europeans think about 'biotechnology', what first springs to mind for nearly half of them is the cloning of animals and humans. One in three think of scientific research, health and technological development; one in four think about GM foods; and only one in twelve think about the environment. Cloning elicits strongly negative emotions, whereas research, health and environment are viewed positively.

- While a majority of Europeans[80] continue to think that technologies such as solar energy, information technology, telecommunications and the internet 'will improve our way of life in the next 20 years', only 41% think this of biotechnology — down from 46% in 1996. Only nuclear power (26%) attracts less confidence.

- Not surprisingly, different biotechnology applications receive varying levels of support. There was clear agreement that it is morally acceptable to use genetic tests to detect inherited diseases, to develop GM bacteria to clean up pollution and to introduce human genes in bacteria to produce medicine or vaccines. There was more limited acceptance of cloning human cells or tissue to help a patient or to transfer plant genes to other plants to obtain resistance to insects. The use of biotechnology in food production to improve taste or nutritional content and the cloning of animals, even for medical applications, had far less support.

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78 Eurobarometer 52.1, *The Europeans and Biotechnology*, <http://europa.eu.int/comm/research/quality-of-life/eurobarometer.html>, 1 October 2001.

79 And apparently they are: 35% of Europeans agreed with the statement that 'ordinary tomatoes do not contain genes while genetically modified tomatoes do', while 30% said they did not know — thus only 35% realised that all tomatoes (must) contain genes.

80 The highest level of optimism about biotechnology is found in Sweden, Spain, Portugal and Belgium, while the lowest is in Greece, the UK and Italy.

- There is considerable suspicion of public authorities and technical experts. In response to a question about which sources of biotechnology information are trusted, consumer organisations (55%), the medical profession (53%) and environmental protection organisations (45%) fared best.[81] Universities (26%), animal protection organisations (25%), and the media (20%) had modest levels of support; but there was a high degree of scepticism about international institutions (17%), national public authorities (15%), farmers' associations (15%) and religious organisations (9%). Levels of trust for all sources of biotechnology information had decreased significantly since the last survey in 1996.

- Less than half (45%) feel that their governments regulate biotechnology well enough.[82]

2.12 In 2000, the University of Western Australia's Survey Centre conducted a telephone survey of 1,000 people in that State,[83] 75% of whom reported that they were aware that genetic research was being conducted using human DNA. Eighty-four per cent stated that such research would benefit the community generally, and 70% thought it would benefit themselves or their families, especially by way of elimination of genetically linked disease (50%), cures for general diseases and better quality of life (26%) and fewer children being born with birth defects (7%). Forty per cent of respondents expressed concerns about associated risks and dangers with genetic research, especially in relation to 'inappropriate use of information' and the fear of eugenics. In terms of regulation or oversight of genetic research, respondents thought that any community advisory group established for this purpose should include the general public, medical professionals, scientists and religious leaders.

2.13 Biotechnology Australia, a federal government agency, also commissioned a major quantitative and qualitative study in this area, conducted by the research firm Millward Brown, in April–May 2001. This survey,[84] which updated a similar study conducted in late 1999, found that there was:

- Some level of concern expressed about gene technology by 80% of the community, but these concerns were rated much lower than environmental concerns, such as pollution or greenhouse gases.

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81 The roles of the media and consumer organisations are viewed positively in the Netherlands, Finland and Greece, but less so in the UK, Italy and Sweden.

82 Compared with 29% who disagree, and 26% who are not sure.

83 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.

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

- An increased awareness of biotechnology issues in Australia (67%, compared with 57% in 1999), and a general view that genetic engineering would improve our lives over the next 20 years (51%, from 42%).

- An increased acceptance of some applications, such as modifying crops to make them more pest resistant (37%, from 31%), testing embryos for predisposition to disease (25%, from 20%) and using human genes in medicines and vaccines (29%, from 22%).

- A decreased acceptance of using animal genes in plants (31%, down from 51%), or of modifying human genetic material with animal genes (44%, down from 51%), and an increase in the perceived risk of using human genes in animals to grow organs for transplantation (75%, up from 66%). Particular concern was expressed about cloning, with 58% stating they believed it would make things worse in the next 20 years.

- Significant concern that screening for genes that may cause incurable diseases could lead to discrimination (59%).

- An increased level of trust in government agencies as both a source of factual information and as regulators — in stark contrast to the experience in the UK and the rest of Europe, where confidence has been shaken by the mad cow and foot and mouth disease crises, among other things. 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.

2.14 Perhaps most concerning is the evident high level of anxiety about the pace of biotechnological change and society's capacity to regulate it effectively (at least in part pushed along by serious concerns about human cloning):

> 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.[85]

85 Ibid, 29.

Balancing competing interests

2.15 The major challenge for this inquiry is to find a sensible path through these concerns in order to develop policies to recommend to government which meet the public appreciation of the need to foster innovations in genetic research and practice that serve humanitarian ends, while providing sufficient reassurance to the community that such innovations are subject to proper ethical scrutiny and legal control.

2.16 Although relatively easy to articulate, achieving the proper balance is difficult in practice, since various interests will compete and clash across the spectrum of activity.[86] For example, consider the conflicting needs of:

- Genetic researchers, who require ready access to a pool of research materials (tissue banks, data banks, registers and so on), ideally containing as many identifiable markers as possible to select the relevant research subjects, with the aim of making important medical discoveries (gene therapy, regenerative medicine, smart drugs) — versus the interests of all of the individuals whose information or tissue is held, who want to assert their right to human dignity and autonomy (requiring informed consent before use or re-use) and who need to be confident of the privacy of that information.

- Genetic researchers who need to be able to secure the willing and active participation of many volunteers — versus the legitimate fear of many potential volunteers that any such participation will generate information that they may subsequently be required to disclose to insurers, employers or others.

- Employers who must act to fulfil their common law and statutory duties to provide a healthy and safe work environment for all employees — while at the same ensuring that in so doing, they do not later face a law suit alleging disability discrimination because of restrictions placed on employees who have a genetic susceptibility to a disease triggered by specific environmental factors or substances that may be present in the workplace.[87]

- Doctors and hospital authorities, who often must make very difficult decisions in advising about diagnostic testing, therapeutic options and the allocation of scarce resources, and who might be aided in this respect by access to genetic information — versus an individual patient's legitimate

86 Although the balance between competing interests in genetic research is arguably no different from the privacy issues in epidemiological research, where private and public interests also must be carefully weighed: see the discussion below about whether genetic information is 'special'.

87 See US Department of Labor, *Genetic Information and the Workplace*, US Department of Labor, <http://www.nhgri.nih.gov/HGP/Reports/genetics_workplace.html>, 1 October 2001.

concerns about privacy and the right to consent (or not) to genetic testing and to the use and disclosure of any genetic tests results.[88]

2.17 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.

2.18 If legislative action ultimately is seen as necessary, it may be more desirable to amend existing legislation, such as the *Privacy Act 1988* (Cth), the *Disability Discrimination Act 1992* (Cth), and the *National Health and Medical Research Council Act 1992* (Cth), to take account of the special characteristics of genetic information, rather than enacting legislation to deal specifically with genetic information, as distinguished from all other health and personal information.

2.19 It is beyond the terms of reference, time and the resources of this joint inquiry to undertake a fundamental re-conception of the structure, philosophy and content of all of these areas — and some areas, such as the extension of privacy laws to the private sector on a national basis, only recently have been developed after a period of public consultation. Rather, the inquiry sees its primary brief as scrutinising the existing regimes, and then tailoring them — if necessary, and to the extent possible — to the particular needs and demands of genetic testing and information. Where necessary, we will recommend new forms of regulation where necessary to meet any resulting gaps.

2.20 As noted in Chapter 1, 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.

2.21 As a society, we regularly have to strike difficult balances between competing interests and countervailing social trends. For example, current community opinion strongly favours greater accountability, transparency, and freedom of information, both in respect of public institutions and private ones. At the same time, there is also a strong push for greater privacy protection for individuals, and this recently has been extended to cover the non-government

88 Tissue matching for clinical transplantation requires the use of genetic information to ensure compatibility between donor and recipient. For example, more than 160,000 Australians have consented to having their genetic information being registered on the Australian Bone Marrow Donor Registry (ABMDR) and there are over six million volunteer donors registered internationally. There is no suggestion that such a critical program, involving the informed consent of volunteers, should be subject to greater restrictions: Australian Bone Marrow Donor Registry Inc, *Submission G13*, 26 September 2001.

sector. The notion that confidentiality attaches to communications within certain relationships (eg, lawyer-client, journalist-source, priest-parishioner) is also well understood as an ethical obligation — and sometimes a legally enforced obligation. However, for public policy reasons, there are also qualifications and interventions in this area. For example, doctor-patient confidentiality is given very great respect, but doctors are nevertheless placed under legal obligations to report some matters to the authorities, such as where there is a 'notifiable disease' under public health laws, or a reasonable suspicion of child abuse under child protection laws.

2.22 Policy-makers need to assume that, in practice, we live in an imperfect world — which is why we have, and regularly need to enforce, criminal law, privacy law, and other regulatory regimes. We also have to anticipate that there sometimes will be discrimination, whether based on ignorance, laziness or venality. For example, some employers may prefer to make hiring decisions based upon a simple 'score', perhaps derived from psychological testing, rather than go through the more time-consuming process of vetting CVs and conducting searching interviews to choose the best applicant. Where the 'simple' factor seized upon has little or nothing to do with merit — for example, where it concerns race, religion, ethnic identity, or perhaps a genetic test result — then such behaviour may infringe anti-discrimination and other human rights protections.

2.23 Dealing with the potency of genetic testing and information poses new challenges for our social systems. However, there is some experience with precedents and analogous developments that can be drawn upon to guide the policy-making process. For example, over the last decade, the Australian health system, legal system and social services have had to learn how to deal with HIV-AIDS in such a way as to take very seriously the risk of the spread of infection, while at the same time endeavouring not to stigmatise or discriminate against persons who are HIV positive, nor unduly breach their privacy. Although not perfect, Australia's record in this regard is strong compared with many other societies, and certainly provides some valuable lessons for dealing with issues of genetic privacy and discrimination.

Background events

2.24 Concerns about the use of genetic information are not new. The extent to which genetic information should remain private, and the ability to treat people differently on the basis of their genetic information, are matters that have been debated extensively in the United States, Canada and Europe.

2.25 This inquiry is in the fortunate position of proceeding from a foundation of research already developed in Australia and overseas, by such bodies as the NHMRC, the House of Representatives Standing Committee on Industry, Science and Technology, the Senate Legal and Constitutional Committee, and the Human

Genetics Society of Australasia in Australia; the Human Genetics Commission and the House of Lords Science and Technology Committee in the UK; the National Human Genome Research Institute, the American Society of Human Genetics and the Congressional Research Service in the United States; the Law Reform Commission of Canada;[89] the Danish Council of Ethics;[90] and the European Commission.

The 1992 House of Representatives Standing Committee inquiry

2.26 In Australia, privacy issues relating to genetic technology were identified in the 1992 report of the House of Representatives Standing Committee on Industry, Science and Technology entitled *Genetic Manipulation: The Threat or the Glory?*[91] This led to the federal Privacy Commissioner's release of an information paper in 1996, entitled *The Privacy Implications of Genetic Testing*.[92] The Privacy Commissioner recommended a coherent and consultative approach to developing policy on privacy questions raised by genetic testing. (See Chapter 4 for further discussion of the developing privacy protection regime in Australia.)

The Genetic Privacy and Non-discrimination Bill 1998

2.27 Broad public debate was prompted by Australian Democrats Senator Natasha Stott Despoja's Genetic Privacy and Non-discrimination Bill, introduced into federal Parliament in March 1998. This Bill was based on the *Model Genetic Privacy Act* (which has influenced genetic privacy laws introduced in some American states),[93] and the US *Genetic Confidentiality and Non-discrimination Act* 1997.[94]

2.28 The primary objectives of the Stott Despoja Bill were to:

- establish an enforceable right to privacy of genetic information of an individual, by proscribing disclosure of such genetic information except with the authorisation of the individual, or in other limited circumstances;

- define the circumstances in which genetic information and DNA samples may be collected, stored, analysed, and disclosed;

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89 See B Knoppers, *Human Dignity and Genetic Heritage*, (1991) Law Reform Commission of Canada.

90 See L Nielsen and others, *Health Science Information Banks - Biobanks*, (1996), The Danish Medical Research Council, The Danish Central Scientific-Ethical Committee & The Danish Council of Ethics, Copenhagen.

91 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory* (1992), Parliament of Australia, Canberra.

92 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney.

93 Developed by Professors George Annas, Leonard Glantz and Patricia Roche of the Boston University School of Public Health.

94 Bill sponsored by US Senators Peter Domenici, Christopher Dodd and James Jeffords.

- prohibit discrimination based on genetic information;[95] and
- establish mechanisms to enforce the rights and responsibilities established under the Bill.

2.29 The Stott Despoja Bill was considered by the Senate Legal and Constitutional Affairs Committee, which received more than 50 submissions from the public. In its March 1999 report on the Bill, the Committee concluded that, as genetic technology is still in an early stage of development, it would be premature to legislate on genetic privacy and non-discrimination, and that further examination of the appropriate regulatory structures was needed.[96] The Committee also considered that creating specific legislation for genetic privacy and discrimination would cut across a number of regulatory systems already in place, or in the process of being established; and suggested that it would be more appropriate to amend existing privacy and discrimination legislation where necessary, to ensure that issues raised by genetic technology are adequately covered under that legislation.[97]

The Barlow-Stewart and Keays studies

2.30 Separate studies were conducted in Australia in 1999 by genetic counsellor Dr Kristine Barlow-Stewart and post-graduate law student David Keays, based on anonymous responses received from survey forms distributed by clinical geneticists and genetic support networks in Australia and New Zealand.[98] Genetic discrimination, defined in these studies as less favourable or adverse treatment because of a positive genetic test result, was reported with respect to a wide range of genetic tests, including those for haemochromatosis, inherited breast cancer, inherited bowel cancer, familial melanoma, Alzheimer's disease, Huntington's disease, and hyperlipidemia.[99]

2.31 Most of the allegations of genetic discrimination touched on insurance, with 45 cases reported in respect of life insurance, income protection insurance, trauma insurance, superannuation, or health insurance.[100] The actions complained of involved loading premiums, denial of requested increases to pre-existing

95 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), Parliament of Australia, Canberra, 1.
96 Ibid, 37.
97 Ibid, 37–39.
98 Dr Barlow-Stewart received 703 anonymous responses, in which there were 43 cases of alleged discrimination. Keays conducted interviews with five other persons who had reported instances of alleged genetic discrimination: see K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 251–252. Barlow-Stewart initially presented work in progress to the 'Dolly McBeal Genetics and the Law' Seminar in Sydney on 14 August 2000. Keays presented his findings to the Australian Institute of Health, Law and Ethics Conference in July 2000.
99 Ibid, 252.
100 Ibid, 253.

insurance coverage, and blanket refusal to provide insurance.[101] (See Chapter 11 for further discussion of insurance and superannuation issues.)

2.32 There also were three reported cases of alleged genetic discrimination in employment (one termination of employment and two demotions based on a genetic predisposition to late-onset neurological conditions in otherwise asymptomatic persons), and a further two cases in which job applicants were required to undertake genetic testing as part of the selection process.[102] (See Chapter 10 for further discussion of employment issues.)

2.33 Finally, there were two cases in which individuals reported that they had been unfairly denied access to health services.[103] One case involved the denial of access to IVF treatment, allegedly based on gene positive status for familial early-onset Alzheimer's disease; the other allegation involved the denial of a surgical procedure because of gene positive status for Creutzfeldt-Jakob Disease (CJD). (See Chapter 12 for further discussion of other services.)

2.34 The studies suggested that in many cases the discriminatory decision or action was inappropriate, based on misinformation or a lack of understanding of genetic information and the nature of genetic disorders. The studies received widespread media publicity in mid-2000, and were a significant factor in the initiation of this inquiry.

The ACCC's authorisation of IFSA policy

2.35 In August 1999, the Investment and Financial Services Association (IFSA), whose members account for 98% of the life insurance industry in Australia,[104] lodged applications with the Australian Competition and Consumer Commission (ACCC) in relation to its draft policy on genetic testing. The ACCC was asked to grant authorisation under national competition laws[105] for IFSA's draft policy on genetic testing.

2.36 Briefly, the critical aspect of IFSA's draft policy (contained in clauses 2 and 4) was that member insurers could ask individuals to disclose existing genetic tests for the purpose of risk assessment, but that member insurers could not initiate any genetic test on applicants for insurance (directly, or indirectly — such as

101 Ibid, 253.
102 Ibid, 254.
103 Ibid.
104 In terms of market share.
105 Under the *Trade Practices Act 1974* (Cth), organisations who engage, or propose to engage, in certain anti-competitive business arrangements or conduct that could breach the Act may apply to the ACCC for authorisation of such arrangements or conduct. The ACCC may grant authorisation where the public benefit of the subject arrangements or conduct outweighs the public detriment, including the anti-competitive detriment. If granted, an authorisation provides immunity from legal proceedings under the Act in respect of the arrangements or conduct.

through the offer of lower than standard premium rates for individuals with negative test results).

2.37 IFSA's original application was opposed by the Human Genetic Society of Australasia (HGSA), the Australian Medical Association (AMA), AHEC, and the Commonwealth Department of Health and Aged Care (DHAC), all of whom sought concessions from the insurance industry aimed at minimising the risk of discrimination against persons based on genetic testing — although mindful of the fact that the traditional questions about family medical history also amount to 'genetic information'.

2.38 The ACCC's Draft Determination, issued 14 June 2000, proposed *not* to grant authorisation for such arrangements, on the basis that:

> the provisions of the IFSA draft policy were not likely to result in a public benefit, and that significant anti-competitive detriment would arise from a collective agreement to prevent the offer of lower than standard premiums based on genetic test results.[106]

2.39 In other words, the ACCC wanted insurance companies to have increased opportunities to *discriminate in favour* of persons who could show a 'good' genetic test result by offering them especially favourable rates.

2.40 However, in November 2000, the ACCC granted IFSA a two-year authorisation, noting 'the complex issues involved' and deciding to provide a 'breathing space' during which the issues surrounding genetic testing could be debated and government policy developed. A major factor in the ACCC's decision was the government's announcement of the joint inquiry.

> The ACCC considers that there are complex issues involved in this matter. The ACCC therefore welcomes the proposed government inquiry into human genetic information privacy and discrimination issues. There is a need for some consideration of all the issues by government. An important part of the debate would also include the issue of whether or not industry self-regulation is appropriate in respect of the issues involved.[107]

2.41 Chapter 11 contains further discussion of IFSA's policy on genetic testing and the ACCC's consideration of it.

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106 Australian Competition and Consumer Commission, *Draft Determination re Application for Authorisation Lodged by Investment and Financial Services Association (IFSA) in Relation to the Implementation of a Draft Policy on Genetic Testing*, (2000).

107 Australian Competition and Consumer Commission Media Release, 'ACCC Authorises Life Insurance Bar on Genetic Testing', 22 November 2000.

The Human Genome Project

2.42 Less than 50 years ago, in 1953, Watson and Crick published their letter in *Nature* introducing the now famous double helix structure of DNA, for which they were later awarded the Nobel Prize, and suggesting modestly that 'this structure has novel features which are of considerable biological interest'.

2.43 The Human Genome Project (HGP) is an international consortium involving about 1,000 research scientists worldwide, initiated jointly by the US Department of Energy and the National Institutes of Health. The HGP also has a multidisciplinary element, with a Working Group and multiple task forces devoted to exploring the Ethical, Legal, and Social Implications (ELSI) of the Project.

2.44 The initial mapping exercise was largely completed in 1999, first by the French group and then by the US and British public consortium. In February 2001, the HGP published a series of scientific papers in *Nature*, providing a first pass sequence for most of the 30,000–40,000 or so genes now thought to form part of the human genome, and thus providing an extraordinary research tool for further investigation into human development, physiology, medicine, and evolution.[108]

2.45 This sequencing, described by the HGP as 'deciphering the Book of Life', covers 96% of the human genome and is still mainly in draft form, although about 33% has been finalised. The project consisted of decoding the 3.2 billion letters of the human genome to provide an exact sequence of DNA's four chemical bases (Adenine, Thymine, Cytosine, and Guanine, — commonly abbreviated as A, T, C, and G) along the human chromosomes (see below). The HGP has made a commitment to fill all gaps and resolve all ambiguities in the sequence with 99.99% accuracy by 2003.

2.46 Ridley has noted that:

> 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. … The genome is a very clever book, because in the right conditions it can both photocopy itself and read itself.[109]

2.47 The genomes of many other species also have been sequenced as part of the HGP including other primates, with comparative genomics offering important insights into development, disease and resistance to disease, among other things.

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108 From the Remarks of Dr Francis Collins, Director of the National Human Genome Research Institute, announcing the sequencing and analysis of the human genome, 12 February 2001, published at F Collins, *National Human Genome Research Institute Announces Sequencing and Analysis of the Human Genome*, <http://www.nhgri.nih.gov/NEWS/initial_sequencePR.html>, 12 February 2001.

109 M Ridley (1999), 7–8.

2.48 As has been widely reported, the human genome is about 98% identical to that of chimpanzees, and 97% identical to that of gorillas. The principal genetic difference is that chimpanzees, gorillas, orang utans and other great apes have 24 pairs of chromosomes, rather than the 23 pairs that characterise human beings — which 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.[110]

2.49 According to the National Human Genome Research Institute — the public sector consortium that played the leading role in the HGP, along with the private biotechnology firm Celera Genomics — the most important revelations of the project to date include that:[111]

- The distribution of genes (made up of 'coding' DNA) on chromosomes among mammals, including humans, is striking in that most of the genes have accumulated in close proximity in certain regions, leaving vast expanses of what are referred to as 'non-coding', or sometimes 'junk',[112] DNA. This distribution of genes is in marked contrast to the genomes of many other organisms, such as the mustard weed, the worm and the fly, whose genes are relatively evenly and uniformly spaced throughout.

- Although there is still no definitive count of human genes, scientists now estimate that the human genome contains some 40,000 genes — far fewer than the estimated figure of 100,000 used for about the last decade.[113] This means that humans do not have vastly more genes than the microscopic round worm (19,000 genes), the fruit fly (13,000 genes) or the mustard cress plant (25,000 genes), the three other multi-cellular organisms whose genomes have been analysed, indicating that human complexity is not a product of the number of genes, but rather their versatility. For example, instead of producing only one protein per gene (as Watson and Crick originally believed), the average human gene produces three different proteins by 'reading' the sequence in different ways — and each protein is associated with multiple functions.

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110 Human chromosome 2 is not only the same size as the two ape chromosomes put together, but it also contains the same pattern of black bands: ibid 24.

111 This material is drawn directly from the National Human Genome Research Institute's website: <www.nhgri.nih.gov>, 1 October 2001.

112 The inquiry's preference is for 'non-coding DNA' — it is very possible that further advances in our scientific understanding will give new meaning and significance to this 'junk'.

113 The HGP initially settled upon a figure of 30,000, but this has since been revised upwards. Dr Craig Venter, head of Celera Genomics, has suggested that it will take 5–10 more years to get 'a really accurate count plus or minus 100 genes': N Wade, 'Human Genome Now Appears More Complicated After All', *The New York Times*, 24 August 2001. See also T Chea, 'Doubts cast on size of gene pool', *The Age* (Melbourne), 25 August 2001.

- The full set of proteins (the *proteome*) encoded by the human genome is much more complex than those of invertebrates because humans and other vertebrates have rearranged old protein domains into 'a rich collection of new architectures'. In other words, humans have for the most part achieved innovations by rearranging and expanding tried-and-true strategies from other species, rather than by developing novel strategies of their own. The scientific field of 'proteomics' is now beginning to emerge out of genomics.

- Scientists have identified more than 200 genes in the human genome whose closest relatives are in bacteria. Analogous genes are not found in invertebrates, such as the worm, fly, and yeast. This suggests that these genes were acquired at a more recent evolutionary past, perhaps after the emergence of vertebrates. Scientists have not found any single bacterial source for the transferred genes, indicating that several independent gene transfers from different bacteria occurred over time.

- Our non-coding DNA, characterised by long stretches of repeating sequences, represents a rich fossil record of clues to our evolutionary past.[114] It is possible to date groups of so-called 'repeats' to when in the evolutionary process they were 'born' and to follow their fates in different regions of the genome and in different species. The HGP scientists used three million such repeating elements as dating tools. Based on such 'DNA dating', scientists can build family trees of the repeats, showing exactly where they came from and when. These repeats have reshaped the genome by rearranging it, creating entirely new genes, and modifying and reshuffling existing genes.

- We have a greater percentage of non-coding DNA in our genomes (50%) than the mustard weed (11%), the worm (7%), or the fly (3%). There seems to have been a dramatic decrease in the activity of repeats in the human genome over the past 50 million years, but not in other species such as rodents.

- By dating the three million repeat elements and examining the pattern of interspersed repeats on the Y chromosome, scientists estimated the relative mutation rates in the X and the Y chromosome and in the male and female germ lines. They found that the ratio of mutations in males versus females is 2:1. Scientists point to several possible reasons for the higher mutation rate in the male germ line, including the fact that there are a greater number of cell divisions involved in the formation of sperm than in the formation of eggs.

114 So-called 'junk DNA' is also used in DNA profiling for law enforcement purposes: see Chapter 13.

- HGP scientists also have created a catalogue of 1.4 million single-letter differences, or single nucleotide polymorphisms (SNPs) — and specified their exact location in the human genome. This publicly available catalogue of SNPs promises to revolutionise both mapping diseases and tracing human history.

> The pharmaceutical sector has been using gene technology in the development of new drugs for some time now, including in the production of human insulin and 'factor VIII' (a blood coagulation factor) by means of recombinant DNA. The Human Genome Project provides a springboard for further research and discovery.[115]

2.50 Indeed, the whole way that therapeutic drugs are currently developed, tested and marketed will probably change, with the emphasis shifting away from finding drugs that work across entire populations (and do not have negative side-effects for too many people) to those that are tailored to the needs of particular individuals or small groups of individuals (even if they may be toxic to many others). The Dutch Ministry of Health has described some of the new branches of science that recently have emerged in this area, and the possibilities they hold for better health care:

> Pharmacogenomics uses the information about DNA sequences in the human genome to develop new drugs. On the one hand it is concerned with finding new medication 'targets', on the other with obtaining greater understanding of the genetic variation that is relevant to medication. Pharmacogenetics focuses on genetic variation as the cause of differences in the effect of drugs. … Results obtained from pharmacogenetic research will lead to greater insight into the differences in metabolism and in the absorption of medicines that occur in patients. … The Health Council of the Netherlands expects that by applying pharmacogenetic knowledge about increased sensitivity it will be possible to tailor drug dosages to the individual patient more effectively, which should mean faster recovery and fewer side effects.[116]

2.51 Professor Richard Dawkins has noted that:

> What is truly revolutionary about molecular biology in the post-Watson–Crick era is that it has become digital … the machine code of the genes is uncannily computer-like.[117]

2.52 The elucidation of the underlying molecular mechanisms of disease made possible by DNA sequencing and related research also will allow scientists to harness new high-performance computing techniques to engage in sophisticated matching, analysis and modelling of the data. This new science of 'bioinformatics'

115 Dutch Ministry for Health Welfare and Sport, *The Applications of Genetics in the Health Care Sector* (2001), 19.
116 Ibid, 11.
117 R Dawkins (1976), 6.

should dramatically shorten the cycle of discovery, and lead to the design of more effective diagnostic tools, drugs and therapies.[118]

2.53 However, there is still a great deal of work ahead, with some scientists suggesting that the dramatic announcement in February 2001 substantially over-sold the value of the mapping and sequencing exercise, since there are still vast areas that remain unknown (and some of what we now 'know' may turn out to be incorrect). Nevertheless, there is no doubt that the Human Genome Project has captured the public imagination, substantially raised awareness of genetic science and biomedical research, and raised hopes about major improvements to diagnosis and medical treatment.

A basic genetics primer

DNA, RNA, genes and chromosomes[119]

2.54 Every cell in the human body (with the exception of mature red blood cells, which lose their nucleus and so have no chromosomes) contains a nucleus within which are tightly coiled threadlike structures known as chromosomes. (See Figure 1.) Humans normally have 23 pairs of chromosomes, one member of each pair derived from the mother and one from the father. (See Figure 2.) Each chromosome has within it, arranged end-to-end, hundreds or thousands of genes (see Figure 3),[120] each with a specific location, consisting of the inherited genetic material known as DNA (deoxyribonucleic acid).

2.55 DNA is so called because it consists of a large acid molecule mainly found in the nucleus *(nucleic)*, to which many sugar groups (*ribo*) missing an oxygen molecule (*deoxy*) are attached. DNA contains a code that directs the 'expression' or production of proteins, which form much of the structure of the cell and control the chemical reactions within them. The DNA of each gene is characterised by a unique sequence of bases which, when arranged in triplets ('codons') in various orders, represent the 'genetic code'.[121]

2.56 There are many different definitions for a gene, but one of the most commonly accepted is that a gene contains all of the information required to determine the expression of a specific protein, or a chain of amino acids (a 'polypeptide'). Sometimes a polypeptide can form a complete protein on its own

118 M Manktelow, 'Biotech: The Next Bonanza', *The Sydney Morning Herald*, 18 September 2001.

119 This section is drawn from a number of sources, including: R Hawley and C Mori (1999); M Ridley (1999); R Trent (1997); the website of the Cooperative Research Centre for Discovery of Genes for Common Human Diseases <http://www.genecrc.org>; and an ALRC in-house seminar on 'Introduction to Genetic Testing', presented by Dr Richard Linsk, University of Michigan, 20 February 2001.

120 As noted above, recent work by the Human Genome Project and related research mapping the human genome suggests that human beings have about 30 000–40 000 genes.

121 For an excellent popular account of modern genetics, see M Ridley (1999).

(such as in the case of insulin), but in most cases a number of polypeptides combine to create a single functional protein — which means that a number of different genes are concerned with coding for that protein.

2.57 There are four basic building blocks ('nucleotides') for DNA: Adenine (A) and Guanine (G), which are known as 'purines'; and Thymine (T) and Cytosine (C), which are known as 'pyrimidines'. These nucleotides link together to form long polynucleotide chains. (See Figure 4.) 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, known as '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.

2.58 There are roughly six billion of these base pairs of DNA making up the human genome. The two chains link together in a ladder-like shape, twisted into the now famous double helix, with sugars and phosphates forming the sides or backbone of the ladder and the base pairs forming the rungs. (See Figure 5.)

2.59 Proteins are critical components of all cells, determining colour, shape and function. Proteins can have a structural role (such as keratin, from which hair is made), or a functional role in regulating the chemical reactions that occur within each cell (such as the enzymes used to digest food). Proteins are themselves made up of a chain of amino acids. Within the DNA there is a code that determines which amino acids will come together to form that particular protein. The genetic code for each amino acid, consisting of three base sequences, is virtually identical across all living organisms.[122]

2.60 Different genes are switched on and off in different cells, leading to different proteins being made or expressed with different structures, appearances and functions — leading to the production variously of brain cells, nerve cells, blood cells, and so on. As discussed in chapter 1, contemporary stem cell research is based around the idea that it should be possible to use gene switches to coax stem cells into developing into the specialised cell or tissue needed for therapeutic purposes.

2.61 When the instructions in a gene are to be read, the DNA comprising that gene unwinds and the hydrogen bases holding the two strands separate. A special enzyme, called RNA polymerase, allows a complementary copy of one strand of the DNA to be made. This copy is made from RNA nucleotides, and is called

122 There are 64 different possible codons (given the four letters in the building blocks), and no codon can code for more than one amino acid. As there are only 20 different types of amino acids, some codons must encode the same amino acid. See R Hawley and C Mori (1999), 32.

'messenger RNA' (or mRNA), because it serves to carry the coded genetic information to the units in the cell called ribosomes.[123] This process of reading the message in the DNA is called 'transcription'. On the ribosomes, the amino acids are assembled in the precise order coded for in the mRNA.[124] The process of converting the message encoded in the RNA (mRNA) to protein using the ribosome is called 'translation'. When the whole message has been translated, the long chain of amino acids folds itself up into a distinctive shape that depends upon its sequence, and is now known as a 'protein'.[125]

Genetic difference: genotypes, phenotypes and the environment

2.62 While all humans have the same basic set of about 40,000 genes, according to the latest estimates, the precise DNA sequence varies in different individuals. This fact explains both the similarities among people that are the result of our common inheritance, and the many individual differences found even within a nuclear family.

2.63 Having considered the striking similarity across the human genome — and indeed, across most forms of life — it is also the case, of course, that there are many genetic variations across the population. 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 (ie, 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 in some way (a mutation). A mutation can result in the gene producing abnormal protein, reduced amounts of protein, or no protein at all.

2.64 Some genetic differences make little or no difference to health — for example, hair colour. However, some mutations do affect basic functioning, with the protein produced in such a way that it works differently — whether this difference makes for a protective or improved function, or creates a susceptibility to a disease, or even directly causes a 'genetic disorder' (also referred to as a 'genetic condition' or a 'genetic disease'):

> 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

123 RNA also carries the linear code and employs the same building block letters as DNA, except that it uses U (for uracil) in place of T (for thymine).

124 Transfer RNA molecules (tRNA) also play a key role in carrying specific amino acids to the ribosome to be linked to the growing polypeptide or protein.

125 See M Ridley (1999), 9.

> 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.[126]

2.65 The unique combination of alleles found in a particular individual's genetic make–up is said to constitute that person's *genotype*. The outward expression or 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.

2.66 According to the Human Genome Database,[127] 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 more obvious links already have been found, since of the last 3,783 genes to have been mapped, only 17 have been identified with a genetic disorder.

2.67 See Table 2–1 on genetic disorders and genetic testing at the end of this chapter, which describes the scientific and medical nature of a number of genetic disorders, including the mutation(s) involved, prevalence, and the opportunities for diagnosis, prevention and treatment.[128]

2.68 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,[129] 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).

2.69 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*:

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126 R Hawley and C Mori (1999), 6. For example, Huntington's disease (HD) is caused by a mutation to a gene that lies on chromosome 4, which contains the single 'word' CAG repeated over and over again. Most people have 10-15 repeats; 39 or more repeats means 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 causes another rare but serious disease, Wolf-Hirschhorn syndrome. See M Ridley (1999), 55.

127 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.

128 The inquiry thanks Associate Professor Eric Haan, a member of the Advisory Committee, for the preparation of this Table.

129 See eg S Rose, L Kamin and R Lewontin (1985).

- the product of his or her genes;
- the intricate interaction of those genes; and
- the elaborate interaction between that genetic legacy and environmental factors.

2.70 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 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.

2.71 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.[130]

2.72 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 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.

2.73 There is also some early, but very exciting, research in the UK by Professor Colin Blakemore and others that shows that in the case of transgenic mice, at least, early intervention involving environmental enrichment may delay significantly the onset of Huntington's disease[131] — a serious degenerative disease

130 M Ridley (1999), 75.

131 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.

once thought to be the paradigm of a genetic-linked disease that could be predicted with certainty through DNA testing, and which was incurable. Taking the genetic link as a given, this research focused on the physiological effects of the disease on the brain, and looked at how these effects could be countered, or at least muted, by environmental factors.

2.74 Similarly, Alzheimer's disease is a good example of a disease that is 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.[132]

Patterns of inheritance

2.75 As mutations can affect the functioning and expression of the alleles of genes, resulting in particular traits or characteristics, it is possible to follow the pattern of inheritance of the different alleles of a gene in a family. For most genes, two copies are found in the one individual. If the two copies are the same allele, the individual is said to be *homozygous*. If there are two different alleles for that gene present, the individual is referred to as *heterozygous* for that gene. (The exceptions to this are traits coded for by genes found on the X chromosome; see below.)

Traits that follow a pattern of autosomal recessive inheritance

2.76 Autosomes are the chromosomes that do not determine sex (ie, in humans, all of the chromosomes except for the X and Y). Scientists have numbered these autosomes from 1–22, with chromosome 1 being the longest. Everyone has two copies of the autosomes and therefore two copies of the genes carried on these chromosomes. A *recessive* trait, which may be a genetic disorder, is one that is expressed only if an individual is homozygous for that gene — ie, he or she must have two copies of the mutated allele coding for it, one inherited from the mother and one from the father. Two parents who themselves do not express a particular trait nevertheless may have a child with the trait, if each parent is a heterozygous *carrier* for the mutated allele — that is, each parent has one copy of the recessive mutated allele and one copy of the 'correct' allele. As the correct copy of the allele is present in the parents, enough protein is produced by that correct copy to ensure that the trait is not expressed.

2.77 Autosomes are the chromosomes that do not determine sex (ie, in humans, all of the chromosomes except for the X and Y). A *recessive* trait is one that is expressed only if an individual is homozygous for that gene — ie, he or she

132 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.

must have two copies of the allele coding for it, one inherited from the mother and one from the father. Therefore, if both parents are carriers, a child has a one in four chance of inheriting both abnormal alleles and so developing a clinical disorder. (See Figure 6.) Two parents without a particular trait nevertheless may have a child with the trait, if each parent is a heterozygous *carrier* for that trait — that is, each parent has one copy of the recessive allele and one copy of the dominant allele.

2.78 To provide a prosaic example, two brown-eyed parents with recessive alleles for blue eyes can produce a blue-eyed child.[133] Of more concern is the situation in which both parents are carriers of a mutated gene that causes a genetic disorder such as cystic fibrosis. Each parent has one 'normal' or correct copy and one recessive, mutated copy of the gene, and each is unaffected by the disease as the normal copy of the gene produces enough protein to remain healthy. The children of these parents, however, have a one in four chance of inheriting the mutated allele from each parent and being born with cystic fibrosis. Other examples of autosomal recessive (AR) conditions include haemochromatosis, β-thalassaemia, and Tay–Sachs disease (see Table 2–1, below).

Traits that follow a pattern of autosomal dominant inheritance

2.79 Some mutations are so powerful that an individual with only one copy of the mutated allele (inherited from either parent) manifests that trait. Accordingly, the children of persons who have a dominant mutated allele have a one in two chance of inheriting that allele (and trait). (See Figure 7.) Examples of autosomal dominant (AD) traits include Huntington's disease, myotonic dystrophy, hereditary non-polyposis colorectal cancer, Factor V Leiden, familial adenomatous polyposis (FAP), and early onset familial Alzheimer's disease (see Table 2–1, below).

Traits that follow a pattern of X-linked inheritance

2.80 X-linked traits are determined by genes found on the X chromosome. Since males have an X and a Y chromosome, they can only have one copy of each of the genes found on the X chromosome, and will always express these genes. (See Figure 8.) Since a woman has two X chromosomes, having a recessive mutated allele may not cause the trait to be expressed, because she will have a correct allele on the other X chromosome. X-linked conditions (XL) caused by recessive genes include haemophilia, Fragile X mental retardation and Duchenne muscular dystrophy (see Table 2–1, below).

133 It should be noted, however, that the development of eye colour is complex and involves more than one gene. For a discussion of the genetics of hair colour, eye colour and other physical characteristics, see R van Oorschot and others (2001).

Disease, disorder or protective trait?

2.81 As noted above, there is a tendency to label many genetic variations as 'diseases' or 'disorders' — but some mutations may confer a benefit in terms of survivability, at least in certain environmental contexts. The following examples all involve autosomal recessive conditions[134] in which the genetic 'abnormality' does not cause significant clinical problems for the carrier (but would do so in a child who inherits affected genes from both parents).[135]

2.82 *β-thalassaemia* is common in the Mediterranean area and in many parts of Southeast Asia. The genetic defect involves impairment in the synthesis of a protein (globin) found in red blood cells. The carrier state affords protection against malaria, however, because carriers have pale and small red blood cells that do not provide the malaria parasite with a good environment in which to grow. Carriers tend to have very mild anaemia (not enough to cause serious health problems), but the homozygous affected person is severely affected with anaemia (in the worst cases, requiring life-long blood transfusion).

2.83 *Tay–Sachs disease* (TSD) is ten times more common in the Ashkenazi (Central and eastern European) Jewish community than in non-Jews or Sephardic (Middle Eastern) Jews. It is a neurological degenerative disease that usually results in death by the age of four or five. Carriers of the mutated allele for TSD do not have any symptoms of the condition, but it is thought that the carrier state provided protection against tuberculosis in the cramped conditions of the ghettos in which the Jewish population had to live in times past.

2.84 *Cystic fibrosis* (CF) is common in many ethnic groups but particularly among Caucasians — about one in 25 of whom are carriers of the mutated allele for CF. The defect in CF involves movements of chloride across cells and causes severe problems in lung and pancreatic functions for those with the disease. Those people who are carriers of the mutated allele for CF do not move chloride (ie salt) across their membranes as well as those who are not carriers, and so are at less risk of dying from diarrhoea. Over the many thousands of years of evolution, this would have been a useful mutation to carry when cholera and dysentery were endemic. Carriers generally do not have the symptoms of CF (in fact carrier status only can be determined through a DNA test),[136] but a child inheriting the CF mutated allele from both parents may develop severe health problems (although CF is very variable in its severity).

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134 See Table 2–1.

135 Information provided by Advisory Committee members Professor Ron Trent and Dr Kristine Barlow-Stewart. See also R Trent (1997) 10-11.

136 However, a man who is a carrier of a mutated allele and has a polymorphism in the other allele may not have outwards symptoms of CF, but may be infertile.

2.85 *Haemochromatosis* is very common in persons of northern European descent (one in 10), and leads to an accumulation of iron in the body. Carriers have no problems, but those with both genes abnormal will get complications related to iron accumulation. Being a carrier for the haemochromatosis gene historically would have helped in circumstances in which there is the possibility of iron deficiency (eg, malnutrition, blood loss, pregnancy). Unlike the disorders mentioned above, there is no strong laboratory proof for the selective advantage of the haemochromatosis gene defect, but it is not too difficult to see how being a carrier would provide an advantage in an environment which made a person lose iron or get little iron from the normal diet.

2.86 *Sickle cell anaemia* is caused by a mutation in the haemoglobin gene, and is common among persons from Africa and the Mediterranean area. The carrier state affords protection against malaria, however, because carriers have abnormal red blood cells that die soon after being infected with the malaria parasite, compared with normal red blood cells, which continue to work and to provide an environment in which the malaria parasite can grow. In an evolutionary sense, being a carrier for sickle cell disease is a good thing if one lives in a region in which there is endemic malaria.

Medical genetics

2.87 Ridley has pointed out that identifying specific genes as the cause of diseases obscures their vital role in physiology:

> 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. This gene causes Niemann-Pick disease; that one causes Wolf-Hirschhorn syndrome. The impression given is that genes are there to cause diseases. …
>
> 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.[137]

137 M Ridley (1999), 54–55.

2.88 It would be simplistic and inaccurate to suggest that an individual's health can be assessed solely by the sequence of bases in his or her DNA or that genetic susceptibility equates with genetic inevitability. An individual's genes are only one of the factors that will determine that person's future health, albeit a significant factor in many cases.[138] Other factors include:

- environment;
- lifestyle;
- complex interactions between inherited genes;
- spontaneous gene mutations occurring during life;[139] and
- chance.

2.89 Medical conditions or diseases linked to genes can be classified in a number of ways, including:[140]

- single-gene (or 'monogenic');
- polygenic;
- multifactorial;
- chromosomal (such as Down syndrome);[141] and
- somatic cell.[142]

2.90 A monogenic disorder is one in which a mutation in one or both alleles of just one of the 40,000 genes 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, as Ridley has noted, such diseases are atypical and 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.[143]

138 See D Hamer and P Copeland (1998).
139 See reference to 'somatic cell' genetic disease, below.
140 R Trent (1997), 37.
141 Ibid, 69–70.
142 The 'spontaneous gene mutations occurring during life' referred to above, typically associated with ageing, auto-immune disease and congenital malformations: Ibid, 210–211.

2.91 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 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.[144]

2.92 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).[145] In the latter, 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 (insulin-dependent); and
- cancer.

Genetic testing

DNA test processes

2.93 A genetic test is a process that reveals genetic information. It may be performed on DNA, RNA or protein (the 'gene product'), or involve measurement of a substance that indirectly reflects gene function.

2.94 Testing involves the targeting of a segment of DNA (and RNA) and then using a technological process known as polymerase chain reaction (PCR) to produce multiple amounts of that targeted region ('DNA amplification').[146] Further

143 M Ridley (1999), 64.
144 Ibid, 66.
145 R Trent (1997), 55, 211.
146 Ibid, 19.

processes are used to 'sequence' the DNA (enumerating the nucleotide base pairs), and then to analyse the data for 'markers' known to be linked to particular genetic disorders.

2.95 As noted above, a single DNA sample contains all of an individual's genes. Each of us has a unique DNA sequence that is a major contributor to our individuality. By birth, even the sequences of identical twins have differences, albeit very small. Thus genetic testing also provides a powerful tool that can be used to identify an individual from a tiny DNA sample (DNA 'fingerprinting' or 'profiling').[147]

2.96 Genetic testing is still a relatively slow and expensive process. However, the technology is advancing rapidly, and the development of automated 'DNA chip' technology in particular will soon make it possible (and financially practical) to conduct multiplex testing (screening for numerous mutations at the same time in a single test procedure).[148] It may soon be the case that the genetic information available will outstrip the capacity of health systems to interpret all of it and to counsel patients effectively.[149]

Types and timing of genetic tests

2.97 There are a number of different types of genetic tests:

- *Diagnostic testing* — performed to make or confirm a diagnosis of a specific disorder in a person who generally already has symptoms and/or signs of that disorder.

- *Predictive (or presymptomatic) testing* — performed on a person who has no symptoms of a specific disorder at the time of testing, to determine whether or not he or she has a genetic variant or variants which increase the likelihood that the person may,[150] or will,[151] develop symptoms of the disorder in question at some time in the future.

- *Carrier testing* — performed on a person to determine whether or not he or she has a mutated allele or chromosome abnormality that will not affect the person's health, but increases his or her chance of having children with the disorder in question. The outcome of such testing can have an effect on future reproductive decisions.

147 See Chapter 13 on the uses of DNA testing for law enforcement purposes.
148 Also known as 'gene chips', 'biochips' and 'DNA microarrays'. See S Moore, 'Making Chips to Probe Genes', *IEEE Spectrum*, 1 March 2001, 54.
149 Council on Ethical and Judicial Affairs — American Medical Association, 'Multiplex genetic testing' (1998) 28(4) *Hastings Center Report* 15.
150 As in the case of a genetic susceptibility requiring an environmental trigger.
151 As in the case of adult onset disorders, such as Huntington's disease.

- *Prenatal testing* — performed on the foetus in utero (or pre-implantation, in the case of embryos used in ART procedures).[152] Technological advances have increased the scope for prenatal DNA testing and diagnosis, with the potential in the future for this to become a non-invasive test by isolating foetal specific DNA from the mother's blood.[153] Prenatal genetic testing typically is performed where there are 'at risk' parents, such as parents who are carriers of mutated alleles for CF, Tay-Sachs disease, or β-thalassaemia. Early detection will permit use of some prenatal therapies, such as blood transfusion and surgical correction (and soon, perhaps, gene therapy), or postnatal therapy.

- *Forensic testing* — 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, such as for use in criminal investigations (to exclude or to help identify a suspect), in searches for missing persons, in the identification of unknown deceased persons, or in determining paternity.[154]

2.98 The Human Genetics Society of Australasia (HGSA) has emphasised the need to distinguish between diagnostic and predictive testing. In a submission to the Parliamentary Committee considering the Stott Despoja Bill, the HGSA stated its view — with which many clinicians agree — that there are no greater privacy implications for *symptomatic* patients in diagnostic genetic testing (such as a child having a gene test to see if the recurrent cough might be cystic fibrosis, or a person having a test for haemochromatosis because of liver indices) than in any other diagnostic testing (such as blood tests, MRI or X-rays) — whereas predictive genetic testing requires counselling and additional privacy protection.[155]

2.99 As discussed below, there also are arguments that genetic information carries with it special ethical (if not always special privacy) considerations compared with other diagnostic tests, because of the wider implications for family members. These considerations are canvassed further, below.

Accuracy of individual genetic tests

2.100 Since its development in the US in 1985,[156] PCR testing has become a routine diagnostic, research and forensic procedure in molecular biology laboratories. However, every lab testing procedure, no matter how standard, inevitably involves errors, uncertainties and problems in interpretation.

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152 See also the discussion of prenatal and pre-implantation testing in Chapter 1.

153 R Trent (1997), 75.

154 See Chapters 13–14 on law enforcement and evidence, respectively, for further discussion of these matters.

155 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.

156 For which its developer was awarded the Nobel Prize: see R Trent (1997), 4.

For graphics see attached PDF file.

For graphics see attached PDF file.

For graphics see attached PDF file.

The relative ease of contamination is said to be a major disadvantage of PCR, with such contamination coming from extraneous DNA (such as from other samples — especially the previously amplified products — or from the operator). There are also occasional errors with the sequence fidelity of amplified products, resulting in reading errors.[157]

2.101 The 'sensitivity' of a testing procedure refers to the statistical likelihood that a 'true-positive' will return a positive test result. The 'specificity' of a testing procedure refers to the likelihood that a 'true-negative' will test negative. These concepts of measuring accuracy are based on traditional chemical tests such as the blood sugar level. However, genetic (DNA) tests are more complex, because apart from the conventional laboratory issues to consider, genetic disorders and their detection at the DNA level require consideration of:

- the multiplicity of DNA mutations which can give rise to a defect (in some genetic disorders, each individual has his/her own specific mutation); and

- the geographic or ethnic based origin for some mutations.

2.102 Hence, in terms of the two features just noted, *finding* a mutation through genetic testing is much more helpful than receiving a negative result — because the latter might be explained by the person being 'normal', *or* alternatively, that he or she has a particular mutation which was not tested for, or has an ethnic background which is not covered by the range of mutations tested for.

2.103 Clinicians — and, of course, patients — desire 100% accuracy. However, very few laboratory tests currently are more than 98% sensitive and specific.[158] Similarly, every test result requires individual interpretation, with a further opportunity, however slight, for error to be introduced. Because genetic tests are 'scientific', many non-experts invest excessive confidence in their significance and predictive value.[159]

2.104 Thus, a small but still significant number of people who take genetic tests will receive inaccurate information about their condition — whether this involves the trauma and stigma of a false positive, or the spurious re-assurance of a false negative — and will plan their lives and act accordingly. Although in recent years there has been considerable attention paid internationally to developing policies in relation to the ethical and lawful use of genetic information, there has been relatively less discussion about the impact of erroneous information.

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157 Ibid, 20.

158 ALRC in-house seminar on 'Introduction to Genetic Testing', presented by Dr Richard Linsk, University of Michigan, 20 February 2001.

159 This is also a problem in relation to the presentation of evidence in court based on genetic testing: see chapters 13-14.

The importance of penetrance

2.105 'Penetrance' is the term describing the degree of likelihood (based on clinical studies) that an individual carrying a trait will exhibit the phenotype associated with that allele:

> If 7 out of 10 heterozygotes [for a dominantly inherited condition] show the clinical phenotype, the disorder is described as being 70% penetrant. That is, there is a 70% probability that an individual carrying a mutant gene at a certain age will display the clinical phenotype.[160]

2.106 The degree of penetrance indicates the likelihood that someone who has the genetic sequence that could cause a disorder will actually develop it. This can vary from very low to very high, but it is not always straightforward. For instance, it is possible to speak of the penetrance for each particular mutation (or combination of mutations) causing cystic fibrosis. 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.[161] The severity of the disease also may vary with the mutation, as for cystic fibrosis (CF) — some individuals have mild CF, while others have severe CF.

2.107 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 with a BRCA1 or BRCA2 gene will develop breast cancer during their lifetimes, while 15–40% will not do so. Thus, the penetrance of these genes for breast cancer is said to be 60–85%. 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.

2.108 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.[162] 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. Further, as discussed above, in relation to the interaction of genes and environment, there is now promising research indicating that an enriched

160 R Trent (1997), 47.

161 Eg, in the case of cystic fibrosis, clinicians must consider whether male infertility in the absence of any other clinical signs is a 'condition', or a 'disease', or nothing of significance.

162 R Trent (1997), 58. See also M Ridley (1999), 55–66.

environment (mental stimulation, physical activity etc) may delay significantly the onset of HD and other degenerative diseases, such as Alzheimer's.[163]

2.109 In Table 2–1, below, there is a column that contains further information about penetrance for a range of medical conditions. Note, however, that the figures provided must be read in context. As discussed above, the penetrance and severity of CF may not be the same for all persons. A similar point can be made about thalassaemia. Finally, note that the Table's reference to the penetrance of haemochromatosis ends with a question mark — because there are so many variables (both genetic and environmental) in this disorder, it is not possible to offer a single, precise penetrance figure.

Defining 'genetic information'

2.110 Genetic information includes both DNA sequence information as revealed by a genetic test and inferences that can be made from knowledge of the sequence.

2.111 Genetic information also may be revealed by:

- studying entire chromosomes, RNA, proteins, substances in blood or tissues in certain circumstances, and medical imaging techniques;
- diagnosing a genetic disorder by clinical examination; or
- studying a person's family medical history if that allows inferences to be made about the DNA of family members.

2.112 Genetic information can relate to a condition that is:

- clinically apparent — such as when a genetic test is performed to confirm a diagnosis in someone who has signs or symptoms of a particular disorder; or
- latent — such as when a genetic test is done on someone who is apparently free of a disorder at present to determine the likelihood that he or she will or may develop the disorder in the future or where a condition is non-penetrant.

2.113 Genetic information can be about individuals, families or groups of people with common ancestry (see below). General inferences may be possible about the genetic information of an individual who belongs to such a group if information is known about other members of the group.

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163 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.

2.114 As discussed above, information generated by DNA testing can be very precise — indicating that a particular mutation is or is not present. However, this precision often will prove unhelpful when it comes to predicting future health. Thus, 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 develop the disorder. Also, in some cases, genetic testing may not find a mutation even though the clinical evidence is to the contrary.

Is genetic information special?

2.115 One of the key issues for the inquiry is whether genetic information is so fundamentally different (qualitatively or quantitatively) from other forms of health information that it requires a special regime to regulate its collection, use and disclosure.

2.116 The Chair of the ELSI Task Force on Genetic Information and Insurance, Thomas Murray, has noted that 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 bulbs at the base of the hairs we continuously shed' — 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.[164]

2.117 As noted above, genetic information is not only pertinent to an individual but may tell us something about close blood relatives, in both succeeding and preceding generations. For example, demonstrating that an individual is a carrier of a mutated allele for CF implies that one of that person's parents is also a carrier. In some cases, genetic information is pertinent to whole communities. For example, Tay-Sachs disease is primarily (but not exclusively) found in persons of Ashkenazi (European) Jewish descent; sickle cell anaemia primarily affects persons of black African descent; and haemochromatosis is very common in persons of northern European descent. Thus, genetic information can be said to flow 'from before the cradle to after the grave'.

2.118 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 potentially imprecise, could be incorporated into decision making by the individual and/or by others (such as employers, insurance companies or public authorities).

164 T Murray (1997), 60.

2.119 Further, opportunities for access to genetic information in the health sector are increased by the multidisciplinary nature of much medical practice and developments in information technology. Its novelty also creates a risk that both the information and its implications will be misunderstood or over-stated by health professionals, the families of those tested, or others in the community who have access to the information.

2.120 Developments in genetics pose ethical questions for individuals and families, as well as for society. Some arise from the nature of genes and genetic information, which are at the same time both personal and shared with family members and, in many cases, with people outside the family (eg, with members of an ethnic group).

2.121 Other questions arise from the fact that, until now, individuals and society have not had to deal with predictive information of such quantity and ostensible accuracy, 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.

2.122 At the same time, genetic information has the corresponding potential to empower people to make choices about health for themselves and their families to a much greater extent than is the case with most other health information. Genetic testing for haemochromatosis, glaucoma, some cancers and other medical conditions can alert the individual to begin preventive measures before the disease causes harm.

2.123 As noted above, even with a severe degenerative disease such as Huntington's, which always has been thought of in black-and-white terms, there is now research suggesting that early intervention with environmental enrichment may delay the onset of the disease[165] — which also serves to increase the argument for presymptomatic testing in Huntington's disease, since this could bring maximum benefits to those who carry the mutation.[166] Similarly, as noted above, there is evidence that the onset of Alzheimer's disease can be delayed significantly by environmental factors, including physical exercise and mental stimulation.[167]

2.124 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.

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165 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.

166 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.

167 Prof Bob Williamson: Ibid.

2.125 Further, there should be no implication that 'genetics' is about bad things; in truth, there is no such thing as an 'HD gene' or a 'breast cancer gene' — these genes are (in most of us) genes for health. Community and professional education and the ready availability of information when needed can minimise misunderstanding of, over-reaction to, and misuse of, genetic information.

'Genetic exceptionalism'

2.126 Professors Annas, Glantz and Roche of the Boston University School of Public Health, the authors of the US Model Genetic Privacy Act (which strongly influenced the Stott Despoja Bill in Australia) have argued that genetic information is sufficiently unique and more powerful than other forms of health information so as to require special protection or other exceptional 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.[168]

2.127 Annas, Glantz and Roche offer three justifications for this view.

- 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.[169]

- Second, that genetic information about an individual also 'divulges personal information about one's parents, siblings, and children'.[170]

- 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.

2.128 Gostin also suggests that there are 'compelling justifications' for special privacy protection for genetic information, which are grounded in:

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168 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.
169 Ibid, 360.
170 Ibid.

> 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.[171]

2.129 However, Murray has noted that 'after many attempts to make the case for genetic exceptionalism, the task force abandoned the effort' — at least in this particular context.[172] Murray argues that much of the drive behind genetic exceptionalism is based upon a generalised image of genetic information as 'a mysterious, powerful and inexorable force that will dominate and control our futures'.[173] He disputes the view that the predictive nature of genetic information compels special treatment:

> The argument from genetic prophecy is not compelling. Genetic information is neither unique nor distinctive in its ability to offer probabilistic peeks into our future health. Many other things afford equally interesting predictions. Some of them would be impossible to conceal and so fall outside the concern of privacy — some people, for example, are avid skydivers or parasailers. Other types of information would be hidden, just like most genetic information; examples include asymptomatic hepatitis B infection, early HIV infection, and even one's cholesterol level. These have implications for future health that are every bit as cogent and sensitive as genetic predispositions.[174]

> In complex disorders with many contributing factors, such as many cancers and heart disease, genetic information may indicate only a rough range of probabilities, something that falls short of a 'probabilistic future'.

> Genetic exceptionalism depends on what we have come to call the 'two-bucket theory' of disease. According to this model, there are two buckets — one labelled 'genetic,' and the other labelled 'non-genetic' — and we should be able to toss every disease and risk factor into one of the two. So Huntington disease goes into the 'genetic' bucket and getting run over by a truck goes into the 'non-genetic' one. But many diseases and risks don't fit neatly into either bucket.[175]

2.130 Murray also rejects the view that genetic information is uniquely sensitive because it may apply to family members and others beyond the individual most concerned:

> it is difficult to claim uniqueness, or even special importance and sensitivity for genetic information. That one member of a family has tuberculosis is certainly relevant to the rest of the household, all of whom are in danger of infection, along with everyone who works with or goes to school with the infected individual. Likewise, if a partner in a marriage has a sexually transmitted disease, that information is important for the other partner. Or suppose the main wage earner in the

171 L Gostin, 'Genetic Privacy' (1995) 23(4) *The Journal of Law, Medicine and Ethics* 320, 326.
172 T Murray (1997) 61.
173 Ibid, 64.
174 Ibid, 64.
175 Ibid, 67.

> household showed early signs of heart disease that could bring disability and death. Wouldn't the other family members have a profoundly important stake in knowing this?[176]

2.131 Finally, Murray also dismisses the argument based around the greater potential for discrimination, stating 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. In underwriting for health insurance, for example, insurers use evidence of current disease or future disease risk — whether it is genetic or non-genetic doesn't matter — to decide who gets a policy, what the policy covers and how much it costs.
>
> … If we are less inclined to worry about discrimination on the basis of health risk factors that are open to modification and individual choice [such as smoking and thrill-seeking], then let us recognize *that* as the relevant difference, and not confuse it with the distinction between genetic and non-genetic factors.[177]
>
> … Perhaps what really frightens and galls us about discrimination on the basis of genetic information 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.[178]

2.132 In abandoning genetic exceptionalism, Murray writes that the Task Force 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 our the scope of our responsibility and outside of that scope. The distinction between genetic and non-genetic factors is not the crucial one.[179]

Question 2–1. Should genetic information be treated as being so unique or so much more powerful than other forms of health information that it requires special legal protection or other exceptional measures? If so, in which contexts, and how should this special status be accommodated in practice?

176 Ibid, 65.
177 Ibid, 66.
178 Ibid.
179 Ibid, 71.

The dangers of 'genetic essentialism'

2.133 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.[180]

2.134 Similarly, Murray warns 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.[181]

> … 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.[182]

2.135 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 the way we think about what it means to be human. 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 determined? Will this challenge our fundamental ideas about free will, and our understandings (and legal principles) of individual moral responsibility and of social responsibility?[183]

2.136 'Genetic essentialism' is a reductionist view of human beings as essentially consisting of their genes, with human worth describable in the language of genetics. It is associated with 'genetic determinism' — a view that human health and behaviour are predetermined by, if not co-extensive with, a person's genetic make-up:

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180 D Nelkin and S Lindee (1995), 198.
181 T Murray (1997), 70.
182 Ibid, 71.
183 See L Andrews (2001); M Ridley (1999) ch 22; D Hamer and P Copeland (1998).

> personal traits are predictable and permanent, determined at conception, 'hard-wired' into the human constitution ... [T]his ideology minimizes the importance of social context.'[184]

2.137 A number of concerns have been raised about naïve forms of these views. Over-concentration on research on genes and their health implications could lead to neglect of the effects on human health of other factors, such as the physical, social and economic environments in which people live.[185]

2.138 Current attitudes of social solidarity could be threatened by genetic essentialism. An example of loss of solidarity in society would be the expectation 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.

2.139 Aldous Huxley's *Brave New World* was perhaps the first cultural response to the fascination with eugenics in the 1920s and 1930s as a principle for social organisation and improvement.[186] In light of recent scientific advances, popular culture is again beginning to consider the chilling vision of a society organised around genetic determinism. Quoting James Watson that 'We used to think our future was in the stars. Now we know it is in our genes', the 1997 Hollywood film GATTACA portrays a society, not too many years away, in which:

> every family has the power to draw its own line — to decide, if they can afford it, just how perfect a child they want to create. This leads to a society that worships total predictability and perfection — a cooler, more ordered and scientific world than the one we live in today, a world that does not welcome the burning desires and dreams of [someone who may not be genetically 'perfect'].[187]

2.140 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

184 R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 316-321.

185 See eg R Lewontin (2000).

186 A Huxley (1932).

187 'GATTACA' is taken from the four-letter building blocks for DNA. The film's website is found at <http://www.gattaca.com/> (1 October 2001).

> implacable programmers of a Calvinist predestination and the environment as the home of liberal free will is a fallacy.[188]

2.141 Harkening back to the introduction to this chapter, the challenge for our society http://www.spe.sony.com/Pictures/SonyMovies/movies/Gattaca/the_film/production_notes/bigphotos/pr_gattaca.htmis 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.

Advisory and regulatory approaches

2.142 The central focus of the terms of reference of the inquiry is on 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 above, there may valuable lessons to be learned from other challenges faced by the health system, legal system and social services in recent times, such as with respect to dealing with the outbreak of HIV-AIDS in such a way as to take seriously the medical issues and the risk of the spread of infection, while at the same time endeavouring not to stigmatise or discriminate against persons who are HIV positive, nor unduly breach their privacy.

2.143 The ALRC and AHEC are interested in obtaining initial comments on the merits of available regulatory approaches.

The need for a sophisticated approach to regulating genetic science

2.144 With the rapid advances in genetic science and biotechnology, Professor Bartha-Maria Knoppers [189] has argued for a more sophisticated approach to regulation. Knoppers identifies four tools that should be employed in parallel to 'adopt a stewardship or ecosystemic approach that takes public values into account'.[190]

> The first tool is human rights. Using it means waiting for someone to take a new science or technology-related issue before the courts so that it can be assessed for compliance with the constitution and with human rights charters and codes.
>
> The second tool is self-regulation. Professional associations and researchers should not only be aware of the ethical, social, and legal implications of their work, but

188 M Ridley (1999), 302-303.
189 Faculty of Law, University of Montreal.
190 B-M Knoppers (2000).

> should also cooperate with their patients, the participants in their research, and the local community to establish a framework for self-regulation, by drawing up a code of ethics, for example.
>
> The third option, and generally the most popular with the public, is legislation. However, legislation that targets techniques rather than outcomes to be avoided often proves ineffective. Considerable care is needed when drafting laws on emerging fields of scientific activity.
>
> The last tool, the one preferred by the United States, is the market approach. Market forces will eliminate bad science and keep the good. Those who develop the best and safest technique will survive. Today's savvy consumers will reject techniques that do not yield satisfactory results. Liability-related legal action strengthens this approach.

2.145 A natural first step in the inquiry's work is to map the existing regulatory frameworks for dealing with considerations of privacy, discrimination and ethical practices, and to identify whether those frameworks are adequate, and sufficiently enmeshed, in the way that they apply to genetic information. Much of the balance of this paper presents material dealing with this issue.

The trends towards a national approach

2.146 One fundamental question is the extent to which a national approach to biotechnology regulation may be required, rather than relying upon the traditional mix of federal, state and territory laws.

2.147 To some extent, this shift is already taking place. For example, the extension of privacy protections to cover the private sector is being achieved through federal law, regulations and processes, and will be overseen by the Federal Privacy Commissioner (see Chapter 4). Aspects of federal anti-discrimination law and industrial law already cover the field (see Chapters 5 and 10). Intellectual property rights for advances in genetics are determined according to federal laws and international agreements (see Chapter 1). The *Gene Technology Act* 2000 (Cth) s 5 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'. On 8 June 2001, the Council of Australian Governments (COAG), representing the federal, state and territory governments, decided to adopt a national approach to human cloning, stem cell research and related matters, and the September 2001 report of the House of Representatives Standing Committee on Legal and Constitutional Affairs recommends a uniform, national approach to legislation and the establishment of a national licensing body

to regulate human cloning and research using cloning techniques (see Chapter 1).[191]

2.148 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 Issues Paper, and the constitutional limitations on the exercise of federal legislative power,[192] only a cooperative approach involving the Commonwealth, the States and the Territories would assure the successful establishment of a comprehensive national scheme.[193]

2.149 The joint inquiry would be interesting in views about whether the protection of human genetic information is an area in which the public interest would best be served by a more uniform, national approach to regulation.

Question 2–2. Should there be a more uniform, national approach to the protection of human genetic information?

The international trend towards standing advisory bodies

2.150 A related issue concerns whether there is promise in examining the establishment of a standing body in Australia to advise the government on the ongoing development of a regulatory framework for human genetics — that is, something similar to the UK's Human Genetics Commission (HGC).

The UK Human Genetics Commission

2.151 The Human Genetics Commission (HGC) was established following a comprehensive review by the British government in May 1999 of the regulatory

191 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.

192 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. Areas not specifically mentioned are reserved for the States — except to the extent to which the Commonwealth might hang the exercise of power on a general peg within s 51, such as the enforcement of treaty obligations under the external affairs power: s 51(xxix). The advantages of a dispersed, rather than a centralised, legislative power are outlined in G de Q Walker (2001).

193 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.

and advisory framework for biotechnology, and replaces an earlier advisory committee. The 22 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.

2.152 The HGC is meant to play 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.

2.153 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.[194] It recently announced plans to set up a Consultative Panel of about 100 people affected by a genetic disorder (including patients, relatives, and carers), to provide further insights into the concerns of people with a genetic disorder and to act as a sounding board for the HGC's reports and recommendations.[195]

194 See the Human Genetics Commission, *The Human Genetics Commission Website*, <http://www.hgc.gov.uk/>, 5 October 2001.

195 See the Human Genetics Commission website: <http://www.hgc.gov.uk/cpanel/index.htm> 8 October 2001.

The European Life Sciences High Level Group

2.154 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.[196]

The Canadian Biotechnology Advisory Committee

2.155 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[197] on a broad range of ethical, social, regulatory, economic, environmental and health issues related to the development and application of biotechnology. CBAC members are drawn from a wide range of backgrounds and cover many areas of expertise, including science, business, ethics, and the environment, as well as members of the general public.

2.156 The CBAC's role is to advise on policy directions and priorities, but it is not involved in specific regulatory decisions. The CBAC also has a special mandate to raise public awareness and participation, produce plain language materials accessible to members of the general community, and engage Canadians in a dialogue concerning issues raised by the development and use of biotechnology.

An Australian Human Genetics Commission?

2.157 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

196 See European Commission, *Genetics and the Future of Europe*, <http://europa.eu.int/comm/research/quality-of-life/genetics.html>, 1 October 2001.

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

and technology. However, no such standing body on human genetics currently exists in Australia.[198]

2.158 Do we need our own version of the UK's HGC, or Canada's CBAC? Such a body could be established by the federal government, but could develop an inclusive national approach with input from and consultation with the States and Territories. For example, the Chairs of the NMHRC and AHEC, both bodies established under federal legislation, cannot be appointed by the federal Minister for Health without full consultation among his or her State and Territory counterparts.[199] A further consideration is the need for a balance of interests, expertise and experience to be found among members of any such advisory body.

Question 2–3. Should a standing body be established to advise government on issues related to human genetics and the ongoing development of the regulatory framework governing human genetics? If so, how should it be comprised?

198 The *Gene Technology Act 2000* (Cth) provides for the establishment of a Gene Technology Technical Advisory Committee (s 100), and a Gene Technology Ethics Committee (s 112), but the focus of both is on 'gene technology, GMOs and GM products' (ss 101; 112), rather than on human genetics.

199 *National Health and Medical Research Council Act 1992* (Cth) ss 21(2), 36(4). The NHMRC also contains representatives from each state and territory health authority: s 20(d).

Table 2–1 Genetic disorders and genetic testing

Disorder	Prevalence	Gene(s)	Inheritance	Age of onset	The mutations				Prevention/ Surveillance with view to early diagnosis	Treatment
					% affected families with mutation in this gene / these genes	Mutations / mutational mechanism	Common mutations / mutational mechanisms	Penetrance of mutation		
Alzheimer disease — early onset	1:2,500	PS1, PS2, APP	AD	40s-50s	30-40%	Base substitution, deletion, other	100%	PS1: 100% by 65y PS2: <100% by 80y	None	None
Charcot-Marie-Tooth disease type 1A	1:2,500	PMP22	AD	First two decades	100%	Duplication, base substitution	Duplication: 98%	~100%	None	Physio-therapy, podiatry, modification of physical environment
Cystic fibrosis	1:2,500	CFTR	AR	Birth-first years	100%	Base substitution, deletion, other (over 900)	ΔF508: 75%	100% when homo-zygous	Early diagnosis by newborn screening.	Physio-therapy, antibiotics, diet,
Duchenne muscular dystrophy	1:3,500 boys	Dystrophin	XLR	First years	100%; however, 1/3 of cases are new mutations and cannot be predicted from family history	Deletion, duplication, base substitution	Deletion: 65-70%	100%	None	Physio-therapy, orthotics

Disorder	**Prevalence**	**Gene(s)**	**Inheritance**	**Age of onset**	**The mutations**				**Prevention/ Surveillance with view to early diagnosis**	**Treatment**
					% affected families with mutation in this gene / these genes	Mutations / mutational mechanism	Common mutations / mutational mechanisms	Penetrance of mutation		
Factor V Leiden	Heterozygotes1:30 Homozygotes 1:4,000	Factor V	AD	Very variable	100%	Base substitution	100%	Heterozygotes: relative risk 3-4 for venous thrombosis Homozygotes: relative risk 80-100 for venous thrombosis	Prevention of thrombosis in those with phenotypic resistance to activated protein C	Standard treatment of thrombosis
Familial adenomatous polyposis (FAP)	1:3,500 <1% of all colorectal cancer	APC	AD	Polyps from teens, colon cancer from 20s	100%	Base substitution, deletion, other	Many different mutations	100% for polyps and colorectal cancer in families with classical FAP. <100% for 'attenuated FAP'	Surveillance by sigmoidoscopy from 10-15 years. Colectomy once polyps appear.	Standard treatment if cancer develops
Familial breast cancer	5-10% of all breast and ovarian cancer	BRCA1, BRCA2 1:1,000-1:500 women have a mutation in a high risk gene. 1:100 women of Jewish descent	AD	Very variable 20s–80s	Up to 50% of families meeting specific criteria for familial breast cancer	Base substitution, deletion, other	Many different mutations	60–85% for breast cancer, 30-60% for ovarian cancer	Breast exam-ination, mammo-graphy, prophylactic mastectomy or oophorect-omy, ovarian cancer surveillance	Standard treatment if cancer develops

Disorder	**Prevalence**	**Gene(s)**	**Inheritance**	**Age of onset**	**The mutations**				**Prevention/ Surveillance with view to early diagnosis**	**Treatment**
					% affected families with mutation in this gene / these genes	Mutations / mutational mechanism	Common mutations / mutational mechanisms	Penetrance of mutation		
Fragile X mental retardation	1:4,000 boys 1:2,000 girls	FMR1	XL	Birth	100%	Triplet repeat expansion	Triplet repeat expansion: 100%	>230 copies, 100% in males and 60% in females	None	Educational and behavioural support
Haemochromatosis	>1:600	HFE	AR	From ~ 30s	>95%	C282Y, other base substitution	C282Y: >90%	? 50-60% when homozygous	Surveillance for iron overload	Venesection
Haemophilia A	1:10,000 boys	Factor 8 C	XL	First months when severe	100%	Inversion intron 22, other	Inversion intron 22: 45% of severe hae-mophilia A	100%	Not relevant	Factor 8
Hereditary non-polyposis colorectal cancer (HNPCC)	5-10% of all colorectal cancer	MLH1 MSH2 MSH6 PMS1 PMS2	AD	Very variable 20s-80s	Up to 60% of families meeting the definition of HNPCC	Base substitution, deletion, other	Many different mutations	70-90% for any cancer. In men: colorectal cancer 80-90%. In women, colorectal cancer 30-80%, endometrial cancer 40%, ovarian cancer 10-20%	Colonoscopy, colectomy once cancer develops, endometrial and ovarian cancer surveillance	Standard treatment if cancer develops
Huntington disease	1:20,000	IT15	AD	35-55y	100%	Triplet repeat expansion	Triplet repeat expansion: 100%	36-39 copies: <100% >39 copies: 100%	None	Supportive

Disorder	**Prevalence**	**Gene(s)**	**Inheritance**	**Age of onset**	**The mutations**				**Prevention/ Surveillance with view to early diagnosis**	**Treatment**
					% affected families with mutation in this gene / these genes	Mutations / mutational mechanism	Common mutations / mutational mechanisms	Penetrance of mutation		
Myotonic dystrophy	1:20,000	DMPK	AD	Very variable. Birth to 80s	100%	Triplet repeat expansion	Triplet repeat expansion: 100%	50-150: mild effects 100-1,000: classical adult onset form 500->2,000: congenital form	Surveillance for complications	Treatment of compli-cations
β-thalassaemia	Various depending on ethnic background	β-globin	AR	First months	100%	Base substitution, deletion, other	Many different mutations	100% when homo-zygous	None	Blood transfusion, iron chelation
Werdnig-Hoffmann disease	1:10,000	SMN	AR	First 6 months	100%	Deletion, base substitution	Deletions: 98%	100% when homo-zygous	None	Supportive

3. Ethical considerations

Contents

Introduction

3.1 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 uses of human genetic samples and

information in Australia. The inquiry is also directed to have regard to the range of Australian ethical opinion as to which, if any, uses and applications of human genetic information are ethically acceptable.

3.2 In many ways ethical ideas about what constitutes a desirable society for people to live in form the basis of laws protecting privacy and prohibiting discrimination. Therefore, ethical considerations may be seen as the basic sounding board for the inquiry's deliberations.

3.3 This chapter contains background on the meaning and content of commonly accepted ethical considerations generally and on the nature and content of bioethics and health professional ethics specifically. The chapter discusses certain selected ethical considerations particularly relevant to the collection and use of genetic information.

What is meant by 'ethics'?

3.4 Ethics are an accumulation of values and principles that address questions of what is good or bad in human affairs. Ethics search for reasons for acting or refraining from acting; for approving or not approving conduct; for believing or denying something about virtuous or vicious conduct or good or evil rules. Ethics are, therefore, a rational activity that appeals to reason and not emotion or prejudice.

3.5 Characteristically ethics consider normative questions — those that ask what conduct ought to be followed in a given situation and offers answers to these and reasons for those answers. Much of the activity of ethics is about disputed questions or controversies. This means that ethics commonly do not provide a single answer to such questions but rather offer more than one answer supported by reasons. The choice of which answer to adopt will depend on which reasons provide the most satisfactory outcome and justification for the decision maker.

Meanings of the term

3.6 The term 'ethics' is commonly used in three different but related ways:

- a general pattern or way of life;
- a set of rules of conduct or a moral way of life; and
- an inquiry about a way of life and rules of conduct.

Michael McDonald refers to these three meanings as descriptive ethics, normative ethics and theoretical ethics (often called meta-ethics).[200]

Descriptive ethics

3.7 Descriptive ethics describe what a given community of people think is or is not right, morally appropriate and laudable. The main aim of descriptive ethics is to identify underlying principles and perspectives of specific ethical views.[201]

Normative ethics

3.8 Normative ethics describe what values people ought to have. This includes the making of moral judgments about right and wrong action, what is fair and unfair, who is virtuous and who vicious; and about what is or is not conducive to the welfare of society. These moral judgments will be informed by descriptive ethics that offer an account of what that community considers right and also by theoretical ethics that provide knowledge of explanatory and justificatory theories.

Theoretical ethics

3.9 Theoretical ethics examine concepts central to ethics. It is theoretical ethics that identifies the distinctive features of moral standards to be:

- associated with certain emotions and attitudes including guilt, shame, remorse, self-esteem and indignation;
- based on impartial considerations;
- concerned with matters important to human well-being;
- unchanged by authoritative rulings; and
- standards that override considerations of self-interest.[202]

3.10 On another view, these different meanings of ethics occupy a kind of loose hierarchy of justification.[203] At the most general or fundamental level lie the sources identified by theoretical ethics, whether religious or humanistic beliefs and values. From these are derived what are usually called principles — broad propositions such as: we should respect the dignity of individual persons; we should treat people fairly.

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200 M McDonald, *Biotechnology, Ethics and Government: A Synthesis* (2000), Canadian Biotechnology Advisory Committee, Ottawa, 7.
201 Ibid.
202 Ibid, 8.
203 T Beauchamp and J Childress (1999).

3.11 From these broad principles are derived what are usually called rules — more specific propositions, typical of normative ethics, such as: consent should be given before people are subjected to medical treatment. Although often called rules, these propositions are perhaps better understood in the common expression, 'as a rule, people should …' in the sense that they can never be absolute.

3.12 At the last, and most detailed level, are what can be called decisions or acts; these are the final decisions to act or refrain from acting in certain ways. Such a hierarchy also operates as a measure of another overall ethical value; that of consistency in justification. Where such consistency can be shown, the final decisions or act will be justified by reference to a rule that can, in turn, be justified by reference to a principle, which in turn finds its source in a value.

3.13 Such an account of the purpose and content of ethics plainly adopts one other element of ethics that is characteristic of contemporary ethics — that it is rational: a pursuit open to reasoned argument.

Ethics and public policy

3.14 The extent to which ethics has informed public policy can be obscured where public policy has been implemented in legislation. However, the justification of that legislation will be sought usually in an appeal to such ideas as equality before law, democratic participation in government, accountability and transparency, equal dignity of persons, pluralism, tolerance and the like.[204] Typical of legislation resting on such underlying ethical justifications are those protecting personal privacy and prohibiting certain forms of discrimination. These laws can be justified by appeals to the essential equality of humans, to the respect that is owed for their personal autonomy and freedom, and to ideas about fairness or justice in human affairs.

3.15 In this sense, descriptive ethics that examine and explain what Australians regard as morally right in relation to personal privacy and the limits of appropriate discrimination are a foundation for this inquiry and not merely another set of relevant considerations. These underlying values and principles are appealed to when seeking to justify existing laws as well as when seeking to justify change.

Sources

3.16 The sources of ethics — being ethical reasons and justifications for decisions or actions or arguments against these — lie in fundamental values that individuals hold. Thus, ethics can have a theological source based on a fundamental belief in a god and in the application of divine wisdom and guidance

204 M McDonald, *Biotechnology, Ethics and Government: A Synthesis* (2000), Canadian Biotechnology Advisory Committee, Ottawa, 14.

for human behaviour for humans. It is meaningful to speak of 'Christian ethics' or 'Hindu ethics' in the sense that it is in these religious traditions that the sources of ethics can be found.

3.17 Alternatively, classical Greek (and especially Aristotelian) political and social philosophy is used as a source of ethics in western societies, drawing on the wisdom and insight into the motivations and consequences of human conduct. An important contribution of this tradition has been the recognition that ethics concerns the conduct of people living in communities or societies.

3.18 A similarly humanist source can be found in the work of such philosophers as Immanuel Kant and others, reflecting ideas emerging from the Enlightenment period in philosophy in Europe of the eighteenth century. These philosophers focussed upon the nature of humans and how they might live together.

3.19 An important distinction needs to be made between the sources of ethics and the content of ethics. It is possible to have different sources that agree on content. For instance, a Christian and a humanist will have different sources for their agreement that respecting the individual dignity of human beings is an essential ethical principle.

Status and sanctions

3.20 The question of the status of ethical rules or principles — and the consequences of breach — will depend on the nature of the decision at hand and the context in which it is made. For instance, a decision that is made by a doctor that plainly infringes a rule of the medical profession's code of ethics may be a basis for professional discipline. On the other hand, the fact that a homeowner behaves in a way that his or her neighbours find unethical will remain a source of criticism and perhaps ill feeling but, unless the conduct is illegal, little else will follow.

3.21 In social life, unethical conduct is sanctioned by disapproval and perhaps exclusion from social privileges once enjoyed. Some conduct that is unethical has also been made illegal, such as deceptive practices in trading. It is not common to refer to such regulated conduct as unethical; however, its legal status will be of more importance where formal action is sought.

3.22 Where a community with a common interest agrees to a set of ethical rules, guidelines or a code of practice, it will be common for these to be published and for members to conform when acting in that capacity, for example as medical researchers. Infringement of the rules will usually be met with criticism (sometimes public) and perhaps exclusion from recognition as a member of that

community (a sanction that may be significant where recognition is a qualification for privileges or funding). When an identifiable sub-group in society (most typically a profession) adopts a statement of ethical rules, infringement of those by a member will commonly be met with some defined penalty. This status may be made legally binding if that profession is regulated by statute and the regulatory framework provides for legal enforcement of ethical codes of conduct.

Health care ethics

3.23 Ethics about health care (often called bioethics) are of particular relevance to the uses of human genetic samples and information. Health care ethics and the related ethical considerations applying to medical practitioners (professional ethics) are discussed in more detail below. The content of such ethics is a matter of debate.

The content of health care ethics

3.24 The issues that have come to characterise inquiry and debate in health care ethics include:

- allocation of limited resources for health care;
- regulation of the provision of health services;
- use of humans in experimentation and research;
- the scope of the medical professional prerogative;
- the limits of acceptable medical and health research;
- responsibility for dependent people, such as children and people with an intellectual disability;
- treatment of the dying and the determination of death; and
- the doctor–patient relationship generally.[205]

3.25 In exploring these matters, a number of relevant ethical concepts have emerged, including autonomy, coercion, normalcy, naturalness, rights, dependency, justice, responsibility and personhood.[206]

205 S Gorovitz (1978), 53–4.
206 Ibid, 55–56.

3.26 Other approaches to the content of health care ethics focus on a smaller number of enduring essential principles, such as:[207]

- 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. In relation to genetic information, there may be a need to extend the concept of informed consent to provide a similar degree of respect to a family or even a broader community.

- The principle of beneficence, most commonly expressed in the requirement that health care be aimed to produce beneficial outcomes. This principle would be relevant to the debate about whether it is beneficial to conduct genetic tests on families or communities (especially where there is no known treatment), or to exclude some people from work situations to protect them from exposure to risks for which they show a genetic susceptibility.

- The principle of non-maleficence, most commonly reflected in the requirement that, on balance, treatment should not cause harm. This principle would be relevant to the debate about conducting genetic tests on children who have not shown any symptoms but might be emotionally and intellectually harmed by the test results.

- The principle of justice, most commonly expressed in the requirement that treatment be made available on a fair and equitable basis. This principle would be relevant to the debate about how genetic information can be used so as to avoid unfair (or unlawful) discrimination. There is an ethical concern that the principle of justice may be accidentally or deliberately ignored when genetic information is misused; for example, when people are unfairly discriminated against in terms of employment, insurance or access to services.

3.27 The ethical value or principle of justice is also relevant as a measure of the extent to which genetic testing is accessible. As a matter of social justice, access to genetic testing services which have been shown to have potential to provide significant health benefits should not be dependent on where a person lives or on his or her socio-economic status.[208]

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207 T Beauchamp and J Childress (1999).

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

3.28 There is likely to be tension between this value and other interests and rights, especially those derived from intellectual property and patent law. There also will be tensions in practice in determining the allocation of scarce resources to competing needs.

3.29 Another approach to the content of health care ethics draws on the concept of human virtues that would be displayed in ethically acceptable or desirable behaviour.[209] A virtuous person is more likely to be self-motivated to behave in the desired way and is less likely to require rules that, in any event, can be circumvented. [210] These virtues have been identified as fidelity, trust, compassion, phronesis or practical wisdom, justice, courage, fortitude, temperance, integrity and self-effacement.[211]

3.30 By way of contrast, other approaches to the content of health care ethics reject the individualist emphasis in favour of recognising the importance of communal values that are important to the preservation of a society.[212]

Professional ethics

3.31 The social identification of health professionals and the grant to them of the right to treat individuals is accompanied by professional responsibilities. Some of these responsibilities are now contained in legal controls. However, the history of the development of the health professions also reveals enduring ideas of good professional conduct. These are usefully referred to as professional ethics.

3.32 The main focus of professional ethics is the relationship between the individual professional and his or her patient or client. The need for that focus and the clarification of obligations lies in the typical imbalance of knowledge, and therefore power, between the two. It is the risk that professionals may misuse their power to which professional ethics is largely directed. Typical of the obligations of health professional ethics are those of maintaining confidentiality of all personal information about patients, giving highest priority to patients' interests and avoiding conflicts of personal interests. The development of health care ethics in the past three decades has drawn heavily on professional ethics, resulting in a close relationship and considerable overlap between the two. The ethical considerations and regulation applying to the conduct of medical practitioners are discussed in more detail in Chapter 8.

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209 eg the National Statement states that the guiding value for researchers is 'integrity', which is expressed in a commitment to the search for knowledge, to recognised principles of research conduct and in the honest and ethical conduct of research and dissemination and communication of results: National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 1.1.

210 P Foot (1978); R Beehler (1978); G Pence (1980).

211 E Pellegrino and D Thomasma (1993).

212 M Sandel (1982); A MacIntyre (1988); E Emmanuel (1991).

Ethically relevant characteristics of genetic information

3.33 Genetic information may have some characteristics that are particularly significant to the ethical considerations that should guide decisions about how genetic information is collected and used. Some of these characteristics are examined below.

Certainty and uncertainty

3.34 Genetic information can at once apparently be certain and yet uncertain. Although the mapping of a person's genes may be scientifically precise, what that map means is not. The value to the person of the genetic information is only realised when other knowledge about how certain genes and environmental factors are related to certain diseases or conditions is added. Then it may be possible to infer that the person has a risk of developing a disease even before any symptoms show. However, this information only can be expressed as a prediction in percentage risk terms or even comparative risk terms. That is, that a person has a 60% greater chance than most people of developing the disease or disorder. The same degrees of uncertainty can be used to assess the risks of harm from exposure to some environmental conditions that some genetic combinations cause.

Relevance to families

3.35 Genetic information that is identifiable in respect of any one person also will enable some predictions about the genetic status of that person's family members — both immediate and at some stages removed . What can be predicted or known will vary widely according to the relative certainty or uncertainty of the initial individual genetic findings, the nature of the particular disorder, the presence or absence of risk factors, and so on.[213]

Relevance to populations

3.36 Not only will identifiable genetic information confer knowledge about family members, it also will confer some knowledge and enable some predictions about whole communities, especially racial or ethnic populations in which some genetic conditions are known to be more prevalent. This can lead to fears of stigmatisation or discrimination (see Chapter 5).

Absence of a cure for many genetic disorders

3.37 Difficult issues arise in testing for genetic conditions or disorders for which there is no known treatment or cure. The burden of knowledge of a positive test result is difficult to weigh against the possible benefits to a person of a

213 For an extended discussion of these issues, see National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra.

negative test result.[214] These issues are made more complex when contemplating testing of embryos derived by artificial fertilisation techniques before implantation, prenatal testing (see Chapter 14) or the testing of children.

Ethical considerations relevant to genetic information

Ethics are central to the collection, storage, knowledge, use, re-use and disclosure of genetic information, because all involve human conduct that has potential for good or evil, for benefit or harm. Questions about what action or decision is to be preferred arise in relation to each of the following aspects of genetic information:

- how it is obtained;
- what it reveals;
- about whom that information is revealed;
- the degrees of certainty and uncertainty of that information;
- who among those affected should know, and who should not know, some or all of that information;
- which third parties (such as employers, insurers or others) should know or not know;
- what constraints, if any, should limit what people can do with genetic information about others;
- what restrictions, if any, should apply to people because of the genetic information about them;
- what effect, if any, does self-awareness of genetic knowledge have on people; and
- what effect, if any, will widespread knowledge and use of genetic information have on the broader society?

How is genetic information obtained?

3.38 The testing of a person's DNA and/or the accumulation of information about the health of members of a person's family can reveal genetic information. Consent based on an understanding of what that information can reveal is important.

214 However, even where there is no known treatment, a positive result also can have benefits in terms of certainty and the ability to plan life choices.

What does genetic information reveal?

3.39 Tests of a person's DNA can provide thorough and complete identification of all that person's genes. Family or community histories of health and illness or research on relations between genes and disease can reveal that a person has or does not have a likelihood of developing a particular condition.

About whom?

3.40 Importantly, parents, siblings and children will share some of the same genes. Indeed, so will some cousins and other more distant blood relations. This is the second important feature of genetic knowledge: it reveals information about other people.

Is genetic information special?

3.41 Three features of genetic information have been used to argue that genetic information is exceptional, so justifying distinct regulatory regimes:

- the prophetic potential that genetic information has;
- the implications it has for family members; and
- its potential to stigmatise and victimise.

3.42 The United States Task Force on Genetic Information and Insurance considered these factors in detail in its 1993 report;[215] however, the Task Force rejected the 'exceptionalism' case. According to the Chair of the Task Force, this would be an 'overly dramatic view of the significance of genetic information in our lives'.[216]

3.43 The preferred view appears to be that the challenges that genetic information present are not themselves different but signal the need for a new paradigm in the ways that all health information is protected.[217] A comparison might be made with the confidentiality and other health policy issues that arose in connection with the challenge of AIDS/HIV in the 1980s and 1990s.

3.44 One view is that genetic identity needs to be recognised as a new and integral element of human dignity, a concept basic to ideas about respect for individuals. Genetic identity needs to be recognised as part of that essential nature

215 National Center for Human Genome Research, *Task Force Report: Genetic Information and Insurance* (1993), National Institutes of Health, Bethesda.

216 T Murray (1997), 71.

217 L Ross, 'Genetic Exceptionalism vs Paradigm Shift: Lessons from HIV' (2000) 29 *Journal of Law, Medicine and Ethics* 141, 141–148; Z Lazzarini, 'What Lessons Can We Learn from the Exceptionalism Debate (Finally)?' (2000) 29 *Journal of Law, Medicine and Ethics* 149, 149–151.

of individual humans. At the same time, the fact that genetic information can relate an individual to a wider population adds new ethical dimensions to how communities need to be conceptualised and defined.

Who of those affected should know?

3.45 It is usually argued that the person who had the test from which the information was derived or to whom it directly relates should know the information. However, some people may prefer not to know. Should they be told? Does it make a difference that such knowledge would allow them to take steps to avoid some risks to their health or life? Where genetic information shows that a person is at a high risk of developing a serious and incurable illness, should he or she be told? What if the person is a child?

3.46 The family dimension of genetic information raises an important set of ethical considerations. The vulnerability of family members to the effects of testing and the high importance of appropriate pre-test and post-test counselling is highlighted.[218]

Prenatal and pre-implantation testing and diagnosis

3.47 Should genetic testing of foetuses or embryos derived through IVF techniques[219] be made available and, if so, on what terms and conditions? This and related questions raise profound ethical questions about the uses of genetic information that might be derived from such testing. Concerns have been voiced about the risk that such information could lead to a re-definition of concepts of disability and an encouragement for parents to make choices related more to their ambitions or ideals as parents than to those of the child.[220]

3.48 Similarly, arguments have been advanced about the obligations of parents in respect of the choices they should make in the knowledge of risks of genetic factors discovered by such testing.[221] As discussed in Chapter 1, given the existing state of the science and the nature of the terms of reference, the inquiry does not intend to focus on the area of prenatal testing.

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218 See National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra 10, 48–51.

219 J Botkin, 'Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis' (1998) 26 *Journal of Law, Medicine and Ethics* 17, 17–28.

220 Hastings Center, 'The Disability Rights Critique of Pre-Natal Genetic Testing: Reflections and Recommendations' (1999) *Hastings Center Report* , S1-S22.

221 R Green, 'Parental Autonomy and the Obligation Not to Harm One's Child Genetically' (1997) 25 *Journal of Law, Medicine and Ethics* 5, 5–15; L Biesecker, 'Clinical Commentary: The Law of Unintended Ethics' (1997) 25 *Journal of Law, Medicine and Ethics* 16, 16–18; E Clayton, 'Legal and Ethical Commentary: The Danger of Reading Duty Too Broadly' (1997) 25 *Journal of Law, Medicine and Ethics* 19, 19–21.

Who else should know?

3.49 Where genetic information reveals information about risks to a person's health or life, who other than those directly affected should know? Should insurance providers be told in order to more accurately measure the risk they insure? Should employers be told to arrange employment situations to reduce or remove risks to persons affected or to others? Should government authorities be made aware where services or entitlements might be affected?

Constraints on those with the information

3.50 Genetic information cannot be known without the intervention of medical and technical experts to conduct the tests, interpret the results, and draw the inferences from the test results and other knowledge of the relation between genes, disease and risk. Professional ethics is likely to be one valuable source of answers to questions about how these experts, technicians and others (such as clerical staff in their employ) should be constrained in the use of this information. If individuals other than health professionals have access to genetic information, such as insurers or employers, how should their use of that information be constrained?

The effects of information on those who have it

3.51 Individuals are commonly assumed to have a right to their own genetic information although it is often also recognised that they may choose not to be informed. If a person has genetic information indicating a genetic disorder or a susceptibility to a serious disease or disorder, what effect may knowing it have? Will the person come to regard himself or herself as defective, or of less worth than others, or to blame for passing on inherited conditions?

3.52 Is it necessary (or possible) to develop effective ways of gaining consent from groups or communities who are known or likely to have common genetic conditions and may be similarly affected by genetic information? Some examination of the concept of community consent has exposed significant difficulties in this proposal. First, there appears to be too little overlap between genetic and cultural identity. Second, even when there is sufficient communality, the deference to forms of legitimate authority in the community may obscure differing interests within the group, especially the interests of those less powerful.[222]

The effects of genetic information on society

3.53 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

222 D Davis, 'Groups, Communities and Contested Identities in Genetic Research' (2000) 6 *Hastings Center Report* 38, 38–45.

of any social benefits or services, or in any way to classify people — may change the way we think of human beings. Will we come to measure (the worth of) people by their genetic makeup? Will we come to regard much illness and even behaviour as genetically caused? Will this risk changing our ideas about individual and social responsibility?

3.54 These considerations have been referred to as 'genetic essentialism', 'geneticisation' or simply 'geneticism'. All involve varying degrees of reducing human worth or assessment to genetic matters, so giving genetic information high social significance. Genetic essentialism refers to the view that:

> personal traits are predictable and permanent, determined at conception, 'hard-wired' into the human constitution ... [T]his ideology minimizes the importance of social context.[223]

3.55 Geneticisation has been described as the tendency to label as 'genetic' diseases and disorders with scant or no genetic evidence and the 'construction of genetic disease'.[224] The term probably includes a wider sense of according responsibility to genetics for many other disorders and also of a tendency to eliminate personal responsibility for conduct that may have a genetic component. Susan Wolf argues that neither of these terms goes as far as geneticism, which she describes as:

> a long standing and deeply entrenched system for disadvantaging some and advantaging others. It can be seen in the pervasive individual and institutional use of genetic information and concepts to disadvantage people whether singly or by creating groups. It predates any accurate understanding of genetics, and now refers to social structures, practices, beliefs, and predispositions that together support disadvantaging based on a mixture of accurate and inaccurate genetic ideas.[225]

3.56 Caplan explains that the solution to these difficulties lies in recognising that genetic dysfunction or abnormality must be disvalued to be regarded as a disease and that not all genetic dysfunctions or abnormalities are disvalued. What is a disease or impairment is a matter of value and people will vary in their evaluation of the same state. It will be important to carefully establish agreement as to what genetic differences are disvalued, and so may be classified as diseases. This is a process that will need to be approached cautiously as skills in clinical genetics grow.[226]

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223 R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 316–321.

224 A Lippmann, 'Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities' (1991) 17 *American Journal of Law and Medicine* 15, 15–50.

225 S Wolf, 'Beyond "Genetic Discrimination": Toward the Broader Harm of Geneticism' (1995) 23(4) *The Journal of Law, Medicine and Ethics* 345 345–353.

226 A Caplan (1997), 181–193.

Guidance on ethical issues in genetics

3.57 The Australian Health Ethics Committee (AHEC) has provided recent guidance on many relevant ethical issues in a set of related publications.[227] There is more detailed discussion of some of these publications in later chapters.

- *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000): This is a comprehensive account of basic human genetics, the types of genetic tests and what information they can provide and a detailed account of the ethical questions about consent to testing, access to and disclosure of results. The paper has been designed for the public and is written in accessible language.

- *Guidelines for Genetic Registers and Associated Genetic Material* (2000): These guidelines are directed at the establishment and conduct of genetic registers of information or that involve storage of DNA samples. They deal with issues of consent to inclusion on a register, access to and disclosure of information on the register and notification of family members.

- *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies* (1999): These guidelines address the matters that ethic committees need to consider when reviewing research proposals for this specific type of gene therapy research.

- *National Statement on Ethical Conduct in Research Involving Humans* (1999): This document contains ethical guidance for the design, review and conduct of any research involving humans. The National Statement addresses human genetic research and contains guidance on the social significance of such research, the protection of privacy and confidentiality, the information that potential participants need before deciding whether or not to participate, circumstances where a review committee can approve the waiver of consent and on the importance of genetic counselling.

Application of ethics

3.58 As discussed above, the purpose of ethics is to provide a principled and reasoned basis for action and decisions. The following collection of scenarios, derived from those contained in an ethical code produced by the New South Genetics Service Advisory Committee,[228] illustrates the complexity of the ethical considerations applicable to decision making about genetic testing.

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227 These publications are available in print from Ausinfo shops. Synopses are also available on the NHRMC website: <www.nhmrc.gov.au>.

228 NSW Genetics Service Advisory Committee, *Ethical Code Governing the Provision of Genetics Services*, (1998) NSW Health Department.

Example 3–1. Susan, who is 40, discovers during an exploration of her family history that her mother's sisters and some cousins had been diagnosed with breast cancer, some at an early age. Susan had known that her mother had been diagnosed with the disease at about the same age she is now.

Concerned at her own risk, she was informed by her doctor that a mail order genetic screening test was available. Susan undertook the test and was told that she had an 80% chance of developing breast cancer. Uneasy at telling her extended family, Susan told only her daughter that she had a 50% chance of inheriting the same gene, and told her doctor not to tell her sisters and brothers. Her doctor advised her against this. Two years later, Susan's older sister, Barbara, was shocked to be diagnosed with advanced breast cancer, being otherwise unaware of her risk.

What should Susan have done? Whom should she have told and when? Should her doctor have discussed with her the options and ethics of disclosure before she took the test? What should the doctor do if Susan's sisters and brothers are also the doctors' patients?

Example 3–2. Sally is married to Barry, who recently has discovered that his grandfather died of Huntington's disease.[229] His mother was tested and found to have inherited the faulty gene. She will develop Huntington's disease at some stage and Barry has a 50% chance of having inherited the gene.

Sally is 12 weeks pregnant and is worried that their baby may inherit the Huntington's gene. She is not sure whether, if this was true, she would terminate the pregnancy. She asks for prenatal testing. If the test is positive for the Huntington's gene, it will mean that Barry also has it. However, if it is negative, Barry still may have inherited the gene as there is only a 50% chance that he would pass it on to his children.

Should Sally have the test? Should Barry's consent, or at least his knowledge, be required? What advice should her doctor give her beforehand? If the test is positive, who should tell Barry that he has the gene? What are the implications of prenatal testing?

229 Huntington's chorea is a neurological degenerative disease with an onset usually between 40 and 60, which involves a slow deterioration of movement, cognition and functioning, and has no cure.

Example 3–3. Following routine screening, Alison and Andrew are told by their doctor that their baby son has had a positive screening test for the genetic disorder cystic fibrosis (CF). CF causes respiratory and digestive problems. When both parents carry the relevant mutation, there is a one-in-four chance of their children being affected although those who carry the gene are not themselves affected.

A later test shows that the baby is only a carrier and will not be affected, although he may have children with the disease if his partner is also a carrier.

Alison and Andrew are anxious to find out if their other two children, aged five and seven, are also carriers. They insist on the test against the policy of their genetic advisers who do not perform carrier testing on children under 16 where the status will have no affect on the health of those children.

Should the children be tested for carrier status? Should they receive counselling beforehand? Should their informed consent be required? Should they be told before they are 16 that they are carriers?

Ethics and conduct

3.59 How effective are ethics as a system for influencing conduct? This is not a simple question to answer as long as the ethics concerned exist as a set of reasons or arguments that can be derived from values, principles and rules and the users are individuals making decisions about their own conduct or that of others to whom only social or family consequences count.

3.60 Where the decision makers are members of a profession whose relevant ethical principles have been codified and published and there is some professional accountability attached to their observance, then perhaps a more definitive answer could be given.

3.61 It is intrinsic to the nature of ethical obligation that it be felt and followed because of an individual's commitment to it, whatever the source of that commitment: whether to a principle, because of a virtue or a felt obligation to a community. One motivation for behaviour that is not usually regarded as significant is the threat of enforcement or regulation. To ascribe the efficacy of an ethical code to the efficiency of its enforcement mechanism or to its regulatory force might be said to confuse the nature of ethical obligation with that of legal obligation. Evidence of the efficacy of ethics, or health care ethics, is perhaps better found in the conforming behaviour of the people taken to be subject to the obligations.

3.62 The role of ethics and its efficacy in the current regulatory framework probably need to identify the role of ethics as a factor in conduct that is regulated. There, their influence might be measured by some enforcement mechanism, that is, by the record of professional, if not legal, sanction of failure as well by the constancy of conforming conduct. The regulation of health professionals would be such a context (see Chapter 8).

3.63 Ethics function to engender conforming behaviour through education and internalisation of principles and values and through peer influence. Ethics remain an important influence on professional conduct, whether or not mirrored in regulatory frameworks that have the force of law.

Question 3–1. Is it acceptable to leave ethical concerns relating to the collection, use and disclosure of genetic samples and information to be regulated largely by the personal and professional ethics of health practitioners, researchers and others? Or should certain ethical concerns be given recognition, or greater recognition, in law?

4. Privacy of genetic information

Contents

Introduction

4.1 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.

4.2 The privacy of human genetic samples and information is one aspect of the concept of information privacy, which can be defined as the right of an individual to control the collection, use and disclosure of information relating to them (personal information). Genetic information has special characteristics that distinguish it from most other forms of personal information. However, 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.

4.3 This Chapter examines the existing regulatory framework that protects the privacy of genetic information and seeks comment on possible deficiencies in this protection. If deficiencies in legislative privacy protection are identified, the approaches to reform might include:

- changes to general information privacy laws (such as the *Privacy Act 1988* (Cth)), so that these laws provide more adequate protection for genetic samples information;
- the enactment of new sectoral health information legislation that would cover all or most forms of genetic samples and information; or
- the development of a regulatory framework for the protection genetic samples and information specifically.

4.4 The adequacy of the existing regulatory framework for information privacy is relevant to a wide range of issues concerning genetic information, including issues relating to:

- informed consent to medical treatment;
- informed consent to involvement in medical research;
- the ethical and legal concepts of medical confidentiality;

- the creation and use of human genetic databases for clinical and research purposes; and

- the collection, use and disclosure of genetic information in particular contexts, such as in medical research, insurance and superannuation, employment, and law enforcement.

4.5 These issues are discussed in more detail elsewhere in this paper. In addition to information privacy, the scope of the inquiry requires some consideration of physical privacy concerns. For example, the taking of body samples intended for DNA testing may compromise a person's physical privacy where this does not occur with informed consent.

Information privacy regulation

4.6 There is much existing federal, state and territory regulation of information privacy. At the federal level, information privacy is regulated by the *Privacy Act 1988* (Cth) (*Privacy Act*).[230] The *Privacy Amendment (Private Sector) Act 2000* (Cth) was passed by the Parliament on 6 December 2000 and comes into effect on 21 December 2001. This legislation extends the coverage of the *Privacy Act* to much of the private sector.

4.7 A key issue for the inquiry involves reaching a view on the extent to which the *Privacy Act*, including its extension of coverage to the private sector, forms an adequate regulatory framework for protecting the privacy of human genetic samples and information.

4.8 The fact that the private sector provisions are yet to come into operation and will only have operated for six months by the reporting date of this inquiry makes it difficult to review the adequacy of the *Privacy Act* regime. The operation of the new legislation will be reviewed by the Privacy Commissioner two years after it comes into effect.

4.9 While the federal *Privacy Act* is the major focus of consideration, state and territory legislation is also discussed in this Chapter. The inquiry aims to identify whether there are any gaps in the privacy protection of genetic information and, if so, what regulatory mechanisms are available to remedy these deficiencies.

230 *Privacy Amendment (Private Sector) Act 2000* (Cth).

Is genetic information different?

4.10 The inquiry is closely considering whether and to what extent genetic information may differ from other forms of personal or health information, and whether these differences justify additional or different privacy protection.

4.11 Genetic information is most often collected from clinical genetic testing for the purposes of providing medical and other health services to the individual being tested or to a genetic relative. Therefore, for many purposes, genetic information may be considered a subset of health information. Nevertheless, genetic information has a range of characteristics that may be seen as differentiating it from most other health information. These characteristics may be summarised as follows.[231]

- The science relating to genetic information is new and developing. This increases the possibility that genetic information may be incorrect or subject to misinterpretation. Individuals may not always be able to be advised about the long–term implications of this information.

- Genetic information may allow inferences to be drawn about individuals other than the individual to whom the information most directly relates and, in particular, about genetic relatives. Genetic information is shared familial or collective information.[232]

- Genetic information is capable of revealing 'family secrets', including information about paternity (or non-paternity), adoption, or the use of artificial reproductive technology.

- Genetic information (whether derived from family history information or from genetic testing) may be predictive of the future health of a person who has no current symptoms at the time the information is obtained.

- The familial and predictive nature of genetic information raises issues about whether information should be disclosed to people other than the person to whom the information most directly relates — who else has a right to know?

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231 See M Scollay, *Submission 40 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 29 May 1998.

232 The consequences include, for example, that in order to make a genetic diagnosis, genetic relatives may need to be tested; genetic information may have to be validated by information from relatives and other people; genetic tests may reveal information about genetic relatives, including information that may have important medical value for them: See L Skene, *Patients' Rights or Family Responsibilities?: Two Approaches to Genetic Testing*, (1998) unpublished appended to The Research Group for the Study of the Legal and Ethical Implications of Human Genetic Research in Australia, *Submission 19 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 13 May 1998.

- Similarly, the familial and predictive nature of genetic information raises issues about people's 'right not to know' about their predicted health experience, particularly if there are no, or limited, treatment options.

- The predictive nature of some genetic information, and assumptions about its predictiveness, mean that disclosure may lead to unlawful discrimination or other negative consequences for the individuals to whom it relates.

- A person's genetic information is unalterable and permanent. There is nothing a person can do to change his or her genetic makeup.

- Every cell in a person's body, with the exception of sex cells, contains all his or her genes. Therefore, the testing of any biological sample taken at any time can reveal the full complement of a person's genetic information. There is potential for stored genetic samples to be re-tested as new tests are developed.

- Genetic information is an intimate part of people's identity and influences a very large number of personal physical and behavioural characteristics. While much is unknown about the extent and nature of this influence, the scientific understanding of these influences is likely to develop rapidly.

4.12 Many of these characteristics are not unique to genetic information and may also be characteristic of other health information. For example, other health information derived from presymptomatic medical testing is also predictive of future health, such as blood pressure or cholesterol testing results. Other health information may be used for unlawful discrimination and be unalterable, such as that relating to chronic illness or permanent disability. However, genetic information may have these characteristics to a greater degree[233] and, therefore, the potential for misuse of information may be higher.

4.13 A question for the inquiry is whether the nature of genetic information makes it so qualitatively different from other health information that it requires special privacy protection. Medical information receives special treatment with regard to privacy laws and policies in many jurisdictions, and it can be argued that this additional level of protection is all that is required for genetic information.[234]

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233 M Scollay, *Submission 40 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 29 May 1998.

234 In Australia, Loane Skene has argued that genetic testing is different from other areas of medical practice and therefore new ethical and legal principles need to be considered in its regulation: See See L Skene, *Patients' Rights or Family Responsibilities?: Two Approaches to Genetic Testing*, (1998) unpublished, appended to The Research Group for the Study of the Legal and Ethical Implications of Human Genetic Research in Australia, *Submission 19 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 13 May 1998. There is

4.14 Some of the concerns about the possible misuse of genetic information may derive from how society currently reacts to genetic information rather than from characteristics that make it different from other health information. So long as genetic information retains a certain 'novelty' value, there may be a need to provide additional protection from misinformation, misunderstanding and misuse.

Privacy Act 1988

An introduction to the Privacy Act

4.15 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.

4.16 The *Privacy Act* contains privacy safeguards set out in a number of Information Privacy Principles (IPPs) and National Privacy Principles (NPPs).[235] The IPPs cover collection, storage and security, use, disclosure and access to 'personal information', which is in a 'record' held by an 'agency'. In general terms, the privacy protection afforded by the IPPs extends only to the personal information handling practices of an 'agency', as that term is defined in the *Privacy Act* (s 6). With limited exceptions, agencies include only Commonwealth public sector entities.

4.17 A breach of the IPPs is an interference with privacy under the *Privacy Act*, and may give rise to an investigation by the Privacy Commissioner. Under the *Privacy Act* the Commissioner has powers to make determinations. Such determinations may only be enforced by the Federal Court after a new hearing.[236] The Commissioner also has the power to initiate investigations without waiting for a complaint and has powers to seek injunctions (s 98). In addition, the Commissioner has the power to audit the handling of personal information by Commonwealth agencies.

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much North American literature discussing whether genetic information is fundamentally 'different' from other health information. See eg T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347; L Gostin and J Hodge, Jr, 'Genetic Privacy and the Law: An End to Genetic Exceptionalism' (1999) 40(1) *Jurimetrics* 21; J Beckwith and J Alper, 'Reconsidering Genetic Anti-discrimination Legislation' (1998) 26 *The Journal of Law, Medicine and Ethics* 205.

235 *Privacy Act 1988* (Cth), s 14 (IPPs), Schedule 3 (NPPs).

236 Ibid, s 55. This provision was inserted by the *Human Rights Legislation Amendment Act 1995* (Cth) in consequence of the decision in *Brandy v Human Rights & Equal Opportunity Commission* (1995) 183 CLR 245.

4.18 Until the new private sector provisions come into force, the protection provided by the *Privacy Act* over health information is limited to information held by Commonwealth agencies. In the absence of federal privacy legislation covering the private sector, health care organisations and professionals are able to collect, use and disclose personal genetic and health information as they see fit, except to the extent that there are other laws or professional codes of ethics which constrain this.

4.19 From 21 December 2001, most private sector organisations will be covered by the new private sector provisions in the *Privacy Act*. The organisations covered by the new private sector provisions 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).

4.20 Private sector organisations must comply with the NPPs. The NPPs set out how they 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 trans-border 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).

4.21 Under the Act, organisations can develop their own privacy codes; where they do not do so the NPPs apply. Where an organisation provides its own code this must be approved by the Privacy Commissioner and must include levels of privacy protection at least equivalent to the NPPs.[237] Where the code has a complaints procedure, there must be an independent adjudicator to handle complaints, otherwise, the Privacy Commissioner will carry out this function. The Privacy Commissioner or a code adjudicator can ask the Federal Court to enforce a complaint determination.

4.22 The Privacy Commissioner's Office has developed *Guidelines on Privacy in the Private Health Sector*[238] to assist private sector or non-government health service providers apply the NPPs to health information. The guidelines provide specific guidance on how the NPPs will operate for health consumers and health service providers. The Office has also released *Guidelines to the National Privacy*

237 *Privacy Act 1988* (Cth), s 16BB.

238 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney.

Principles.[239] While these advisory guidelines are not legally binding, they indicate how the Privacy Commissioner will interpret and apply the NPPs.[240]

State and territory government bodies

4.23 Most state and territory government bodies and local government are not covered by the Act.[241] Public hospitals and other state, territory or local government health service providers are not subject to the *Privacy Act*.[242] Private sector health service providers working under contract for a state, territory or local government agency are not covered by the federal *Privacy Act*. State and territory government agencies and private sector organisations working for them may be covered by state or territory privacy legislation, in some cases applying similar information privacy principles to those in the federal *Privacy Act*. Relevant state and territory legislation is summarised below.

Private sector coverage

4.24 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*.

Small business

4.25 Small business operators — those with an annual turnover of less than $3 million — have extensive exemptions from the Act. However, all organisations or individuals that provide health services and hold any health information (except in an employee record) are subject to the private sector provisions, regardless of their size and income.[243]

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239 Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), Office of the Federal Privacy Commissioner, Sydney.

240 *Privacy Act 1988* (Cth), s 27(1)(e).

241 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*: Ibid s 6C.

242 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*: s 8.

243 *Privacy Act 1988* (Cth), s 6D(4)(b). In addition, an entity is not a small business operator if it discloses personal information about another individual for benefit, service or advantage without the individual's consent or other legal authority; if it provides a benefit, service or advantage to collect personal information about another individual without the individual's consent or other legal authority; or if it provides a contracted service for the Commonwealth: See *Privacy Act 1988* (Cth), s 6D(4)(c)–(e).

4.26 Due to the broad definition of health service and health information for the purposes of the *Privacy Act*, health service providers are not limited to hospitals, medical practitioners and others traditionally considered to be part of the health care system. Such organisations and individuals may include gyms and weight loss clinics. Alternative medicine practitioners, pharmacists, mental health professionals, optometrists, and social welfare and counselling service providers would also be considered to be health service providers, whether the service is provided face-to-face, over the phone, via mail order or the internet.[244]

Privacy Act and employee records

4.27 Section 7B(3) of the *Privacy Act* specifically exempts acts or practices relating to employee records of organisations from the operation of Act. The term 'employee record' is defined in the *Privacy Act* as a record of personal information relating to the employment of the employee by an organisation (that is, a private sector organisation). It includes health information on the record, such as information relating to a disability, the medical condition or family medical history of the employee.[245]

4.28 The exemption applies to acts or practices that are directly related to the employment relationship. For example, it could be argued that disclosure of an employee's personal information to a marketing agency is not related to the employment relationship, and is, therefore, covered by the *Privacy Act*. On the other hand, the disclosure of the information to the employer's insurance company in order to obtain an insurance policy to cover employees may be exempt.

4.29 The exemption only applies to current or former employees, not to prospective employees. Therefore, the gathering of information on prospective employees is covered by the *Privacy Act*. If the information is health information, then the additional requirements in NPP 10 regarding collection of health information will apply. However, once an individual becomes an employee, the information on the record becomes part of an employee record and future dealings with the information may not be covered by the *Privacy Act*. Similarly, the *Privacy Act* does not provide protection to current employees regarding what information can be collected so long as the information is directly related to the current employment relationship.[246]

4.30 For example, if an individual is required to undertake a medical check for a prospective employer, the *Privacy Act* governs the way in which that person's personal information, including health information, can be collected, used,

244 See Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, iii–iv, for a discussion of the definition of a 'health service provider'.

245 *Privacy Act 1988* (Cth), s 6(1).

246 Ibid s 7B(3).

disclosed and stored. If the individual is not successful, the *Privacy Act* will continue to govern how the individual's personal information can be treated. If the individual is employed, information from the medical check held by the employer would be considered part of the employee record, and exemptions will apply. Any information held by the health provider that undertook the medical check would continue to be covered by the *Privacy Act*.

4.31 Private sector employee records were specifically exempted from the *Privacy Act* because the government considered that protection of employee records is more properly a matter for workplace relations legislation.[247] The Attorney General's Department and the Department of Employment, Workplace Relations and Small Business is currently conducting a review of existing federal, state and territory laws, to consider the extent of current privacy protection for employee records and whether there is a need for further measures.[248] Issues of genetic privacy and employment are discussed further in Chapter 10.

The Privacy Act and genetic information

4.32 A key interest of the inquiry is to examine how the *Privacy Act* regime will protect genetic information. The inquiry is interested in obtaining comment about whether this protection is likely to be adequate for protecting genetic information.

4.33 To assist in this process, the following material briefly maps some of the key protections that will be provided to genetic information by the *Privacy Act* with reference to the NPPs.[249] For the purposes of this discussion it is assumed that the relevant genetic information falls within the definition of health information in s 6 of the *Privacy Act*. However, in some circumstances, genetic information may not be covered by the provisions of the *Privacy Act* relating to health information (see below).

4.34 It is also assumed that the organisation involved in collecting, using or disclosing genetic information is covered by the federal *Privacy Act*. This may not always be the case. Health information may be subject to protection under state or territory legislation, particularly if held by a state public sector body, such as a public hospital.

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247 See Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 12 April 2000, 15077 (The Hon Daryl Williams Attorney-General).

248 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', 29 November 2000.

249 In practice most genetic information will be collected by entities other than Commonwealth agencies and therefore be covered by the NPPs rather than the IPPs.

4.35 The NPPs are expressed as high level principles that must be interpreted in the particular context in which genetic information is, or is proposed to be, collected, used and disclosed. It would be a difficult exercise to summarise comprehensively the possible application of the NPPs to the many circumstances in which questions about the privacy protection of genetic information may arise. The discussion below is necessarily brief and focuses only on the collection, use and disclosure and access principles. Those interested in obtaining a more detailed knowledge of the NPPs and their application to health information should refer to the full text of the NPPs and to the Office of the Federal Privacy Commissioner's *Guidelines on Privacy in the Private Health Sector*,[250] *Guidelines to the National Privacy Principles*[251] and related information sheets.[252]

Collection of genetic information

4.36 NPP 1 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. 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. In general, an organisation must collect personal information about an individual only from that individual, rather than from any third party.

4.37 In addition, 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:

- where collection is required by law;
- in specified circumstances relating to the provision of health services; and
- in circumstances related to public interest, such as for research relevant to health and safety.

250 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney.

251 Office of the Federal Privacy Commissioner, *Guidelines to the National Privacy Principles* (2001), Office of the Federal Privacy Commissioner, Sydney.

252 These information sheets are available on the Federal Privacy Commissioner's web-site: <www.privacy.gov.au> (9 October 2001).

Collecting information with consent

4.38 Consent is a key concept and is referred to in many of the NPPs. Whether or not the individual gives consent for his or her information to be collected, used or disclosed in certain situations is a consideration that should guide many decisions about how to handle an individual's health information.

4.39 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.[253]

4.40 The definition of 'consent' under the *Privacy Act* includes 'express or implied' consent.[254] However, it is the Privacy Commissioner's view that if a health service provider is in doubt about whether an individual have given consent or not, it is preferable to seek express consent.

4.41 The *Guidelines on Privacy in the Private Health Sector* state that 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.[255] This might apply, for example, to the proposed inclusion of an individual's genetic information on a genetic register (see Chapter 9) or other human genetic database (see Chapter 7).

4.42 Given the characteristics of genetic information and the ethical considerations involved in decision–making about genetic testing, it may be argued that consent is of particular importance in the collection of genetic information, as compared with ordinary health information. The fact that counselling is considered ethically necessary as a pre-condition to some genetic testing supports this view.

4.43 For consent to be voluntary, a person must be free to make a choice. Consent may not be valid if there is any pressure or coercion. On one view, an individual's consent may not be voluntary and valid if the individual is denied

253 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, xii.
254 *Privacy Act 1988* (Cth), s 6.
255 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, xiii.

some benefit or is disadvantaged in some way because they refused consent. These dimensions of consent may become relevant when considering the application of the NPPs to genetic testing by an employer, prospective employer or for insurance purposes.

Example 4–1. A petrochemical company, some of whose workers are exposed to high levels of benzene, wishes to test job applicants and existing employees for genetic traits that may pre-dispose workers to cancer. The purpose of testing is to enable the company to refuse employment to prospective employees who test positive and to re-deploy existing employees who test positive to jobs that do not involve exposure to benzene.

In relation to job applicants, the position under the *Privacy Act* depends on whether the testing is necessary for the company's activities (see NPP 1.1) and whether proper consent to testing has been given (see NPP 10.1(a)). It may be possible to challenge the necessity of testing by bringing the scientific validity of the test into question. It also may be possible to challenge whether consent is voluntary if job applicants may be refused employment for refusing to consent to testing.

Due to the exemption relating to acts or practices directly related to the employment relationship and to employee records, the *Privacy Act* does not prohibit the testing of existing employees.

Provision of health services

4.44 NPP 10 contains provisions dealing specifically with collection of health information for the purposes of providing health services. 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 certain professional rules of confidentiality.[256]

4.45 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

256 *Privacy Act 1988* (Cth), NPP 10.2.

- must be established by a competent health or medical body — such as medical boards recognised in federal, state or territory legislation.[257]

Research and statistical purposes

4.46 In some situations relating to research and statistics an organisation may collect health information without an individual's consent. These situations arise where information is necessary for research or statistical purposes relating to public health or public safety, the compilation or analysis of statistics relevant to public health or public safety, or the management, funding or monitoring of a health service.[258]

4.47 Health information may only be collected without consent for these purposes if obtaining consent is impracticable, de-identified information would not be suitable, and the collection is carried out in accordance with guidelines issued by the National Health and Medical Research Council (NHMRC) and approved by the Privacy Commissioner under s 95A of the *Privacy Act* (s 95A guidelines).[259]

4.48 These guidelines have not yet been issued or approved but are under development by the NHMRC.[260] It is expected that the guidelines to be developed will put in place similar ethical committee structures and cover many of the same issues as the existing guidelines under s 95 of the *Privacy Act*. That is, the guidelines will include a process by which the proposed research methodology is examined and competing public interests in the research and in privacy are balanced by a properly constituted ethics committee that reflects a broad range of interests (see Chapter 6).

4.49 The existing medical research guidelines must be read in conjunction with the *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).[261] It is expected that the s 95A guidelines will also have to be read in conjunction with the National Statement. The National Statement contains a general section on the protection of privacy in research and specific sections dealing with, among other things, epidemiological research and human genetic research.

257 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, 3.
258 See *Privacy Act 1988* (Cth), NPP 10.3.
259 Ibid, NPP 10.3(b)–(d).
260 See National Health and Medical Research Council, *Draft Guidelines under s 95A of the Privacy Act 1988*, (2001) NHMRC, Canberra.
261 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.

The use and disclosure of genetic information

4.50 NPP 2 provides that, generally, an organisation must not use or disclose personal information about an individual for a purpose other than the primary purpose of collection (that is, for a secondary purpose). The principle then sets out an extensive codification of circumstances in which an organisation may use or disclose personal information for a secondary purpose. Most relevantly, these include:

- where the secondary purpose is related (or *directly* related in the case of health and other sensitive information) to the primary purpose and the person would reasonably expect such use or disclosure;
- where the individual has consented to the use or disclosure;
- in circumstances related to public interest, such as for research relevant to health and safety and for law enforcement purposes.[262]

Use or disclosure for directly related secondary purposes

4.51 Important primary reasons for collecting genetic information include collection for clinical use, research and law enforcement. A number of other primary purposes of collection may be identified. For example, genetic information might be collected in connection with life insurance or employment or for paternity testing.

4.52 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 collection and the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose.[263]

4.53 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. Given that a health service provider may treat an individual for a number of different conditions, the primary purpose is linked to each condition or ailment.[264]

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262 The use of personal information that is not health or other sensitive information for direct marketing is also permitted in specified circumstances: *Privacy Act 1988* (Cth), NPP 2.1(c). However, as genetic information will generally be health information this permitted use is not discussed further.

263 Ibid, NPP 2.1(a).

264 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, 12.

4.54 The guidelines provide a range of examples of secondary purposes for which the use or disclosure of personal information would usually be permissible without consent, provided it is within the reasonable expectations of the individual concerned. These include sharing information with other health service providers within a multidisciplinary health care approach.[265] Other directly related secondary purposes may include many activities or processes necessary to the functioning of the health sector, including use or disclosure in connection with:

- providing an individual with further information about treatment options;
- billing or debt-recovery;
- an organisation's management, funding, service-monitoring, complaint-handling, planning, evaluation and accreditation activities;
- addressing liability indemnity arrangements, for example, in reporting an adverse incident to an insurer;
- disclosure to a clinical supervisor by a psychiatrist, psychologist or social worker.[266]

4.55 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 for clinical or therapeutic purposes for other purposes, such as research. However, other exceptions to the prohibition on secondary use or disclosure are relevant to medical and other research (see below).

Individual consent to use or disclosure

4.56 Individuals may consent to the use or disclosure of their genetic information for a secondary purpose. Providing consent to the use or disclosure is valid, there is no limit on the purposes for which the information may be used or disclosed. An individual may consent, for example, to the disclosure of genetic information by his or her medical practitioner to medical researchers, insurance companies or employers.

Research and statistical purposes

4.57 In general, consent should be obtained from individuals prior to using their data for research or statistical purposes. However, where this is impracticable the use or disclosure of genetic and other health information for research purposes

265 Ibid, 13–14. However, the guidelines also state that it is likely there will be circumstances where a health service provider needs to seek consent before sharing information with another provider and that this may include some second opinions.

266 Ibid, 14–15.

will be permitted if carried out in accordance with the s 95A guidelines.[267] As noted above, these guidelines have not yet been issued or approved. The operation of these guidelines is discussed in more detail in Chapter 6.

Example 4–2. A doctor holds genetic information about her patients on her medical records. The information was collected to diagnose, advise and treat these patients for specific genetic conditions.

The doctor is approached by a medical researcher for access to all records concerning patients with thalassemia. Under the *Privacy Act*, the doctor may not disclose the records except with the consent of the patients to whom they relate (see NPP 2.1(a) and (b)). This is because the primary purpose of collection was clinical and it is not impracticable to seek consent.

Example 4–3. Researchers intend to approach hospitals and airlines to collect medical and travel records for the purposes of a research study investigating links between airline travel and deep vein thrombosis (DVT).

Under the *Privacy Act*, health information may be collected without consent for research purposes relevant to public health or public safety if the collection is carried out in accordance with guidelines issued by the NHMRC and approved by the Privacy Commissioner.[268] In general terms, the research will have to be approved by a Human Research Ethics Committee which will consider whether the public interest in the collection of the information substantially outweighs the public interest in maintaining privacy protection.

Other public interest purposes

4.58 Genetic information, like other personal information, may be used or disclosed without consent in circumstances where use or disclosure is necessary to protect an individual's life, health or safety or to protect public health or safety.[269] It may also be used or disclosed in the investigation of unlawful activity, where required or authorised by or under law, or where necessary to assist certain activities of law enforcement bodies.[270]

267 *Privacy Act 1988* (Cth), NPP 2.1(d).
268 Ibid, s 95A, NPPs 10.3(b)-(d).
269 The organisation must believe there is a 'serious and imminent' threat to any individual's life, health or safety or a 'serious' threat to public health or safety: Ibid NPP 2.1(e).
270 Ibid, NPP 2.1(e)-(h).

Example 4–4. A pathology service has stored DNA samples that have been tested to assist in the diagnosis of genetic conditions.

The pathology service is approached by the police who wish to obtain access to a particular DNA sample in order to identify a suspect in a crime from blood stains left at the scene. The *Privacy Act* permits the pathology service to disclose the sample to the police (see NPP 2.1(h)).[271]

Example 4–5. A doctor diagnoses a patient, Brenda as having the genetic mutation for Huntington's disease (HD), an incurable neurological degenerative disease that has its onset in most people between the ages of 35 and 55. HD involves a slow and progressive deterioration in movement, cognition and generalised functioning. Brenda is 50 years old and works as an air traffic controller. She does not wish to disclose her HD status to her employer.[272]

Under the *Privacy Act*, the doctor may disclose Brenda's HD status to her employer if he reasonably believes that disclosure is necessary to lessen or prevent a serious threat to public safety (see NPP 2.1(e)(ii)).[273] Whether such a belief is reasonable will depend on the patient's age, occupation and existing symptoms, if any.

Related privacy protection

4.59 Decisions about disclosure have to be taken with a view to other relevant legislation, the law and ethics of medical confidentiality and to clinical and ethical guidelines.

4.60 For example, the use and disclosure of genetic information collected for clinical purposes is constrained by obligations of medical confidentiality. Disclosure that is permitted by the *Privacy Act* may nevertheless constitute a breach of professional ethical obligations. Similarly, researchers who collect genetic information are subject to ethical duties of confidentiality and will have obligations under research guidelines issued by the NHMRC.

271 However, the Act permits but does not require disclosure. Disclosure of genetic information collected for clinical purposes may be further constrained by obligations of medical confidentiality.

272 Example drawn from elements of a scenario in NSW Genetics Service Advisory Committee, *Ethical Code Governing the Provision of Genetics Services*, (1998) NSW Health Department, 6–7.

273 Again, the Act permits but does not require disclosure. It may be argued that the doctor should, in any case, tell the patient that the doctor intends to reveal the information to the employer.

4.61 Collection of genetic information for law enforcement purposes may involve the use of DNA profiling information for evidence in criminal proceedings or for inclusion in the national DNA database operated by CrimTrac. The *Crimes Act 1914* (Cth) provides criminal offences for the unauthorised use of this genetic information.

Access to genetic information

4.62 NPP 6 provides individuals with a right to access genetic and other health information and to correct it if it is not accurate, complete and up-to-date. The principle provides for some limited circumstances in which health providers may withhold genetic and other health information, including where providing access would:

- pose a serious threat to the life or health of any individual;
- have an unreasonable impact upon the privacy of other individuals; or
- be unlawful or prejudice various law enforcement interests.

4.63 The Privacy Commissioner has stated that, in practice, it is likely that information will only need to be withheld on some occasions and that on balance, if a situation arises where the individual's right of access weighs equally with the health provider's concerns about providing access, the balance should err in favour of providing the individual with access to the information.[274]

4.64 In the health sector, it may be particularly important to provide the individual with an opportunity to discuss his or her health information when he or she seeks access to it in order to help prevent the information being misunderstood or taken out of context.[275] The possibility of genetic information being misunderstood may be greater than many other kinds of health information and is one reason that pre-test counselling is conducted to ensure the individual is fully informed about the implications of the test results.

De-identification of genetic information and samples

4.65 The *Privacy Act* does not apply to information unless it is personal information 'about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion'.[276] Health or other personal information may be de-identified so that it cannot be linked to the person to whom it relates. The concept of de-identification is referred to in a number of the *Privacy Act* NPPs.

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274 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, 34.

275 Ibid, 31.

276 From the definition of personal information in *Privacy Act 1988* (Cth), s 6(1).

- An organisation may only collect health information about an individual without consent for research purposes where the research cannot be conducted by collecting de-identified information.[277]

- Where health information is collected for research purposes, an organisation must take reasonable steps to permanently de-identify the information before the organisation discloses it,[278] for example, in a research publication.[279]

- An organisation must take reasonable steps to destroy or permanently de-identify personal information if it is no longer needed for any purpose for which the information may be used or disclosed.[280]

4.66 Whether genetic information is collected in a de-identified form or becomes de-identified at a later point in time depends on the purpose of collection. For example, genetic information collected for clinical purposes or forming part of medical or other clinical records will invariably be identifiable to an individual. Information collected for research purposes may be collected in de-identified form. However, genetic research often requires information obtained from genetic testing to be linked to health information contained in clinical records, making permanent de-identification impractical.

4.67 De-identification may raise particular issues in the context of genetic information. The rarity of some genetic disorders might allow certain individuals and families to be identified even though the information is de-identified.[281]

4.68 From one perspective it is impossible to completely de-identify a human genetic sample, at least so long as the person from whom the sample has been taken is alive. A sample can always be re-identified by matching its DNA profile with another identified sample.

Personal information, sensitive information and health information

4.69 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'. Genetic information is not specifically referred to in the Act.[282]

277 Ibid, NPP 10.3.
278 Ibid, NPP 10.4.
279 This does not mean that the information retained by the organisation must be de-identified.
280 *Privacy Act 1988* (Cth), NPP 4.2.
281 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 46.
282 The Explanatory Memorandum to the Privacy Amendment (Private Sector) Bill 2000 (Cth) 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

4.70 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.

4.71 For the purposes of the private sector provisions the *Privacy Act* creates a special category of 'sensitive information' and gives this a higher level of protection. Sensitive information is information or an opinion about an individual's racial or ethnic origin; political opinion; political association membership; religious beliefs, affiliations or philosophical beliefs; professional or trade association membership; union membership; sexual preferences; criminal record; or is health information about an individual.

4.72 '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
>
> © 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.

4.73 There are differences in the way the *Privacy Act* treats personal information, health information and other sensitive information. There are also some particular provisions applying only to health information. Generally, health

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information. 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 ALRC and AHEC 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.

and other sensitive information are provided higher levels of protection than ordinary personal information. Subject to some limited exceptions, NPP 10 requires consent for the collection of sensitive information.[283] 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.[284]

4.74 Some genetic information may not attract the higher level of protection the *Privacy Act* affords to 'sensitive information' or the application of the provisions relating specifically to 'health information'. Generally, only genetic information that can be defined as health information will receive the special protection afforded to sensitive information under the *Privacy Act*.[285]

4.75 Most genetic information about identifiable individuals is obtained from medical genetic testing, whether diagnostic or predictive, carrier or prenatal. Therefore, such genetic information would be likely to fit the definition of health information. In addition, diagnostic testing will count as health information, since it is information about the health of the individual. Predictive testing would generally also qualify, since it is 'information or an opinion about the health or disability (at any time) of an individual' in terms of s 6 of the *Privacy Act* even where it deals only with probabilities.

4.76 In its *Guidelines on Privacy in the Private Health Sector*, the Office of the Federal Privacy Commissioner has stated that health information includes:

> genetic information, when this is collected or used in connection with delivering a health service, or genetic information when this is predictive of an individual's health.[286]

4.77 Personal information derived from genetic testing that is provided to insurers or employers also may constitute 'health information' — even though it is not taken for clinical or therapeutic purposes. It is not necessary that a health service provider collect the information.

4.78 The position becomes less clear with respect to other genetic testing. There are circumstances in which genetic information may not be health information as defined in the *Privacy Act*. For example, carrier testing might fall outside the definition of health information, since it is not information about the

283 cf *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.

284 Ibid, NPP 2.1(a).

285 However, some genetic information might fall within the definition of sensitive information if it constitutes information or an opinion about an individual's racial or ethnic origin or sexual preferences.

286 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, vi.

health or a disability of 'an individual'. That is, the health of the test subject is not at issue — the information is about the health of future children. Nor, perhaps, is the information about a health service provided, or to be provided, to the individual being tested. In Victoria, the *Health Records Act 2001* (Vic) addresses this by defining health information to include '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*'.[287]

4.79 Another form of genetic information that might not fall within the definition of health information is genetic information collected and used to establish paternity. Similarly, genetic information collected and used for forensic purposes appears to fall outside the health information definition.

Privacy Act protection

4.80 The *Privacy Act* provides broad privacy protection for genetic information. From 21 December 2001, the requirements of the NPPs will apply to all significant aspects of the handling of genetic information, including many not highlighted above.[288]

4.81 However, as high level principles that must be interpreted in a myriad of circumstances, the exact application of the NPPs will often depend on the application of 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.[289]

4.82 The fact that the private sector provisions are yet to come into operation makes it difficult to review the adequacy of the *Privacy Act* regime. However, the inquiry invites comments that may assist in identifying factual situations in which privacy protection of genetic information may be inadequate.

Question 4–1. Is the framework provided for privacy protection in the federal *Privacy Act* adequate to protect genetic information? If not, why not, and how might the existing framework be improved?

287 *Health Records Act 2001* (Vic), s 3(1). The Act comes into effect from 1 July 2002.

288 For example, *Privacy Act 1988* (Cth), NPPs 3 and 4 apply standards for data quality and data security respectively.

289 Interpretation of the principles in particular contexts, including those involving the handling of genetic information, may be assisted in future by the content of approved privacy codes developed by private sector organisations, the Privacy Commissioner's guidelines and determinations and by relevant court decisions.

Question 4–2. Does the higher level of protection afforded to 'sensitive information' (including health information) under the *Privacy Act* adequately cover all forms of genetic information?

Question 4–3. Are there any potential privacy problems that arise in the practical application of the *Privacy Act* and the National Privacy Principles to:

- the collection of genetic samples and information?
- the use and disclosure of genetic samples and information?
- access by individuals to genetic samples and information relating to them?
- the de-identification of genetic samples and information?
- other aspects of genetic information privacy?

Some particular genetic privacy issues

4.83 The inquiry is examining whether and to what extent genetic information differs from other forms of personal or health information and whether any differences raise particular privacy concerns. Some particular issues, arising from the characteristics of genetic information, and which might justify additional or different privacy regulation, are discussed below.

The familial nature of genetic information

4.84 The inquiry is interested in whether the familial or collective nature of genetic information is a characteristic that requires recognition as part of privacy protection.

4.85 Genetic information relates not only to the individual but also family members and larger community groupings. For example:

- diagnosis of familial adenomatous polyposis (FAP) (a form of inheritable colorectal cancer)[290] in a person implies that each of his or her children has a 50% chance of developing the disorder as well;

290 Those who have inherited the gene mutation develop large numbers of malignant polyps on the lining of the large bowel. See Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne, 7–8.

- showing that someone is a carrier of cystic fibrosis implies that one of the person's parents is also a carrier.[291]

4.86 Genetic records often contain information about the genetic relatives of the individual to whom the information primarily relates. For example, in most genetic studies a 'pedigree' is drawn. This involves the identification of a number of family members some of whom may be quite distant in terms of their social relationship. The pedigree is likely to be essential to derive the mode of inheritance and, from this, the range of disorders that might apply to the genetic family and the person being tested.[292]

4.87 It has been suggested that rather than adopting regulatory approaches like the *Privacy Act*, which focus on protecting individuals' right to privacy, a 'medical model' of regulation should apply to genetic testing. This model is based primarily on what doctors consider best practice in providing medical care for patients and their families.[293] Control of genetic samples and information would be 'shared' among genetic relatives.

> 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.[294]

4.88 The Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria recommended this approach in its 1997 report and proposed guidelines on ethics and familial cancers (the Ethics and Familial Cancer Report).[295] This model for regulating genetic information, if adopted, would lead to quite different constraints being placed on the collection and disclosure of genetic information than those applicable under the *Privacy Act*.

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291 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 10.

292 See Research Committee of the National Health and Medical Research Council, *Submission 39 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 26 May 1998.

293 L Skene, *Patients' Rights or Family Responsibilities?: Two Approaches to Genetic Testing*, (1998) unpublished, 13 appended to Research Committee of the National Health and Medical Research Council, *Submission 39 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 26 May 1998.

294 L Skene, *Patients' Rights or Family Responsibilities?: Two Approaches to Genetic Testing*, (1998) unpublished, 13–14 appended to Research Committee of the National Health and Medical Research Council, *Submission 39 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 26 May 1998.

295 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne.

Collection of genetic information

4.89 In general, collection of information about genetic relatives without their consent is not permitted under the *Privacy Act*.[296] In contrast, the Ethics and Familial Cancer Report implies that sometimes doctors may be justified in collecting information about genetic relatives directly from other doctors.[297]

Disclosure of genetic information

4.90 The *Privacy Act* also restricts disclosure of genetic information to genetic relatives. 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.[298] In some circumstances, the disclosure of genetic testing information could allow the prevention of serious health consequences in genetic relatives.[299]

4.91 In many situations where there are benefits in informing relatives, consent to do so may be obtained following discussion with the person tested.[300] However, where consent is not obtained, in most circumstances (where disclosure is not for the primary purpose of collection or for a directly related secondary purpose), 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.[301] In most situations the threat of someone not knowing about a genetically based predisposition to illness may not be a sufficiently imminent threat to justify disclosure.[302] Further, while the *Privacy Act* may permit disclosure, this does not create any obligation to disclose.

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296 See *Privacy Act 1988* (Cth), NPP 10.

297 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne para 7.6. L Skene, *Patients' Rights or Family Responsibilities?: Two Approaches to Genetic Testing*, (1998) unpublished, 15 appended to Research Committee of the National Health and Medical Research Council, *Submission 39 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 26 May 1998.

298 See *Privacy Act 1988* (Cth), NPP 2.1 (a)-(b).

299 eg where a genetic test indicates an inherited predisposition to breast cancer that may also have been inherited by genetic relatives: See case study in NSW Genetics Service Advisory Committee, *Ethical Code Governing the Provision of Genetics Services*, (1998) NSW Health Department, 3. Similar issues about disclosure of health information of relevance to other people may arise in the case of serious and communicable diseases, such as HIV/AIDS.

300 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: National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 49.

301 *Privacy Act 1988* (Cth), NPP 2.1 (e)(i).

302 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': Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, 19.

4.92 The Ethics and Familial Cancer Report emphasises that patients should not be able to prevent the disclosure of relevant genetic information to their relations.

> It is *as members of families* that they are at risk, and because of family history which they share with many others that they may end up having a genetic test. The condition is necessarily shared, and the diagnosis of it necessarily implicates their relations.[303]

4.93 Under the Report's guidelines where it becomes necessary to inform relatives of a genetic risk the patient will first be asked to consent and if the patient objects, the information may be disclosed in de-identified form so that the relative is informed that the mutation exists in the family but not about the patient's identity or genetic status (even though these may be able to be inferred).[304] How significant a genetic risk must be to justify disclosure without consent under the guidelines is not clear.

Example 4–6. A genetic test indicates that a woman, Diana, has inherited a pre-disposition to develop breast cancer. She has an 80% chance of developing breast cancer within her lifetime. Diana does not wish to discuss this result with her three sisters, as suggested by her doctor. She also requests that her doctor not communicate the information. Her sisters remain unaware of their increased risk for developing breast cancer.[305]

Under the *Privacy Act*, the doctor may disclose Diana's genetic information to her sisters only if the doctor reasonably believes that disclosure is necessary to lessen or prevent a serious and imminent threat to the sisters' health (see NPP 2.1(e)(i)).

Access and genetic relatives

4.94 The familial nature of genetic information also raises access issues. The *Privacy Act* provides that an organisation that 'holds personal information about an individual' must provide the individual with access to the information on request by the individual.[306]

303 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne, para 10.18.
304 Ibid, Guideline 16.
305 Drawn from elements of a scenario in NSW Genetics Service Advisory Committee, *Ethical Code Governing the Provision of Genetics Services*, (1998) NSW Health Department, 3.
306 *Privacy Act 1988* (Cth), NPP 6.

4.95 In *Breen v Williams*[307] the High Court concluded that there was no basis at common law or in equity to find a general right of patient access to medical records. However, from 21 December 2001, NPP 6 of the *Privacy Act* will provide a legally enforceable right for patients to obtain access to their medical records held by private medical practitioners.

4.96 Where a person is being assessed or treated for a genetic condition by a medical practitioner, the starting point under the *Privacy Act* is that the person has a right of access to the genetic records collected by the medical practitioner. However, these records may contain information about the family as a whole, including, for example, information about non-paternity as well as the genetic status of other individuals. Where the information relates to a genetic relative who is not a patient of the practitioner, the obligation to provide access to the genetic relative under the *Privacy Act* may conflict with a practitioner's legal and ethical duties of confidentiality with respect to his or her patient.

4.97 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'.[308] Therefore, in some circumstances, a medical practitioner may be entitled to refuse access to part of the records. The practitioner could also 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.[309]

4.98 The familial cancer guidelines provide for a presumption that genetic relatives should have access to genetic information and genetic samples in order to be able to assess their own risk.[310]

The right not to know

4.99 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.[311] This principle may be seen as having particular application to genetic testing because of the predictive power, or perceived predictive power, of genetic information in relation to a person's long-term health experience and other physical and behavioural characteristics.

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307 *Breen v Williams* (1996) 186 CLR 71.

308 *Privacy Act 1988* (Cth), NPP 6.1(c). Problems concerning the privacy of the other people referred to in the record will also be minimised if information about them has been collected in compliance with NPP 1. That is, those people will have consented to the collection of information about them knowing that it would be included on another person's medical records and be able to be accessed by that other person.

309 Office of the Federal Privacy Commissioner, *Guidelines on Privacy in the Private Health Sector* (2001), Office of the Federal Privacy Commissioner, Sydney, 35.

310 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne, Guideline 13.

311 Privacy Commissioner of Canada, *Genetic Testing and Privacy* (1992), Privacy Commissioner of Canada, Ottawa, 30–31.

4.100 Under the *Privacy Act* the 'right not to know' is protected to some extent by requiring that, in most circumstances, genetic testing will not be permitted without the informed consent of the individual concerned. The National Statement 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.[312]

4.101 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. This is another reason to approach disclosure of information to other people affected by test results with caution. For example, disclosing genetic information to D's sisters (see Example 4–6 above) may breach those individuals' 'right not to know' about their genetic information. Some genetic relatives may not wish to know about their genetic risk. The Cancer Genetics Ethics Committee 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.[313]

4.102 A related issue is whether there should be more stringent standards for informed consent in the collection of genetic information than those provided by the NPPs. These might include requirements for counselling prior to testing, such as those applicable in some contexts to HIV/AIDS testing,[314] or stricter obligations to seek consent to the use or disclosure of genetic information for research than are provided for other health information.

Question 4–4. What particular issues arise from the application of privacy law to the protection of human genetic samples and information? For example:

- Is the familial nature of genetic information adequately recognised in privacy principles applying to the collection and disclosure of genetic information?

312 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.

313 Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1997), Anti-Cancer Council of Victoria, Melbourne, Guideline 16.

314 eg *HIV/AIDS Preventative Measures Act 1993* (Tas), s 14.

Question 4–4 cont'd

- Are the interests of individuals who prefer 'not to know' about genetic information relating to them adequately protected?

Regulation of health information privacy

4.103 The discussion above has focused on the privacy protection extended to genetic samples and information by general information privacy legislation, and by the federal *Privacy Act* in particular. The following discussion focuses on the regulation of health information privacy specifically.

4.104 While the *Privacy Act* creates a framework for national regulation of health information in the private sector, there remains no comprehensive framework for consistent national regulation of health information across public and private sectors, state and federal.

4.105 Instead, national regulation of heath information privacy is provided by a complex, fragmented and overlapping set of 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.

4.106 Most personal genetic information is collected, held, used and disclosed within the health sector and most of its uses are associated with the delivery of health care to particular individuals. Therefore, it may be argued that the privacy of genetic information is best achieved within a framework for the protection of health information.

Privacy Act and health information privacy

4.107 As discussed above, from 21 December 2001, the *Privacy Act* will extend privacy protection, based on the NPPs, to private sector organisations, including all health services holding health information as defined by the *Privacy Act*.

4.108 The extent of the health information privacy protection under the new private sector provisions of the *Privacy Act* has been criticised on a range of grounds, including the following:[315]

- the amendments entrench an inconsistent and lesser standard of privacy protection in the private sector than that currently applicable in the public sector;
- the NPPs may provide too many exemptions and exceptions from basic privacy principles, for example there are 11 separate grounds on which an individual's request for access to his or her health information may be refused;
- since organisations are free to develop their own codes, this may further contribute to a lack of consistency in how health information is treated[316] — although the statutory scheme for approving codes may help prevent significant inconsistencies from arising;[317]
- the enforcement mechanisms may be too cumbersome to provide effective redress for health consumers;
- the new private sector provisions may not meet the adequacy test contained in the European Commission's privacy directive, with possible consequences for transborder dataflows.[318]

Question 4–5. Does the federal *Privacy Act* provide an adequate framework for national regulation of health information privacy and, if not, why not?

315 See eg 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 6.21–6.24; NSW Ministerial Advisory Committee on Privacy and Health Information, *Panacea or Placebo? Linked Electronic Health Records and Improvements in Health Outcomes* (2000), NSW Department of Health, Sydney, 4, 23.

316 eg it is unclear which health industry body will be responsible for the private sector health guidelines and whether doctors, hospitals and health funds will be subject to separate codes.

317 eg the federal Privacy Commissioner may only approve a code if it incorporates all the NPPs or sets out obligations that are, overall, equivalent to the obligations under the NPPs and specifies the organisations bound by the code: *Privacy Act 1988* (Cth) s 18BB.

318 See Article 29 Working Party on the Protection of Individuals With Regard to the Processing of Personal Data, *Opinion on the Level of Protection of the Australian Privacy Amendment (Private Sector) Act 2000*, 3/2001 (2001), European Union; The Hon Daryl Williams QC AM MP (Commonwealth Attorney-General), 'European Data Protection Commissioners Opinion of Australia's Privacy Law, Press Release No 941', 26 March 2001.

State and territory health privacy legislation

4.109 The *Privacy Act* provides a national framework for privacy protection in the private sector as well as protecting privacy in the Commonwealth public sector. Some States and Territories have health privacy legislation.[319] Legislative privacy protection for health information at state and territory level varies.

Public sector

4.110 New South Wales and the ACT are covered by comprehensive public sector information privacy legislation that extends protection to health information held by public hospitals and other public health service providers.[320] Victoria also has public sector information privacy legislation[321] but this does not apply to health information. Separate legislation will, when it comes into operation, protect the privacy of public and private sector health information.[322] Other state and territory jurisdictions have no general public sector information privacy legislation.

Private sector

4.111 Some state legislation covers health information held in the private sector. The most comprehensive is the *Health Records (Privacy and Access) Act 1997* (ACT), which regulates the privacy of public and private sector health information.

4.112 In Victoria, the *Health Records Act 2001* (Vic) will come into effect from 1 July 2002. This legislation applies health privacy principles to all personal information collected in providing a health, mental health, disability, aged care or palliative care service and all health information held by other organisations.

Other legislation

4.113 In New South Wales, regulations protect the confidentiality of health information held in the records of private hospitals, nursing homes and day procedure centres.[323] The *Health Services Act 1988* (Vic) applies a duty of confidentiality to health workers in public and private hospitals and other health facilities.[324]

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319 *Privacy Act 1988* (Cth), s 3 provides that it is not to affect the 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.

320 *Privacy and Personal Information Protection Act 1998* (NSW); *Privacy Act 1988* (Cth).

321 *Information Privacy Act 2000* (Vic).

322 *Health Records Act 2001* (Vic).

323 *Private Hospitals Regulations 1996* (NSW); *Nursing Homes Regulation 1996* (NSW); *Day Procedure Centres Regulation 1996* (NSW).

324 *Health Services Act 1988* (Vic) s 141.

4.114 All States have legislation relating to the administration of public health services and most of this legislation contains provisions to protect the confidentiality of health information obtained by public sector health administrators in the course of their employment.[325]

4.115 Other legislation relevant to the privacy of health information includes:

- freedom of information (FOI) legislation that facilitates access to and correction of information held by public sector agencies, including public hospitals;
- legislation relating to compulsory notification of certain infectious diseases;
- mental health legislation; and
- legislation dealing with HIV/AIDS-related information.

4.116 HIV/AIDS related legislation may be of particular interest to the inquiry. The fact that it was thought necessary to legislate specifically for confidentiality in this sensitive area may suggest a deficiency in existing safeguards for health information.

4.117 Many jurisdictions have such legislation. For example, in New South Wales, the *Public Health Act 1991* (NSW) contains detailed provisions to protect the identity of patients tested or to be tested for HIV/AIDS.[326] A medical practitioner must not state the name or address of a patient when notifying the Director-General of Health or, except as prescribed, in arranging HIV/AIDS testing. Any person providing testing related services must take all reasonable steps to prevent disclosure of information about testing to another person. HIV/AIDS testing related information may be disclosed only with the consent of the person tested, in connection with the administration of the *Public Health Act*, by order of a court or in connection with providing care, treatment or counselling. Breaches are punishable by fine.

Health privacy codes

4.118 Some states have developed non-legislative privacy codes. For example, the New South Wales Health Department has an information privacy code of practice that specifically addresses genetic information[327] and the New South

325 eg *Health Administration Act 1982* (NSW); *Health Services Act 1988* (Vic); *South Australian Health Commission Act 1976* (SA).
326 *Public Health Act 1991* (NSW), s 17.
327 NSW Health Department, *NSW Health Information Privacy Code of Practice (Circular 99/18)*, (1999) NSW Health Department.

Wales Genetics Service Advisory Committee has issued an ethical code governing the provision of genetic services that includes consideration of privacy issues.[328]

Example 4–7. A medical specialist, Dr Eade, works in a public hospital. Dr Eade is treating Colin who has the genetic mutation for familial adenomatous polyposis (FAP). Genetic information about Colin is held in the records of the public hospital and in Dr Eade's private surgery.

After 21 December 2001, the records in Dr Eade's private surgery will be regulated by the federal *Privacy Act.*

If the public hospital is in New South Wales, the privacy of the records held by the hospital will be regulated by the *Privacy and Personal Information Protection Act 1998* (NSW) and, if in Victoria, by the *Health Records Act 2001* (Vic) (after 1 July 2002). If the hospital is in another State, there will be more limited privacy protection.

Legislative proposals

4.119 There are federal and state legislative proposals, at varying stages of development, which may have implications for the future shape of national health information privacy regulation.

4.120 Moves towards further regulation of health information privacy have been given momentum by moves towards the establishment of electronic health records systems. At federal level, the proposals include Health*Connect*, a proposal for an Australia-wide network for exchanging health information online and the Better Medication Management System (BMMS). Electronic health records are discussed in more detail in Chapter 9.

4.121 Recognising the need for a robust health information privacy framework particularly in the context of the development of Health*Connect*, the Australian Health Ministers Advisory Council (AHMAC) has formed a joint Commonwealth, State and Territory Health Information Privacy Working Group. The aim of the Working Group is to work towards the establishment of a nationally consistent regime for the protection of health information that applies to both the public and private sectors, including the development of a National Health Privacy Code. The National Health Privacy Code is intended to comprise a nationally consistent set of rules for the handling of personal health information.

328 NSW Genetics Service Advisory Committee, *Ethical Code Governing the Provision of Genetics Services*, (1998) NSW Health Department.

4.122 While the mechanisms for implementing the Code are still to be agreed, it is likely that the Code would be adopted under the *Privacy Act 1988*. Consistency would be achieved if States and Territories then recognised the Code in their own jurisdictions. In this context, some States and Territories may decide to incorporate the Code in their own health privacy legislation. For example, the ACT and Victoria have already adopted health information privacy legislation covering health information wherever it is held.

4.123 In NSW, the NSW Ministerial Advisory Committee on Privacy and Health Information has recommended that the development of a system of linked electronic health records in NSW should be governed by specific regulatory legislation to apply to all health records, in whatever form kept, in both the NSW public and private sectors.[329] The Northern Territory has signalled its intention to introduce similar legislation in the near future.

Question 4–6. Should there be uniformity or greater harmonisation of federal, state and territory laws concerning the privacy protection of human genetic information?

Genetic privacy legislation?

4.124 The discussion above has focused on the adequacy of information privacy and sectoral health information legislation as a framework for protecting the privacy of genetic samples and information. An alternative approach might focus on the development of a regulatory framework specifically for genetic information.

4.125 At federal level, such an approach was taken in the Genetic Privacy and Non-discrimination Bill 1998 (Cth), introduced by Democrat Senator Natasha Stott Despoja.[330] Based on a US model, the Bill addressed genetic information and dealt both with information privacy and related issues including consent and genetic discrimination.

329 NSW Ministerial Advisory Committee on Privacy and Health Information, *Panacea or Placebo? Linked Electronic Health Records and Improvements in Health Outcomes* (2000), NSW Department of Health, Sydney, 5.

330 The Genetic Privacy and Non-discrimination Bill 1998 (Cth) pre-dated the enactment of the *Privacy Amendment (Private Sector) Act 2000* (Cth). In additional comments appended to the Senate Committee report Senator Stott Despoja noted that there would have been no need for the Genetic Privacy and Non-discrimination Bill 1998 (Cth) 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.

4.126 The Bill stated that genetic information may only be disclosed with the authorisation of the individual concerned, where required by law or where disclosure is necessary to prevent a serious and imminent threat to life or health.[331] The Bill also set out detailed criteria for valid authorisation of disclosure by the individual, including describing the specific genetic information to be disclosed.[332]

4.127 The Bill covered procedures required for the collection, storage and analysis of DNA samples.[333] It provided that collection of DNA samples for genetic analysis may take place only with the written authorisation of the individual, and after the individual had been provided with certain prescribed information and a notice of rights and assurances.[334] The information to be provided would include information about the genetic information reasonably expected to be derived from the genetic analysis; the implication of the information for the individual and the family members of the individual; the extent of the right of the individual to have the DNA sample removed from a research study and if possible to have genetic information destroyed; the right to revoke consent to the genetic analysis at any time; that analysis might yield information that should be communicated to a family member of the individual and the availability of counselling.[335] The individual would have a right to order destruction of his or her DNA sample at any time.[336]

4.128 Criticisms of the Bill made in submissions to the Senate Legal and Constitutional Legislation Committee included that:

- the Bill, if enacted, would lead to different standards of confidentiality for genetic and other medical information (including family history information that has genetic implications);
- the Bill's broad definition of genetic information was inappropriate and could lead to unintended consequences, especially for the conduct of medical research;
- the relationship between the Bill and existing federal and state legislation applying to the collection, use and disclosure of genetic information was unclear.[337]

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331 Genetic Privacy and Non-discrimination Bill 1998 (Cth), cl 8.
332 Ibid, cl 9.
333 However, the definition of 'DNA sample' excluded tissue samples taken as a biopsy or an autopsy specimen or, as a clinical specimen, blood for a clinical or diagnostic test that is not a DNA test and blood in a blood bank: Ibid, cl 7.
334 Ibid, cl 12–16.
335 Ibid, cl 15.
336 Ibid, cl 14.
337 See eg 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; T Faunce, *Submission 7 to Senate Legal and Constitutional Legislation Committee*

4.129 In particular, concerns were expressed that the Bill was inadequate in not distinguishing between diagnostic and predictive testing. For example, the Human Genetics Society of Australasia stated that diagnostic genetic testing in symptomatic patients has no greater privacy implications than any other diagnostic tests, whereas predictive genetic testing requires counselling and additional privacy protection.[338]

4.130 In its report on the Bill, the Senate Legal and Constitutional Legislation Committee concluded that it would be premature to legislate on genetic privacy and non-discrimination and that further examination of the appropriate regulatory structures was needed.

4.131 The Committee considered 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 (including under the *Privacy Act*).[339]

Question 4–7. Would any deficiencies identified in the privacy protection of genetic information best be addressed through:

- amendments to the existing privacy laws; or
- the enactment of privacy legislation specifically dealing with all forms health information privacy legislation; or
- the enactment of privacy legislation specifically dealing with only genetic information?

International regulation of genetic privacy

4.132 Regulation of privacy in other jurisdictions may provide some useful pointers for reform in Australia. A useful starting point is the UK Human Genetics Commission's (HGC) international comparison of laws relating to the protection of

Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998, 8 May 1998; Australian Health Ethics Committee, *Submission 8 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 8 May 1998; National Centre for Epidemiology and Population, *Submission 41 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill 1998*, 10 June 1998.

338 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.

339 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, 37–39.

genetic information, covering Australia, Canada, the US, Germany, Netherlands and Sweden.[340]

4.133 The US does not have general information privacy legislation. Privacy protection is based on sectoral legislation in a complex patchwork of federal and state provisions. For example, many States have enacted legislation restricting the use of genetic information by health insurers (35 States) and in employment (23 States).[341] The HGC study observed that the US had no comprehensive federal legislation protecting the privacy of health information.[342] However, in April 2001 the US Department of Health and Human Services issued regulations under the *Health Insurance Portability and Accountability Act 1996* (US) establishing the first comprehensive federal standards for medical privacy.[343]

4.134 The other jurisdictions studied by the HGC all have general information privacy (data protection) legislation. Some of this legislation distinguishes between health information and other personal information. However, the legislation does not deal specifically with protection of personal genetic information, with the exception of the Dutch *Personal Data Protection Act 2000*.[344]

4.135 In July 1999, an opinion of the European Group on Ethics in Science and New Technologies to the European Commission[345] recommended that a European Directive on medical data protection was desirable, within the framework of the Council of Europe's Data Protection Directive.[346] This opinion may encourage moves towards sector–specific European legislation dealing with health information privacy.

340 D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London.
341 Ibid, 32, 45.
342 Ibid, 68.
343 *Health Insurance Portability and Accountability Act 1996: Standards for the Privacy of Individually Identifiable Health Information 45 CFR Part 164 1996* (USA).
344 D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London, 78.
345 The European Group on Ethics in Science and New Technologies, *Ethical Issues in Healthcare in the Information Society*, Opinion No. 13 (1999), European Commission.
346 *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).

5. Discrimination and genetic information

Contents

Introduction

5.1 The terms of reference require the inquiry to report on whether, and to what extent, a regulatory framework is required to provide protection from inappropriate discriminatory use of human genetic samples and information.

5.2 Australia has anti-discrimination legislation at the federal level as well as in all States and Territories.[347] The primary pieces of federal anti-discrimination legislation are the *Disability Discrimination Act 1992* (Cth) (DDA), the *Sex Discrimination Act 1984* (Cth) (SDA), the *Racial Discrimination Act 1975* (Cth) (RDA) and the *Human Rights and Equal Opportunity Commission Act 1984* (Cth) (*HREOC Act*).

5.3 Generally, for there to be unlawful discrimination under anti-discrimination laws, an act or omission claimed to be discriminatory must fall within specified grounds or attributes, relate to specified areas of activity, not be subject to an exemption and result in some harm or unfavourable treatment. This chapter examines these elements of the framework for dealing with discrimination in Australia.

5.4 In some circumstances, discrimination on the grounds of a person's genetic make-up may be unlawful under existing racial, sex, and disability anti-discrimination laws. This chapter asks questions about the possible deficiencies in this protection, particularly as it relates to disability discrimination.

5.5 If deficiencies in anti-discrimination protection for genetic information are identified, a key question is whether these deficiencies should be addressed through new legislation dealing specifically with genetic discrimination or within existing anti-discrimination laws.

5.6 There is potential for the discriminatory use of genetic information in a wide range of contexts, including employment and access to insurance and other services. The existing coverage of anti-discrimination law is also discussed in the chapters dealing with these contexts.

5.7 In many situations involving claims of discrimination, state and territory anti-discrimination legislation will overlap with federal anti-discrimination laws. Where this occurs, an individual may have the choice of seeking redress under the relevant federal, state or territory law.

5.8 Genetic discrimination may be based on an individual's or an organisation's misunderstanding of the nature and meaning of the genetic information — for example, by misinterpreting a predisposition to a genetic condition (which may or may not manifest at some time in the future) as determining that an individual will develop the condition. As genetic testing becomes more common, it will become increasingly important for the community to be educated about the nature and implications of this information.

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347 *Racial Discrimination Act 1975* (Cth); *Sex Discrimination Act 1984* (Cth); *Disability Discrimination Act 1992* (Cth); *Human Rights and Equal Opportunity Commission Act 1986* (Cth); *Equal Opportunity Act 1984* (SA); *Anti-Discrimination Act 1977* (NSW); *Equal Opportunity Act 1995* (Vic); *Anti-Discrimination Act 1991* (Qld); *Equal Opportunity Act 1984* (SA); *Anti-Discrimination Act 1998* (Tas); *Discrimination Act 1991* (ACT); *Anti-Discrimination Act 1992* (NT).

Federal anti-discrimination legislation

International human rights obligations

5.9 The principal constitutional basis for federal anti-discrimination legislation is Australia's international human rights obligations. This is necessary for the validity of the Commonwealth legislation because the Commonwealth may only pass laws that fall within the specific powers listed in the Constitution, principally in s 51.

5.10 There is no power in s 51 expressly referring to 'human rights' or 'discrimination'. However, there is an 'external affairs' power (s 51(29)), which the High Court has held to mean that the Commonwealth may enact laws to implement its international legal obligations.[348]

5.11 The RDA is based on, and has as its Schedule, the *International Convention on the Elimination of all Forms of Racial Discrimination*, to which Australia is a party.[349] Similarly, the SDA is based on, and has as its Schedule, the *Convention on the Elimination of All Forms of Discrimination Against Women*.[350]

5.12 The *HREOC Act* has as its Schedules the *Convention Concerning Discrimination in respect of Employment and Occupation* (ILO 111), the *International Covenant on Civil and Political Rights* (ICCPR), the *Convention on the Rights of the Child*, the *Declaration on the Rights of Mentally Retarded Persons*, and the *Declaration on the Rights of Disabled Persons*.[351] The legislation grants the Human Rights and Equal Opportunity Commission (HREOC) the power to investigate alleged breaches of human rights recognised in these instruments.[352]

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348 *Commonwealth of Australia v State of Tasmania (the Franklin Dam Case)* (1983) 46 ALR 625.

349 *International Convention on the Elimination of all Forms of Racial Discrimination*, opened for signature 7 March 1966, 982 UNTS 357, (entered into force for Australia on 30 October 1975).

350 *Convention on the Elimination of all Forms of Discrimination Against Women*, opened for signature 18 December 1979, UNTS 1325, (entered into force on 27 August 1983).

351 Ibid; *Convention Concerning Discrimination in Respect of Employment and Occupation*, opened for signature 25 June 1958, International Labour Organisation, UNTS 885, (entered into force on 15 June 1974); *International Covenant on Civil and Political Rights*, opened for signature 19 December 1966, UNTS 1197, (entered into force on 13 November 1980); *Convention on the Rights of the Child*, opened for signature 20 November 1989, UNTS 1588, (entered into force on 16 January 1991); *Declaration on the Rights of Mentally Retarded Persons*, GA Res 2856 26 UN (XXVI) GAOR Supp (No.29), 93, UN Doc A/8429; *Declaration on the Rights of Disabled Persons*, GA Res 3447 (XXX), UN GAOR.

352 *Human Rights and Equal Opportunity Commission Act 1986* (Cth) s 11(1)(f). However, as with the federal anti-discrimination legislation, the HREOC Act has a number of limitations. First, it contains the 'inherent requirements' exemption in relation to unlawful discrimination. Second, its enforcement powers are limited to conciliation between the parties and, where this fails, to forwarding a report to the Commonwealth Attorney-General. As with the other federal anti-discrimination statutes, if a complainant seeks an enforceable determination, he or she must then apply to the Federal Court of Australia or the Federal Magistrates Court for consideration of the original complaint: *Human Rights and Equal Opportunity Commission Act 1986* (Cth) s 46PO.

5.13 The DDA also refers to a number of international human rights instruments, including the ILO 111, the ICCPR, and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)[353], as well as to 'matters external to Australia' and 'matters of international concern'.[354] The reference to these instruments and 'matters' significantly broadens the application of the DDA provisions.

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5.14 The States and Territories do not have similar constitutional limitations and do not need to base their anti-discrimination legislation on Australia's international human rights obligations. However, anti-discrimination legislation is often expressly, or by necessary implication, based on international human rights obligations. For example, the preamble to the *Anti-Discrimination Act 1991* (Qld) expressly cites the instruments mentioned above as well as the *ILO Convention Concerning Equal Opportunities and Equal Treatment for Men and Women Workers: Workers with Family Responsibilities* and the *ILO 156 Convention on the Rights of the Child*.[355]

Other human rights norms

5.15 In the area of genetic information, the international instrument that is most directly applicable is the 1997 *UNESCO Declaration of Human Rights and the Human Genome* — but it is as yet unclear whether the provisions of this Declaration create obligations in international law sufficient to provide a constitutional foundation for amendments to existing legislation, or the creation of a new Act dealing with discrimination and genetic information.

5.16 On the one hand, it is questionable that the Declaration provides more than a recommendation at international law rather than binding legal obligations: the instrument is a declaration rather than a treaty. On the other hand, the High Court has held that something less than an intentional legal obligation may be a valid basis for Commonwealth legislation,[356] even if only recommendatory in nature.[357]

5.17 International human rights norms also may have an influence on the development of domestic law in Australia through the political process. For example, in *Toonen v Australia*, the United Nations Human Rights Committee

353 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 19 December 1966, 993 UNTS 3, (entered into force on 10 March 1976).

354 Following the reasoning of the High Court enunciated in *Koowarta v Bjelke-Petersen* (1982) 153 CLR 168.

355 *ILO Convention Concerning Equal Opportunities and Equal Treatment for Men and Women Workers: Workers With Family Responsibilities*, opened for signature 23 June 1981, International Labour Organisation, UNTS 1566, 460, (entered into force on 30 March 1991).

356 *Richardson v Forestry Commission* (1988) 164 CLR 261.

357 *R v Burgess; Ex parte Henry* (1936) 55 CLR 608, 687 (Evatt and McTiernan JJ).

(UNHRC) was critical of the provisions in the Tasmanian *Criminal Code*[358] criminalising consenting male homosexual relations, on the basis that this breached the human right to privacy.[359] Although the UNHRC decision had no direct binding effect on Australian law, the ruling, combined with a strong local campaign, put pressure on the federal and Tasmanian governments and led to legislative change.

Limited application provisions

5.18 The DDA and the SDA contain 'limited application provisions'. These provisions recognise that the Commonwealth Parliament has limited constitutional capacity to enact laws regulating discrimination. The Acts navigate this constitutional vulnerability by identifying, in a piecemeal fashion, a number of circumstances in which federal legislation is clearly supported by constitutional heads of power. Their purpose is to extend the reach of the Acts to a much greater extent than would otherwise be 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;
- 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 of international trade and commerce;
- discrimination against Commonwealth employees in connection with their employment, and so on.

Concurrent application of anti-discrimination laws

5.19 While the anti-discrimination legislation is not identical in each jurisdiction, there are considerable similarities and overlap. Under s 109 of the Constitution, in the event of an inconsistency between federal and state laws, the federal law will prevail to the extent of the inconsistency and the state law will be, to that extent, inoperative.

358 *Criminal Code Act 1924* (Tas).
359 *Toonen v Australia* CCPR/C/50/D/488/1992.

5.20 This caused problems in the early days of discrimination legislation in Australia. For example, in *Dao v Australian Postal Commission*,[360] the High Court held that the provisions of the *Anti-Discrimination Act 1977* (NSW), which proscribed racial discrimination and sex discrimination, were inoperative in the circumstances of the case because of inconsistent federal legislation. The complainants, who had brought a claim under the New South Wales law, lost the case because of lack of jurisdiction.

5.21 However, all of the federal anti-discrimination Acts now have 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. Therefore, as noted above, in some circumstances an individual may have a choice whether to commence proceedings under federal, or relevant state or territory anti-discrimination legislation.

Question 5–1. Should there be uniformity or greater harmonisation of federal, state and territory laws concerning discrimination in relation to human genetic information?

The Australian anti-discrimination paradigm

5.22 Despite some differences in the ambit of the legislation, all legislation dealing with discrimination in Australia embodies the same 'paradigm' or framework for identifying the unlawfulness of a discriminatory act or omission. As a general matter, for there to be unlawful discrimination the act or omission complained of must:

- fall within specified grounds or attributes (such as disability, race, religion, sex);
- relate to specified areas (such as employment, education, provision of goods and services);
- result in some harm or unfavourable treatment for the complainant; and
- not be subject to an exemption (such as those for religious bodies and charities).

360 *Dao v Australian Postal Commission* (1987) 162 CLR 317.

Specified grounds or attributes

5.23 The discrimination must occur on the basis of a ground or attribute specified in 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.

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5.24 If a person is discriminated against simply because the discriminator does not like them personally, the victim has no remedy under discrimination law unless the discrimination was based on one of the specified grounds. However, discrimination based on characteristics imputed to, or presumed to be held by, people who fit one of the grounds is unlawful, even if the assumption is incorrect either generally or with respect to a specific complainant.

5.25 Therefore, for example, refusing access to a public swimming pool on the basis that a person has a communicable disease is lawful, whereas refusing access to all people of a particular race on the assumption that all or most members of that race have that disease would be unlawful discrimination. The basis of the discrimination must ultimately relate to a specified ground or attribute. This means that the paradigm makes statutory definitions of these grounds crucial to the operation of the legislation.

Specified areas

5.26 The discrimination generally must occur in an area designated by the legislation. The areas specified in Australian anti-discrimination legislation 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 private, reflecting the public/private distinction that runs through much of Australian discrimination law. The term 'private' is read narrowly in this context, however, private property or premises to which the public regularly go, such as social clubs and entertainment or sporting venues, will generally be regarded as 'public places' for these purposes.

5.27 Some legislation has adopted a slightly different approach. The federal RDA refers to areas,[361] but also contains a more general provision which 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.[362]

361 *Racial Discrimination Act 1975* (Cth) ss 11–15.

5.28 The Genetic Privacy and Non-discrimination Bill 1998 (Cth), which is discussed below, and in Chapter 4, also adopted this approach. Clause 17 of that Bill was in the same terms as s 9 of the RDA, with the substitution of 'genetic information' for the word 'race'.

Unfavourable treatment

5.29 An additional aspect of the paradigm is that the essence of unlawful discrimination is unfavourable treatment. All Australian legislation requires (expressly or by necessary implication) that the complainant was treated less favourably than another person, who does not share the complainant's attribute, would have been treated in similar circumstances.

5.30 The element of differential treatment necessarily requires a comparator. For example, a woman must show that she was differently treated than a man in similar circumstances; a person with a disability must show that he or she was differently treated than a person without the disability, and so on. The law does not rely on 'bad' treatment, but on 'different' treatment. This may mean that the comparator — the choice of which may itself involve a value judgment — becomes a *de facto* standard for social 'normality'.

Direct and indirect discrimination

5.31 Australian anti-discrimination law recognises two main forms in which the relevant harm or unfavourable treatment may be constituted. These are direct discrimination and indirect discrimination.

5.32 Direct discrimination is the type of discrimination that occurs when a person is treated less favourably than another who does not share the first person's attributes. For example, refusing admission to a cinema to anyone other than Caucasians will amount to unlawful racial discrimination of people of all other races, whether the discriminatory policy is worded positively ('Whites Only') or negatively ('No Non-Whites').

5.33 This type of discrimination is the most obvious to identify. The intention of the discriminator is irrelevant: a person who is patronising but believes he or she is doing the right thing — for example, making a pregnant woman leave her job 'for her own good' — is as liable as someone who is blatantly biased and actively discriminatory. Another example, from the 19th century, was the refusal to employ people with fair or freckled complexions in tar and creosote factories because they were believed (without firm evidence) to develop skin cancers as a result of exposure to the petroleum products.

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362 Ibid s 9(1).

5.34 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 depending on the jurisdiction. In most jurisdictions it would have to be shown that the person's race was at least a substantial reason for his or her unfavourable treatment. However, under the RDA, this element of 'substantiality' need not be shown.[363]

5.35 Indirect discrimination is less obvious and more difficult to identify. It is sometimes called 'adverse effect' discrimination because it focuses more on the effect of the action, rather than on the attributes of the person towards whom the action is directed, although the latter is still relevant.

5.36 The law in Australia is not uniform with respect to the elements comprising indirect discrimination. Generally, what has to be shown is that a requirement or condition is imposed which has an adverse impact on people with a particular attribute, in circumstances where this is unreasonable.[364] Again, the intention to discriminate is not relevant.

5.37 For example, a requirement that users of public transport buy tickets that they themselves validate for travel by scratching off segments (rather than purchasing the ticket from the driver or conductor) may appear to be non-discriminatory. However, it was argued successfully in *Waters v Public Transport Corporation of Victoria* that this requirement has a greater adverse impact on people who have various visual, motor or intellectual impairments than it does on others without such impairments.[365] Therefore, such a requirement could amount to indirect disability discrimination.

5.38 The problem in practice is how to determine the differential adverse impact. Under the laws in Victoria and Queensland it must be proved that a higher proportion of people without the complainant's particular attribute are able to comply with the requirement or condition. In effect, a base pool of affected people must be identified and then the relative compliance rates of people with and without a particular attribute are computed. The identification of the base pools and the calculation of the compliance rates can be both difficult and controversial.[366]

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363 Ibid s 18.

364 The importance of showing that a requirement is 'not reasonable' may be of particular relevance in the employment context. In *State of Victoria v Schou* (Unreported, Supreme Court of Victoria, Harper J, 31 August 2001), the Supreme Court of Victoria emphasised that in order for indirect discrimination to be proven under s 9 of the *Sex Discrimination Act 1984* (Cth) the reasonableness of a requirement imposed by an employer must be assessed by reference to the interests of the employer and all affected employees, as well as the interests of the employee claiming to have been subjected to indirect discrimination.

365 *Waters v Public Transport Corporation of Victoria* (1991) 173 CLR 349.

366 See *Australian Iron & Steel Pty Ltd & Anor v Banovic* (1989) EOC ¶92-271.

5.39 Sometimes a calculation is impossible due to the lack of adequate statistical information. The court may have to take 'judicial notice' of what it considers to be an obvious social fact rather than demand a mathematical computation — as happened in the *Waters* case.

5.40 The federal DDA and the legislation in New South Wales, South Australia and Western Australia go further than this and require that a 'substantially higher' differential rate of compliance be shown. On the other hand, the federal RDA and SDA, and the legislation in Tasmania, the ACT and the Northern Territory do not require that any differential compliance rates be shown at all — only that there has been some adverse effect caused by the requirement or condition.

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5.41 The legislation also provides for a regime of vicarious liability, so that an employer or principal will be liable for the unlawful acts of an employee or agent. The defence to this vicarious liability, which arises where an employer or principal has taken reasonable steps to prevent the discrimination occurring, has been interpreted strictly in Australia. As a consequence, failure to know that discrimination was occurring is no excuse: the reasonableness goes to the quality of the preventive steps actually taken, and not to whether some preventive steps should have been implemented at all.[367]

Exemptions

5.42 Discrimination laws contain a number of exemptions. If they apply, an otherwise valid complaint of discrimination cannot be sustained. Typical exemptions in Australian discrimination legislation include the 'genuine requirements of a job', 'unjustifiable hardship' in accommodating a person's disability, acts done to comply with public health or workplace health and safety requirements, and exemptions for religious bodies, private schools and charities.

5.43 It is also possible for a person or body to apply to the agency administering the anti-discrimination law for a special exemption with respect to a particular activity. In relation to the DDA, SDA or RDA, a person may apply to HREOC for a temporary exemption from the operation of the legislation. HREOC may grant an exemption for a period up to five years, provided it is not inconsistent with the objects of the legislation.[368] This aspect of the legislation is meant to ensure that discrimination law operates in a sensible and reasonable fashion, taking account of practical concerns.

367 *Boyle v Ishan Ozden* (1986) EOC ¶92-165.
368 See eg *Disability Discrimination Act 1992* (Cth) s 55.

5.44 For example, discrimination on the basis of a woman's capacity to have children is considered unlawful sex discrimination.[369] In the past, the National Occupational Health and Safety Commission (NOHSC) has recommended the exclusion of women who are pregnant or breastfeeding from employment in the lead industry on the ground that lead exposure may involve a health risk to the unborn or breastfed child. Such exclusion would generally be unlawful under the SDA unless the employer obtains an exemption from HREOC.[370]

Harassment and vilification

5.45 Another aspect of discrimination law is harassment and vilification. The state and territory legislation generally confines harassment to sexual harassment. However, the federal 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.[371] The term 'harassment' is not defined but has been held by HREOC to include nasty remarks relating to a person's disability.[372]

5.46 Vilification is a concept that relates to the making of derogatory remarks, but not necessarily in one of the areas specified by the legislation (eg remarks made in the street). In Tasmania, the *Anti-Discrimination Act 1998* (Tas) makes it unlawful to publicly incite hatred towards, serious contempt for, or severe ridicule of a person on the ground of his or her disability.[373] Most other anti-discrimination legislation in Australia does not contain specific provisions with respect to vilification. Those that do, restrict the provisions to other attributes such as racial vilification.[374]

Grounds or attributes relevant to genetic information

5.47 Potentially, any of the grounds or attributes of discrimination in Australian law may be relevant to the issue of genetic information and the uses to which that information is put. The scope of relevance here will depend upon expanding understanding of genetics and of the role and influence of genes on health, behaviour, personality and so on.

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369 *Wardley v Ansett Transport Industries (Operations) Pty Ltd* (1984) EOC ¶92-002 . In that case, Ansett refused a woman a position as a trainee pilot because of her child-bearing potential. It was held that Ansett had discriminated against her on the ground of her sex.

370 *Sex Discrimination Act 1984* (Cth) s 55. See *Human Rights and Equal Opportunity Commission v Mount Isa Mines Ltd* (1993) 118 ALR 80.

371 *Disability Discrimination Act 1992* (Cth) ss 35–40.

372 *Adams v Arizona Bay Pty Ltd* (1997) EOC ¶92-885.

373 *Anti-Discrimination Act 1998* (Tas) s 19(b).

374 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) s 124A, s 131A.

5.48 Currently, some grounds or attributes are of moderate importance to this question. For example, some conditions, such as sickle cell anaemia and Tay-Sachs disease, are known to be more prevalent in some races and communities than in others, so discrimination on this ground may amount to both direct disability discrimination and to indirect racial discrimination.[375] This may be the case for any genetically determined condition linked to race — or any other attribute.[376]

5.49 Similarly, where discrimination is based on the presence of a genetic marker (BRCA1 and BRCA2) indicating a predisposition to breast cancer, the issue may also become one of sex discrimination as breast cancer is much more prevalent in women than men. These relevant categories will never be closed or static — they will expand or contract as medical and biological knowledge improves.

5.50 As genes influence not only people's medical conditions but also their appearance (eg height, hair and eye colour), discrimination based on this genetic information might be unlawful. However, among the various pieces of Australian discrimination legislation, only the *Equal Opportunity Act 1996* (Vic) expressly includes 'physical features' as a ground for unlawful discrimination.[377] Unless discrimination based on appearance can be linked to discrimination on the basis of sex, race or disability, there may be no remedy available in the other Australian jurisdictions.

5.51 The most obviously relevant ground or attribute will be disability or impairment. Genetic information may be used for diagnostic purposes to make or confirm a conclusion about a person's existing condition. Where genetic information is used for predictive purposes, to indicate the possibility that an asymptomatic person will develop a particular condition in the future, the legal position is more problematic. In these circumstances, precisely what is covered by the terms 'disability' or 'impairment' becomes crucial.

The definition of disability

5.52 While there is some variation, the definitions of these terms in Australian legislation are substantially similar. For example, s 4(1) of the DDA provides:

375 In fact, sickle cell anaemia is an evolutionary positive genetic trait. Therefore, in many cases discrimination against an individual on the basis that he or she has the condition (or is a carrier of the sickle cell trait) will reflect the discriminator's ignorance of the nature of the trait.

376 Schwartz has suggested that one benefit of the Human Genome Project will be to lead us to the understanding that there is only one race in medicine — the human race: R Schwartz, 'Racial Profiling in Medical Research' (2001) 344(18) *New England Journal of Medicine* 1392, 1393. While this suggests that racial discrimination on the basis of genetic information may become less of a concern as more becomes known about the genome, it does not account for discrimination on the basis of genetic traits that are more common in some races and ethnicities than others.

377 *Equal Opportunity Act 1995* (Vic) s 6(f).

'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

© 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.

5.53 It is notable that the DDA definition specifically covers disabilities that 'may exist in the future' as well as present or previous disabilities. The legislation in New South Wales and Tasmania is similar to the DDA in this respect.[378] However, not all Australian legislation has such wide coverage.[379]

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5.54 It is unclear how the courts will interpret the definition of 'disability' in relation to genetic information. For example, where a person has a genetic predisposition to a particular mental illness, this may be covered by paragraphs (g) and (j) of the definition. Alternatively, where a person has a predisposition to heart disease, this may be covered by paragraphs (a) or (e), and (j) of the definition.

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378 *Anti-Discrimination Act 1977* (NSW) s 49A; *Anti-Discrimination Act 1998* (Tas) s 3.

379 The Northern Territory legislation, while not expressly referring to future conditions, nevertheless contains an inclusive definition ('impairment includes …'), so that courts may consider that conditions arising in the future fall within the definition: *Anti-Discrimination Act 1992* (NT) s 4(1). The Western Australian legislation has a definition which refers to impairments imputed to a person, which might also be interpreted to include future conditions, but this is not certain: *Equal Opportunity Act 1984* (SA) s 4(1). All the other legislation contains exclusive definitions ('Disability/impairment means …') which allow no further width of application, and all of them do not refer to, and therefore presumably cannot apply to, future conditions.

5.55 An analogy to an individual with a predisposition to a genetic illness may be drawn with cases involving discrimination on asymptomatic HIV-positive status. It has been held that a person could not be excluded from a football team because of his HIV status,[380] but that someone with a similar condition could be excluded from combat-related positions in the armed services.[381]

5.56 Given the structure of Australian anti-discrimination law, with its emphasis on the characteristics presumed or imputed to apply to people who fit one of the specified grounds or attributes, there is some uncertainty about the applicability of such laws to acts or omissions based on predictive genetic information. While this widens the application of those grounds somewhat, the presumptions or imputations must relate to one of those existing grounds — they do not create new grounds, so that the definitional problems discussed above still persist.

5.57 Six jurisdictions[382] also extend the coverage of anti-discrimination laws to persons related to or associated with someone who comes within one of the other specified grounds. For example, a male child with no physical disability may be the victim of unlawful discrimination on the basis that his mother suffered an act of discrimination on the basis of her gender or her disability. This can be relevant as genetic information obtained from one person may be indicative of the genetic makeup of that person's blood relatives. However, the extension of coverage in this way is nevertheless linked to and dependent on the other grounds for its meaning. Although genetic information has particular potency because of its potential application to other blood relatives, the definitional problems remain significant.

Requesting information

5.58 It is unlawful to make requests for information on which discrimination might be based under the DDA and the laws in Queensland, Victoria, the ACT and the Northern Territory. These provisions make it unlawful — unless an exemption applies — to ask questions (verbally or in written form) with respect to such things as applications for jobs, housing or insurance, which might result in a decision being made on discriminatory grounds.

5.59 Not all anti-discrimination law in Australia expressly forbids the asking of questions aimed at eliciting information that potentially could be used for the purposes of discrimination, even where no relevant exemptions apply (for example, 'Are you married?', 'Are you intending to get pregnant?'). Some legal regimes

380 *Hall v Victorian Amateur Football Association* (1999) EOC ¶92-997.
381 *X v Commonwealth* (1999) 200 CLR 177.
382 Victoria, Queensland, Tasmania, the Australian Capital Territory, the Northern Territory and New South Wales.

look only 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, this is not entirely clear.

5.60 Questions may be raised about whether this amounts to inadequate protection, as the collection of information itself lies at the heart of concerns about genetic discrimination. Further, the collection of genetic information may not always be done in an area to which anti-discrimination law applies (for example, it might be collected in the course of medical treatment but used subsequently by a potential employer). However, federal privacy legislation places restrictions on the collection of personal information and subsequent use of information.[383]

Medical records

5.61 As genetic information may form part of a person's medical record, discrimination in this regard also may be relevant. The HREOC Regulations[384] and the legislation in Tasmania and the Northern Territory[385] are the only Australian laws that specifically refer to discrimination on the basis of a person's medical record as a ground of unlawful discrimination.

5.62 The Tasmanian and Northern Territory legislation refer to discrimination on the grounds of 'irrelevant medical records'.[386] What is or is not considered 'irrelevant' will depend on the circumstances of each case, so the potential application of discrimination law to records containing genetic information is problematic.

5.63 In other jurisdictions, medical records as such are not covered in the enumeration of grounds of discrimination and therefore no protection from discrimination on this basis alone exists.

5.64 Discrimination on the ground of medical records may occur where there has been access to an existing medical record, as well as where a person is required to undergo genetic testing for the purposes of compiling such a record. It is not uncommon for employers, for example, to require potential employees to undergo physical and psychological testing. However, the precise boundaries of application are not clear.

383 For example, *Privacy Act 1988* (Cth) NPP 1, NPP 2, NPP 10.
384 See *Human Rights and Equal Opportunity Commission Regulations 1989 (Cth)* r 4(a)(ii).
385 *Anti-Discrimination Act 1998* (Tas); *Anti-Discrimination Act 1992* (NT).
386 *Anti-Discrimination Act 1998* (Tas) s 16(r); *Anti-Discrimination Act 1992* (NT) s 19(1)(p).

Areas of discrimination relevant to genetic information

5.65 All of the designated areas to which Australian anti-discrimination legislation applies can be relevant to the issue of discrimination based on genetic information. For example, discrimination in the provision of goods and services might apply to a health provider's refusal to provide access to organ transplants to patients whose genetic information is otherwise indicative of a short life expectancy. Discrimination might occur with respect to the provision of education or aged care services for similar reasons.

5.66 The particular contexts in which genetic discrimination may occur are discussed in more detail in the following chapters. These possibilities raise important questions about social values that this inquiry will need to address, and upon which the inquiry would like to hear the views of the public.

Exemptions relevant to genetic information

Exemptions for the insurance and superannuation industries

5.67 As noted above, if an exemption applies there is no basis for an action for unlawful discrimination, no matter how genuine the complaint or how dire the consequences for the complainant.

5.68 Superannuation funds and insurance policies are given very broad exemptions in Australian discrimination legislation (see Chapter 11 for more detail). For example, superannuation funds which already were in existence at the time the relevant discrimination legislation came into force are allowed an exemption for any provisions which might otherwise amount to discrimination on the basis of an impairment or age.

5.69 Superannuation funds created after this time, and all insurance policies, are allowed a similar exemption if the otherwise discriminatory provisions are based on actuarial or statistical evidence on which it is reasonable to rely. Moreover, if there is no such actuarial or statistical evidence, they may discriminate if it is otherwise reasonable to do so.[387]

5.70 This raises obviously important issues about the use of genetic information by the insurance and financial services industry.

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387 See *Disability Discrimination Act 1992* (Cth) s 46; *Anti-Discrimination Act 1977* (NSW) s 49Q; *Equal Opportunity Act 1995* (Vic) s 43; *Anti-Discrimination Act 1991* (Qld) ss 62–63 and 75; *Equal Opportunity Act 1984* (SA) s 78; *Equal Opportunity Act 1984* (SA) s 66P, s 66T; *Discrimination Act 1991* (ACT) ss 28–29; *Anti-Discrimination Act 1992* (NT) s 49.

5.71 These provisions are also expressly subject to other relevant legislation, which in effect provides a further exemption.[388] For example, operating standards for superannuation funds, based on actuarial matters or in relation to the provisions in the funds' trust deeds, may be set in regulations, which would, in effect, become exemptions to anti-discrimination law.

Exemptions for public health and occupational safety

5.72 There are also uniform exemptions with respect to public health and workplace health and safety (see Chapter 10 for more detail). Indeed, employers have a legal duty of care with respect to their workers in any event, both under the common law and under occupational health and safety legislation such as the *Occupational Health and Safety (Commonwealth Employment) Act 1991* (Cth). Under these provisions employers have a duty to take steps to monitor employees' health and safety at work and to maintain health and safety records.

5.73 In addition, the national *Guidelines for Health Surveillance* set minimum requirements for health surveillance in the workplace, including the monitoring of employee health in industries in which employees are exposed to hazardous substances. Although these provisions include standards in relation to the storage and confidentiality of any information gathered, the extent to which the predictive, as opposed to the diagnostic, aspect of genetic information may either create a legal liability for discrimination, or be used to activate the exemptions described above, remains to be seen. To a large extent this will depend on the interaction between these laws, including the effect of s 109 of the Constitution, discussed above, as well as on the duties imposed on the relevant persons and bodies.[389]

5.74 All employers have statutory duties to safeguard the health and safety of their workers, these being found in the various occupational health and safety Acts of the States and Territories, and regulations made under them, which are specific to particular industries and workplaces. Employers also bear a common law duty of care for their workers: a breach of this duty may amount to negligence, or may be a breach of the express or implied terms of a contract of employment.

5.75 These competing requirements can sometimes put employers in an awkward position. On the one hand, employers may incur legal liability if they allow a person who has a particular sensitivity to some harm (for example, a genetic predisposition to susceptibility to dust diseases) to work for them and

388 For example, the *Occupational Superannuation Standards Act 1987* (Cth) s 7.

389 See eg the decision of the Federal Court of Australia in *Human Rights and Equal Opportunity Commission v Mount Isa Mines Ltd* (1993) 118 ALR 80, which held that while codes and guidelines set by the National Occupational Health and Safety Commission with respect to work in the lead industry should warn of the possibility of unlawful sex discrimination in refusing women jobs involving exposure to lead, that body's duty was nevertheless to produce the safest guidelines it could without restricting itself as a result of discrimination laws.

through that exposure the person contracts a disease or aggravates his or her medical condition. On the other hand, employers also may incur a legal liability for unlawful disability discrimination if they refuse that same person the job or move him or her to other duties that are less well remunerated or offer lower prospects of career advancement.

5.76 Generally speaking, requirements found in existing occupational health and safety legislation will amount to exemptions under state and territory anti-discrimination legislation — but the situation needs to be considered carefully in each case. For example, the Supreme Court of Victoria found that discriminating against a worker who had a work history of repeated injuries by placing the worker on restricted duties (which deprived that person of higher payments for overtime work) was authorised by the *Occupational Health and Safety Act 1985* (Vic) and hence was not contrary to anti-discrimination law.[390]

5.77 By way of contrast, however, the Administrative Decisions Tribunal of New South Wales has held that placing on leave without pay an orchestral musician who was subject to seizures amounted to unlawful disability discrimination, despite the occupational health and safety legislation in that State.[391]

5.78 The principal difference in the reasoning and findings of these two cases rests with the fact that, in the latter case, no objective assessment of the safety risk of the musician, either to himself or to other workers, had been undertaken, while in the former case a formal assessment of the risk had been carried out.

Exemptions for inconsistent legislation

5.79 Most state and territory anti-discrimination legislation exempts prima facie discriminatory provisions in other Acts, provided they pre-existed the anti-discrimination legislation. This could include occupational health and safety regimes, but it is not limited to these. The federal anti-discrimination legislation generally does not contain these exemptions.[392] Therefore, provisions that might be discriminatory could still apply and will be valid under state and territory legislation. For example, refusal of access to public places and public transport on the presumption that a person carries a contagious disease might be valid under provisions found in most state and territory public health Acts.

5.80 It may be the case that discriminatory provisions in Acts passed after the basic discrimination legislation would have to comply with that basic legislation.

390 *H J Heinz Company Australia Ltd v Turner* (1999) EOC ¶92-964.

391 *Carr v Opera Australia* (1999) EOC ¶92-998.

392 Except s 47(2) of the *Disability Discrimination Act 1992* (Cth) which exempts anything done by a person in direct compliance with a prescribed law. The prescribed laws are listed in Schedule 1 of the *Disability Discrimination Regulations 1996* (Cth).

However, this is by no means clear. Anti-discrimination laws are not Bills of Rights, nor do they have paramount force over all other legislation.

5.81 In any case, there is a presumption in the rules of statutory interpretation that in the event of an inconsistency between a later piece of legislation and an earlier one, the later one will (with some exceptions) prevail, since it is assumed that the legislators were aware of the earlier law and must have meant to vary its application.

5.82 For this reason, and to put the matter beyond doubt, some areas of the law now incorporate specific anti-discrimination provisions. For example, federal and state industrial relations legislation now includes anti-discrimination principles as a fundamental 'safety net' for awards, as well as incorporating them as part of the grounds for complaints of unfair dismissal. Similarly, s 52 of the DDA specifically exempts anything done in relation to the *Migration Act 1958* (Cth), and s 53 exempts employment in the Defence Forces with respect to combat and combat-related duties, as well as duties in a peacekeeping service.

'Reasonable accommodations' and 'unjustifiable hardship'

5.83 It is a common feature of all Australian anti-discrimination legislation that 'reasonable accommodations' must be made to enable people with disabilities to participate, to the extent reasonably possible, in those activities (work, education, access to public places, and so on) open to the rest of the community. However, there is an exemption available if implementing that accommodation would impose an 'unjustifiable hardship' on the person or body responsible for the implementation. This exemption is covered in more detail in Chapters 10 and 12.

5.84 What will amount to unjustifiable hardship will depend on all the circumstances. These include the nature of the service or facilities being provided, the cost of introducing the accommodation necessary for the person with a disability, the disruption that introducing the accommodation might cause, and the benefits and detriments that might be enjoyed or suffered by all people concerned. The exemption, however, requires careful evaluation before it applies. In *Finney v The Hills Grammar School*,[393] HREOC held that a school denying enrolment to a student with spina bifida amounted to unlawful discrimination. The school's defence of unjustifiable hardship, even though genuinely based on issues of the cost of reconfiguring facilities to provide access and the potential disruption of having the student in class, nevertheless failed because no opportunity had been taken to fully explore the range of accommodation that might be implemented in this case.

393 *Finney v The Hills Grammar School* (1999) EOC ¶93-020.

The 'inherent requirements' of a job

5.85 A significant exemption that is present in all the anti–discrimination legislation, relates to genuine occupational requirements — sometimes called the 'inherent requirements' of a job. This exemption means that an employer can lawfully refuse to employ a person who cannot perform essential aspects of the work. However, it must relate to abilities that not only attach to the job but which are essential to being able to perform it — that is, the 'inherent requirements' should not merely describe the way in which a job has traditionally been done. See Chapter 10 for more detail regarding this exemption.

5.86 In Queensland, s 25 of the *Anti-Discrimination Act 1991* (Qld) gives examples of the application of this exemption: selecting an actor for a dramatic performance on the basis of age, race or sex for reasons of authenticity; and considering only women applicants for a position involving body searches of women. Such examples appear to be straightforward and unquestionable — until one considers that Sarah Bernhardt played *Hamlet*; the pantomime character 'Dame' is traditionally played by a man; Peter Pan often has been played by a woman (most famously by Mary Martin); and most of the gynaecologists in Australia who conduct the most intimate physical examinations of women are men. The exemption is therefore not as straightforward and devoid of value judgments — or misconceptions — as it might at first appear.

5.87 Australian courts have not had an easy time in interpreting this exemption. In *X v Commonwealth*,[394] the High Court considered the case of a soldier who was dismissed after testing positive for HIV/AIDS. The High Court concluded that a genuine occupational requirement for active members of the Defence Forces was an ability to 'bleed safely', without risking the health and safety of their colleagues on the battlefield.

5.88 Such cases illustrate the difficult balance the law must strike in practice. This involves, on the one hand, supporting the rights of individuals to full participation in all aspects of society, and therefore requiring employers to take all possible steps to accommodate that individual's incapacity or disability. In *X v Commonwealth*, for example, this accommodation might have been made by ordering that there be protective measures for all military personnel against blood-borne illnesses, rather than isolating and rejecting specific individuals. On the other hand, there is a legitimate interest in employers not being put to excessive or unreasonable demands in reconstituting their work place or work practices, and even more so in ensuring that employers take all reasonable steps to ensure the health and safety of all of their workers, customers and others.

394 *X v Commonwealth* (1999) 200 CLR 177.

5.89 In another example referred to above, exemptions have been sought by the lead industry to allow the exclusion of women of child-bearing age from working in positions that might expose them to lead. This was accepted by the Federal Court in *Human Rights and Equal Opportunity Commission v Mount Isa Mines*, which held that while care should be taken to avoid discrimination against women to the extent possible, the over-riding duty of the NOHSC was to produce the safest guidelines it could.[395] The NOHSC should, however, point out clearly that the adoption of the standards and codes may involve employers in contraventions of the SDA, unless exemptions are obtained by them under the SDA.[396]

5.90 In order to work properly and effectively, this exemption requires a careful examination of the 'real requirements' of the particular job. In *Flannery v O'Sullivan*, an applicant for a job as a police officer was rejected on the basis of myopia ('short-sightedness') because a specific level of eyesight acuity was listed as a genuine occupational requirement.[397] The applicant's exclusion was held to be unlawful disability discrimination, since it was found that the real requirement was to be able to carry out such tasks as identifying suspects, driving motor vehicles at high speeds, etc. These tasks could be done equally well with corrective spectacles or contact lenses. It was also noted that the level of visual acuity required by Police Services differed among the various Australian jurisdictions, as well as among various overseas police forces.

5.91 In *Qantas Airways Limited v Christie*,[398] the High Court of Australia held that, in determining the inherent requirements of a job, the overall context must be taken into account — and not merely the condition of the person. What the employer in the *Flannery* case had done, in effect, was to confuse the occupational requirement with the test for it.

5.92 More widespread use of genetic testing in future could open up more possibilities for this sort of misapplication of test results, confusing raw health information about a person with his or her ability to do a job. This concern would be particularly acute in relation to genetic information that indicates a predisposition to a medical condition, but not the manifestation of any disorder. Care might need to be taken not to create a caste of people who become unemployable solely because of their genetic makeup.

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395 *Human Rights and Equal Opportunity Commission v Mount Isa Mines Ltd* (1993) 118 ALR 80.

396 Ibid, 106 (Lockhart J). In similar circumstances, the United States Supreme Court decided that excluding women from jobs in the lead industry amounted to unlawful discrimination. The US Supreme Court concluded that it was the *hazard* that needed to be removed from the workplace (such as through the use of protective clothing, better air filtration and so on), rather than the group of workers at risk: *United Automobile Workers v Johnson Controls* (1991) 111 SCT 1196.

397 *Flannery v O'Sullivan (No. 2)* (1993) EOC ¶92-501.

398 *Qantas Airways Limited v Christie* (1998) 193 CLR 280.

Disability standards under the DDA

5.93 Under the DDA, the federal Attorney-General may formulate disability standards with respect to employment, education, accommodation, public transport[399] and the administration of Commonwealth laws and programs.[400] It is unlawful to contravene a disability standard, but equally adherence to such a standard exempts a person from a complaint of disability discrimination.[401]

5.94 It may be that the Attorney-General could introduce such standards with respect to the use of genetic information in so far as these would correlate with the meaning of 'disability' under the DDA. These standards might relate to the meaning and application of terms such as 'DNA sample', as well as to the methods of collection and storage of the information gathered.

5.95 The development of disability standards in the context of genetic information is essentially a technical medical and health issue, rather than a legal one — just as the disability standards with respect to buildings (for example, gradients on paths for wheelchair access) were developed in consultation with architects, engineers and builders, rather than lawyers.

5.96 The DDA also provides that HREOC may publish guidelines for the avoidance of disability discrimination.[402] Such guidelines could include reference to discrimination on the basis of genetic information — but they would not have the binding status of disability standards promulgated by the Attorney-General.

Genetic discrimination legislation?

5.97 This chapter has focussed on the anti-discrimination protection extended by existing anti-discrimination law to discrimination on the basis of genetic status. To the extent that deficiencies in this protection are identified, these deficiencies might be addressed through amendments to existing laws, such as the DDA, or through the development of specific genetic discrimination law.

5.98 At the federal level, the latter approach was taken in the Genetic Privacy and Non-discrimination Bill 1998 (Cth), introduced by Democrats Senator Natasha

399 On 4 October 2001 the Attorney-General announced that draft Disability Standards for Accessible Public Transport had been finalised, and would come into effect upon the commencement of the Disability Discrimination Amendment Bill (2000) Cth. If passed, the Bill will allow HREOC to grant appropriate temporary exemptions from the Disability Standards: The Hon Daryl Williams AM QC MP (Commonwealth Attorney-General), 'Accessible Public Transport', *Press Release*, 4 October 2001.

400 *Disability Discrimination Act 1992* (Cth) s 31.

401 Ibid s 33.

402 Ibid s 67(1)(k).

Stott Despoja.[403] The Bill addressed genetic information and dealt both with information privacy and related issues including consent and genetic discrimination.

5.99 The Bill would have prohibited discrimination against individuals based on genetic information. Unlawful genetic discrimination was defined as 'any act involving a distinction, exclusion, restriction or preference based on genetic information that had the purpose or effect of nullifying or impairing the recognition, enjoyment or exercise, on an equal footing, of any human right or fundamental freedom in the political, economic, social, cultural or any other field of public life'.[404] The reference to human rights and fundamental freedoms was stated to be reference to any kind of right referred to in a Convention,[405] defined as 'any international agreement to which Australia is a party'.[406]

5.100 Submissions to the Senate Legal and Constitutional Legislation Committee inquiry into the provisions of the Bill stated that this was 'not a familiar formulation in Australian anti-discrimination law' [407] and that the areas of discrimination covered by the Bill were too vague.[408]

5.101 The Bill provided two exceptions to the prohibition against genetic discrimination.

- *Employment.* Employers or potential employers would be able to use the genetic information of an employee in order to permit a genetically susceptible employee to avoid occupational exposure to certain hazardous substances or to determine a genotype that is otherwise directly related to the work and is consistent with business necessity.[409] However, the Bill provided that an employer must not use the genetic information of an employee or applicant for any purpose restricting any right or benefit otherwise due or available to the employee or job applicant.[410]

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403 The Genetic Privacy and Non-discrimination Bill 1998 (Cth) pre-dated the enactment of the *Privacy Amendment (Private Sector) Act 2000* (Cth). In additional comments appended to the Senate Committee report, Senator Stott Despoja noted that there would have been no need for the Genetic Privacy and Non-discrimination Bill 1998 (Cth) 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.

404 Genetic Privacy and Non-discrimination Bill 1998 (Cth) cl 17(1).

405 Ibid cl 17(2).

406 Ibid cl 7.

407 Victorian Bar, *Submission 23 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 14 May 1998. However, as noted above, it is similar to the formulation contained in the *Racial Discrimination Act 1975* (Cth) s 9(1).

408 Attorney-General's Department, *Submission 42 to Senate Legal and Constitutional Legislation Committee Inquiry into the Provisions of the Genetic Privacy and Non-discrimination Bill*, 22 June 1998.

409 Genetic Privacy and Non-discrimination Bill 1998 (Cth) cl 18.

410 Ibid cl 18.

- *Insurance*. Insurers would be able to use the results of genetic tests that have already been conducted. The Bill provided that insurers must not: discriminate in relation to the policy of an individual or family member on the basis of any genetic information about a healthy individual or family member; discriminate against an individual's family in the provision of insurance; or require an applicant, or an individual or family member who has insurance to undergo a genetic test or to be questioned about genetic information.[411]

5.102 There were a number of criticisms of the Bill. As noted in Chapter 4, in its report on the Bill, the Senate Legal and Constitutional Legislation Committee stated 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 (including the various federal anti-discrimination acts).[412] The Committee also noted specifically that the Bill did not take into account the exemption for insurers contained in the DDA.[413]

Question 5–2. Do the various federal anti-discrimination laws adequately protect against unfair discrimination on the grounds of genetic status, or is there a need to amend the laws to clarify their application to genetic information? Alternatively, would it be better to enact legislation dealing specifically with genetic discrimination?

Genetic information and discrimination

5.103 The dispute resolution procedures provided by the Australian anti-discrimination regime are relatively speedy, confidential and inexpensive, and tend to utilise alternative dispute resolution techniques (usually conciliation) rather than litigation.

5.104 The shortcomings of the regime include inconsistencies and jurisdictional issues that arise because of the distribution of legislative powers under the federal system.

5.105 There is a tendency to think of scientific information as apolitical, asocial and objective. However, genetic information and the uses to which it legitimately may be put are clearly linked to social and political values. As noted above, anti-discrimination laws are not Bills of Rights. The latter set minimum standards of

411 Ibid cl 19.
412 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, 37–39.
413 Ibid, 25.

conduct; the former rely on differential treatment before they can apply. If everyone is treated at the same low standard, then anti-discrimination legislation is inapplicable (unless a case of indirect discrimination arises).

5.106 Important choices are involved in seeking a balance between such competing interests as: anti-discrimination and health protection, anti-discrimination and free enterprise, and privacy and knowledge. Many employers already use medical and psychological testing to screen potential employees, even though their value may be uncertain. Genetic testing may be materially different to these because of its potential predictive value — the accuracy of which have yet to be ascertained.

6. Medical and other human research

Contents

Introduction

6.1 This chapter examines ethical, privacy and related legal issues in relation to the use of genetic samples and information in the conduct of medical and other research involving humans. The chapter contains background information describing the regulatory framework under which research is conducted in Australia — the processes that are required and the principles, especially ethical principles, that are to be followed.

6.2 The present regulatory framework for the conduct of research involving humans is centred on the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).[414] The chapter examines how this framework, based on review of research proposals by Human Research Ethics Committees (HRECs), operates in practice.

6.3 In addition to the largely self-regulatory scheme for protecting research ethics based on the activities of HRECs, researchers have a range of relevant legal obligations, including those under the *Privacy Act 1988* (Cth), which are also discussed.

6.4 The chapter ends with a critique of the system of ethical review of research and asks questions about whether the existing regulatory framework is adequate to protect genetic samples and information.

The importance of genetic research

6.5 Research has the potential to enhance our understanding of how genes and environmental factors interact to influence the health of individuals and populations and, in doing so, generate knowledge that has a potential to be used 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.

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

6.6 The completion of the Human Genome Project (see Chapter 2) has opened huge potential for research into the ways that these genes are related to human conditions, capacities, diseases, impairments and susceptibilities.

6.7 Some 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.

6.8 However, the focus of this chapter is on research that needs to use or will develop genetic information that is either identified or potentially identifiable. For these purposes potentially identifiable information is data that may have identifiers removed and replaced by a code that makes it possible to re-identify the person to whom the data relates.[415]

The UNESCO Declaration

6.9 The need to balance the freedom of scientists to pursue genetic research with protection of human rights and other ethical concerns has been recognised in international instruments. The major international text on the ethics of genetic research is UNESCO's *Universal Declaration of the Human Genome and Human Rights 1997*.[416] The Declaration contains specific reference to the right to privacy and freedom from discrimination in the genetic context.

6.10 The Declaration emphasises the importance of free and informed consent to research, which can only proceed if directly beneficial to the person's health and if there is no comparable alternative source of relevant information. Research and treatment must directly benefit the person[417] and may only be undertaken after rigorous assessment of the potential risks and benefits involved. Limitations to consent requirements may only be prescribed by law, and only 'for compelling reasons within the bounds of public international law and the international law of human rights'.[418] Data obtained from genetic research must be held confidentially where associated with an identifiable person.[419] Confidentiality requirements may only be varied where prescribed by national law within the bounds of public international law and international human rights law.[420] The person's right not to

415 See Ibid, 9.
416 *UNESCO Universal Declaration of the Human Genome and Human Rights*, 11 November 1997.
417 Ibid, Art 5(e).
418 Ibid, Art 9.
419 Ibid, Art 7.
420 Ibid, Art 9.

know should be respected.[421] These provisions are not legally binding, but may be influential in the development of law and policy.

Familial nature of genetic research

6.11 A particular feature of many genetic research studies is that they require the participation of families, rather than single 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.

6.12 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.

6.13 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. 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.

6.14 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.

Research standards

6.15 Standards are used to assess both the scientific validity and the social value and ethical conduct of research involving humans. Validity is measured by reference to accepted scientific methods applicable in the relevant scientific discipline. Social value and ethical conduct are measured by assessing whether the research will lead to results that are of importance to the whole or part of a community and whether the research is conducted with respect for the human participants.

421 Ibid, Art 5(c).

Standards for research validity

6.16 In Australia, the *Statement and Guidelines on Research Practice* issued by the NHMRC and the Australian Vice-Chancellor's Committee (AVCC)[422] constitutes the most widely accepted statement of standards for the validity of research. The Joint Statement requires institutions to establish procedures and guidelines on good research practice and on steps to be followed if suspicions or allegations exist regarding research misconduct. Those procedures should aim to ensure that research observes accuracy and validity in collection and reporting of data, protects the truth by ensuring adequate peer review and publication, promotes quality and originality in research, respects confidentiality and safety, and ensures disclosure of conflicts of interest of all kinds.

6.17 Separate sections address data storage and retention,[423] authorship of publication of research,[424] publication,[425] supervision,[426] disclosure of conflicts of interest[427] and research misconduct.[428] The Joint Statement does not itself establish sanctions for misconduct but places this obligation on institutions in which research is conducted and recognises that academic awards will contain sanctions.

Social value and ethical conduct

6.18 The Australian standards for research involving humans are contained in the NHMRC National Statement[429] described in detail in this chapter.

6.19 The National Statement reflects the modern international development of standards about the ethical conduct of human research that began with the judgment in the medical case at the Nuremberg trials in 1946.[430] This judgment contained what has been referred to as the Nuremberg Code that set out the principles that ought to be followed when conducting any research with humans. The World Medical Assembly expressed the substance of this Code in 1964 when it issued the Declaration of Helsinki, which has become an international benchmark for ethical standards. Australia ratified this Declaration in 1965, and in 1966 the NHMRC issued an Australian *Statement on Human Experimentation*, largely following the Declaration of Helsinki. This statement was replaced by the National Statement in 1999.

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422 National Health and Medical Research Council and Australian Vice Chancellor's Committee, *Statement and Guidelines on Research Practice* (1997), NHMRC, Canberra.
423 Ibid, para 2.1–2.11.
424 Ibid, para 3.1–3.8.
425 Ibid, para 4.1–4.8.
426 Ibid, para 5.1– 5.4.
427 Ibid, para 6.1–6.3.
428 Ibid, para 7.1–7.8.
429 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra.
430 J Appleman (1954). For the text of the Code see G Annas, L Glantz and B Katz (1977), 21.

6.20 At the time, the importance of prior review and approval of research involving humans by a committee was first expressed, in the 1966 *Statement on Human Experimentation*, such review was considered simply a matter of institutional policy. This position was changed significantly in 1985 when the NHMRC resolved that committee review should be a condition of institutional eligibility for receipt of its research funds.

6.21 The current Australian system is similar in its substantially voluntary status to that in Canada, the United Kingdom and New Zealand.[431] The United States passed the *National Research Act* in 1974 under regulations providing detailed standards for the review of research involving humans. Enforcement can take the form of the withdrawal of research funds or the suspension of all research activities.

6.22 The history of research involving humans since the Nuremberg trials has been marked by recurrent incidents of ethically questionable conduct, some of which has led to significant harm to participants. Many of the notorious incidents have occurred in the United States where, arguably, since 1974, there has been the most detailed and enforceable regulation. While it would be potentially misleading to extrapolate from the United States experience to Australia, it would equally be wrong to suggest that similar events could not occur here.[432]

6.23 There is a tension between the benefits that can only be gained by research, and the rights of the human participants who are essential for such research to have their safety protected and to be treated with dignity. Given that genetic research seems likely to increase in quantity and complexity it is likely to create further tension. Australia will need to develop and refine systems to enable the conduct of research involving genetic information which are effective and appropriate, scientifically valid, socially valuable and ethically sound.

Present regulatory framework for research

6.24 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.[433]

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431 For a brief account of these systems, see D Chalmers et al, *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, Appendix 3.

432 However, as discussed below, the Australian system was reviewed in 1994–96: Ibid. The content of the National Statement reflects a response to the concerns raised by this review.

433 *National Health and Medical Research Council Act 1992* (Cth) ss 6, 20–21.

6.25 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.[434] 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.[435]

6.26 The NHMRC is one of the major providers of funds for medical research to institutions such as hospitals, universities and research institutes. It is a condition of an institution's continuing eligibility to receive those funds that all research involving human subjects conducted in the institution must be approved by an ethics committee that has been established and functions according to guidelines issued by the NHMRC.

6.27 However, there is no statutory requirement for institutions or HRECs operating outside NHMRC funding arrangements to be registered with the NHMRC or to follow the processes set down in its various guidelines.

6.28 In relation to medical research, the 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);[436] one of its principal committees.

6.29 AHEC is constituted by the federal Minister for Health and Aged Care in accordance with the NHMRC Act.[437] The membership is prescribed[438] as being persons with knowledge of the ethics of medical research and the regulation of the medical profession; expertise in law, philosophy and religion; experience in medical research, public health research, social science research, clinical medical practice and nursing or allied health practices; understanding of consumer health issues and the concerns of people with disabilities; and no more than two other persons with expertise relevant to the functions of the AHEC. The Minister is required to consult bodies designated in the relevant section before appointing members to the AHEC.[439]

6.30 The primary functions of the AHEC are to advise the NHMRC on ethical issues relating to health and to develop and give the NHMRC guidelines for the conduct of medical research involving humans. The AHEC also maintains an audit

434 Ibid, s 7.
435 The Medical Research Endowment Fund is established by the *National Health and Medical Research Council Act 1992* (Cth) s 49.
436 *National Health and Medical Research Council Act 1992* (Cth) s 8.
437 Ibid, s 36(1).
438 Ibid, s 36(1).
439 Ibid, s 36(5).

of the compliance by HRECs with relevant procedural guidelines and provides those committees with information and advice.[440] Additional functions of the AHEC are to promote community debate, and consult with individuals, community organisations, health care professions and governments on health and ethical issues; to monitor and advise on the workings of HRECs; to monitor international developments in relation to health ethical issues; and liaise with relevant international organisations and individuals.[441]

The NHMRC National Statement

Origin and scope

6.31 In 1996, a report to the federal Minister for Health and Family Services recommended the review of then existing guidelines on the conduct of medical research under the *NHMRC Act*.[442]

6.32 Those guidelines comprised the *NHMRC Statement on Human Experimentation and Supplementary Notes*. The Supplementary Notes dealt with institutional ethics committees (IECs); research on persons in dependent relationships; clinical trials; in vitro fertilisation and embryo transfer; the human foetus and use of human foetal tissue; epidemiological research and somatic gene therapy.

6.33 The National Statement replaced these guidelines (with the exception of the Supplementary Notes pertaining to the human foetus and use of human foetal tissue and somatic gene therapy). It was issued by the NHMRC on 28 June 1999 in exercise of its statutory obligations to issue guidelines for the conduct of research involving humans.[443] It was subsequently tabled in the federal Parliament on 30 June 1999. 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.[444]

6.34 The National Statement is applicable to all activities involving human participation having the purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge. The National Statement notes that it is

440 Ibid, s 35(3).

441 National Health and Medical Research Council, *The Inside Guide to the National Health and Medical Research Council for the 1997–1999 Triennium*, (1997) Commonwealth of Australia, 18.

442 D Chalmers et al, *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, 59, Recommendation 22.

443 *National Health and Medical Research Council Act 1992* (Cth) s 8.

444 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.

difficult to provide definitions of research or human involvement. Where human involvement in an activity has the potential for infringing basic ethical principles such as respect for persons, beneficence or justice, review of that activity by an HREC is warranted. That potential arises where involvement could cause physical, psychological, spiritual or emotional harm to a person, where there is infringement of a person's privacy or where the involvement is burdensome but provides little benefit.[445]

6.35 In the context of genetic testing there may be a 'grey zone' between research and routine diagnostic testing — where genetic testing is used for diagnosis but the value or significance of the results may not be fully understood. As genetic medicine develops, medical and other health practitioners will be faced with complex situations where the existence of particular genes (and their mutations) is known but there is insufficient empirical evidence to appreciate the clinical significance fully. Such testing may not fit easily into either research or clinical practice.

General principles

6.36 The National Statement:

- contains ethical principles relevant to all research involving humans;[446]
- requires that particular matters are to be addressed when research involves children and young people,[447] persons with an intellectual or mental impairment,[448] persons highly dependent on medical care,[449] those in dependent or unequal relationships,[450] collectivities,[451] and Aboriginal and Torres Strait Islander people;[452]
- requires that specific matters be addressed in the consideration and approval of research involving radiation,[453] assisted reproductive technology,[454] clinical trials,[455] innovative therapy,[456] epidemiology,[457] human tissue samples,[458] genetics,[459] deception,[460] and

445 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, 8.
446 Ibid, para 1.1– 1.21.
447 Ibid, para 4.1–4.4.
448 Ibid, para 5.1–5.4.
449 Ibid, para 6.1–6.9.
450 Ibid, para 7.1–7.3.
451 Ibid, para 8.1–8.2.
452 Ibid, para 9.
453 Ibid, para 10.
454 Ibid, para 11.
455 Ibid, para 12.1–12.13.

- sets out the formation, membership and functions of human research ethics committees (HRECs).[461]

The approval process

6.37 In general terms, the National Statement establishes a system for the ethical review of research involving humans. A researcher proposing to conduct such research is required to submit a written proposal that sets out the purpose and methods of the research to an HREC. The committee, at a meeting, reviews the proposal to decide whether, if the research is conducted as proposed, the rights and welfare of human participants will be adequately protected. The principles of the National Statement applicable to all such research will be relevant considerations for the HREC as will other paragraphs of the National Statement, depending on the type of research and the participants involved.

6.38 Typically a committee will be concerned with satisfying itself that any risks to participants from the research are outweighed by the benefits and that participants will be fully informed about their involvement and all the risks. A committee may request amendments to such matters as the means of initially contacting potential participants, or when it may be considered impracticable to do so or the documentation informing participants. A committee is also required to decide in what way the conduct of the research will be monitored to ensure that it is conducted in the approved manner. When the committee approves a research proposal, it will also notify the researcher of the means of monitoring the conduct of the research.

Ethical principles relevant to research about genetic information

General principles of ethical conduct in research

6.39 The general principles applicable to the ethical conduct of all research are particularly relevant to research proposals involving human participants. These principles include integrity and respect, consent, research merit and safety and ethical review and conduct.

456 Ibid, para 13.
457 Ibid, para 14.1 –14.13.
458 Ibid, para 15.1–15.9.
459 Ibid, para 16.1–16.16.
460 Ibid, para 17.1–17.2.
461 Ibid, para 2.1–2.48.

Integrity and respect for persons

6.40 The ethical principle of integrity requires the researcher to have a commitment to:

- the search for knowledge;
- the recognised principles of research;
- the honest and ethical conduct of research; and
- the dissemination and communication of results.[462]

6.41 The ethical principle of respect for persons requires researchers to have regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage of persons involved in research.[463] That principle also requires that research be so designed that respect for dignity and well being of persons takes precedence over expected benefits to knowledge.[464]

Consent

6.42 The consent of participants in research must be obtained before commencing the research, except in specified circumstances. These include research using de-identified information, anonymous surveys or observation in public. 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.[465] 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.[466] Consent may be withdrawn and advice given as to the consequences of withdrawal.[467] As discussed below, the consent requirement 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*.

462 Ibid, para 1.1.
463 Ibid, para 1.2.
464 Ibid, para 1.4.
465 Ibid, para 1.7.
466 Ibid, para 1.8–1.9.
467 Ibid, para 1.12.

Research merit and safety

6.43 The ethical principle of beneficence requires researchers to minimise risks of harm or discomfort to participants.[468]

6.44 The ethical principle of justice requires that there be a fair distribution of the benefits and burdens of research and the avoidance of an unfair burden of participation in research. The same principle also requires that processes of recruitment of research participants use fair means of exclusion and inclusion and not discriminate on grounds unrelated to the purpose of the research.[469] Further, the principle recognises that where clinical research offers benefits to participants, the risks of participation can be balanced by the expectation of benefits. However, in non-clinical research, where no benefits for participants are expected, there should be no more than minimal risk of participation.[470]

6.45 The ethical principle of research merit requires that every research proposal demonstrate that it is justifiable because of its potential contribution to knowledge.[471] All research should be based on a thorough study of current literature and, where relevant, prior research. Research should be designed to balance risks to participants with benefits[472] and must be conducted by those with experience, qualifications and competence relevant to the research, using appropriate facilities.[473] There should be skills and resources to deal with contingencies affecting participants.

Ethical review and conduct

6.46 The ethical principle of review requires that all research involving humans must not be funded or undertaken before review and approval by an HREC [474] and should be suspended by the researcher if risks become disproportionate to the benefits or if continuation may be harmful to a participant.[475]

6.47 Results of research should normally be published to permit scrutiny, add to knowledge and be available to participants.[476] Where records or results of research contain clinically significant information, they should be securely stored to permit any follow-up.[477] The privacy, confidentiality and cultural sensitivities of

468 Ibid, para 1.3.
469 Ibid, para 1.5.
470 Ibid, para 1.6.
471 Ibid, para 1.13.
472 Ibid, para 1.14.
473 Ibid, para 1.15.
474 Ibid, para 1.16.
475 Ibid, para 1.17.
476 Ibid, para 1.18.
477 Ibid, para 1.20.

participants should be respected in the collection and storage of personal information.[478]

Research using human tissue

6.48 Where research involves genetic information, it may use human tissue in the form of blood, saliva or other tissue containing DNA. The provisions of the National Statement relating to research with tissue may be relevant as well as those directly relevant to genetic research.

Respect for persons

6.49 Research using human tissue should observe the principle of respect for persons, so that donors of tissue should be provided with full information before consenting; tissue should be professionally removed and appropriately and securely stored and confidentiality and privacy ensured in recording, storing and releasing data.[479] Institutions which conduct research using human tissue should develop policies, consistent with relevant law and the National Statement, concerning the conduct and ethical approval of that research and the solicitation and acceptance of donations of tissue. Relevant considerations for such policy formulation include the source, nature, cultural or religious sensitivity of tissue samples, original reasons for collection and purposes of research.[480]

Where consent is required or can be waived

6.50 Consent should generally be required for collection of human tissue for research purposes.[481] Consent should be voluntary, specific to the purpose for which the tissue is to be used and follow full information about the research including advice as to whether any remaining tissue samples are to be stored, following completion of the research.[482]

6.51 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.[483] 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.[484]

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478 Ibid, para 1.19.
479 Ibid, para 15.1.
480 Ibid, para 15.3.
481 Ibid, para 15.4.
482 Ibid, para 15.5.
483 Ibid, para 15.6.
484 Ibid, para 15.7.

6.52 An HREC may waive the requirement for consent to the use of human tissue samples in research but must have regard to certain matters. These matters are the nature of any existing consent, the justifications presented for waiving consent, the protection of privacy and possibility of de-identification of the sample, the risk that the research poses to the privacy or well being of the individual, whether the research is related to prior approved research, the possibility of commercial exploitation and relevant statutory provisions.[485]

Confidentiality

6.53 Where human tissue samples have been collected in the course of a professional relationship, confidentiality must be observed in any research and identification limited to the minimum necessary for the research. An HREC may require procedures to allow research participants to be followed up if the research may lead to information relevant to the health and well being of participants.[486]

Research involving human genetic information

6.54 The National Statement contains a set of specific provisions relating to research involving human genetics. Particular ethical issues arise in this context because such research:

- affects not only participants but also their relatives;
- usually requires that families participate;
- needs to allow for relatives to choose not to be informed about the results of genetic tests; and
- could produce genetic information that can be used to unfairly discriminate or stigmatise the participants.[487]

6.55 Researchers need to consider the social and cultural significance of genetic research, especially in relation to complex and socially significant characteristics or genetic characteristics of collectivities. HRECs considering such research need to be satisfied that contestable ethical values are not assumed by researchers. HRECs need to consider the balance between the contribution to knowledge and the potential for harm to individuals or collectivities.[488]

485 Ibid, para 15.8.
486 Ibid, para 15.9.
487 Ibid, para 16.
488 Ibid, para 16.1–16.2. An important dimension of these concerns in Australia is the impact of genetic research on Aboriginal and Torres Strait Islander people. See M Dodson, 'Human Genetics: Control of Research and Sharing of Benefits' (2000) 1&2 *Australian Aboriginal Studies* 56, 56; S van Holst Pellekaan, 'Genetic Research: What does this Mean for Indigenous Australian Communities?' (2000) 1&2 *Australian Aboriginal Studies* 65, 65.

Privacy and confidentiality

6.56 Researchers must ensure the privacy and confidentiality of stored genetic information or research results relating to identified or potentially identifiable research participants and keep information provided about family members confidential.[489]

6.57 Research protocols must specify whether genetic information is to be stored in identified, potentially identifiable or de-identified forms.[490] The consequences for future research and communication of results to participants need to be considered when proposing to store information in a de-identified form.[491]

6.58 Identifying genetic information may only be released with the consent of the person to be identified.[492] Researchers may transfer genetic information and material to other researchers provided they are collaborating on approved research and that participants cannot be identified from the information or material. An HREC may approve a transfer of identified or potentially identifiable information or material in certain circumstances and, if so, those receiving it must undertake that there will be no reduction in the privacy of participants.[493]

Consent

6.59 Consent by an HREC must be obtained for participation in genetic research and for the use of stored genetic information or material, unless this requirement is waived by the committee.[494] Such consent will occur provided the researchers provide the committee with information on specified issues such as:

- that participants may refuse to consent;
- what arrangements are proposed to ensure privacy and confidentiality;
- whether information will be used in identified, potentially identifiable or de-identified form;
- where the research may reveal information relevant to the health of a participant or participant's offspring;
- whether participants will be informed of research outcomes;

489 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.3–16.4.
490 Ibid, para 16.5.
491 Ibid, para 16.6.
492 Ibid, para 16.7.
493 Ibid, para 16.8.
494 Ibid, para 16.9; para 16.12.

- that participants may decline to be informed of results;
- that the participant's consent will be sought before disclosing information relevant to the health of other family members;
- whether other family information is needed for the research;
- that the participant's consent will be sought before approaching other family members;
- whether the research can detect non-paternity or non-maternity; 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.[495]

6.60 Further information must be given to the HREC in relation to:

- whether the genetic material and information has uses beyond the research;
- whether it is intended to store that material and information; and
- whether the genetic material is to be disposed of on completion of research.[496]

6.61 Where genetic material and information is to be collected from persons because of their membership of a collectivity, consent should be obtained from the collectivity as well as from the individuals.[497]

Waiver of consent

6.62 An HREC may waive the requirement (with or without conditions) for consent to participation in genetic research. In reaching that decision, the HREC must consider the nature of any existing consent, the justifications presented for waiving consent, the protection of privacy and the possibility of de-identification of the sample, the risk that the research poses to the privacy or well being of the individual, whether the research is related to prior approved research, the possibility of commercial exploitation and relevant statutory provisions.[498]

495 Ibid, para 16.9.
496 Ibid, para 16.9.
497 Ibid, para 16.11.
498 Ibid, para 16.13.

6.63 Institutions or organisations in which research on genetic material and information is collected for non-research purposes should develop and publish policies to inform patients.[499]

6.64 When 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.[500] 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.[501]

Human Research Ethics Committees

6.65 Research suggests that at present there are 219 HRECs in Australia, of which 96 are in hospitals, 49 in universities, 36 in government and 38 in other institutions. They are comprised of members that conform to the minimum requirements of the National Statement. The workload of these known HRECs appears to vary significantly: some review in excess of 250 proposals per annum, while others will deal with far fewer.

Institutional status and accountability

6.66 All health research projects involving human subjects must be considered and given ethical approval by an HREC.[502] Institutions in which such research is undertaken should establish, adequately resource and maintain such a committee or obtain approval for research projects from a committee established by another institution.[503] When establishing an HREC, an institution must set out its terms of reference, scope of responsibilities, accountability and reporting mechanisms.[504] Institutions must accept legal responsibility for decisions and advice received from the HREC and agree indemnify to its members.[505]

6.67 HRECs are established by institutions in which research involving humans is conducted. Those institutions include government departments, statutory corporations, universities, hospitals and area health services. The legal status of a committee is directly related to and determined by the institution by which it is established. The committees have no independent source of legal existence. Their legal status will commonly be the same as that of other standing or permanent

499 Ibid, para 16.14.
500 Ibid, para 16.15.
501 Ibid, para 16.16.
502 Ibid, para 2.
503 Ibid, para 2.1.
504 Ibid, para 2.2.
505 Ibid, para 2.3.

committees of those organisations. It is likely that they will normally be considered part of the institution in which they were established.

6.68 To the extent that the function of an HREC is executive, in that it has the power to authorise the research to proceed, the HREC would almost certainly be regarded as part of the institution's 'organisation': the test widely applied to determine whether an institution will be vicariously liable for the conduct of others.[506] Where it adopts the decision of an HREC, the institution will generally also have a direct legal responsibility.

6.69 Where the HREC's role is advisory only, it may nevertheless still be regarded as part of the organisation and the institution will be vicariously liable for harm resulting from the conduct of HREC members where committee members have fulfilled their legal obligations to the institution by acting within their assigned responsibilities.

6.70 Indemnification of HREC members will depend upon the terms of institutional insurance or research sponsor indemnification policies. Institutions may establish insurance policies to cover liability for the conduct of members of HRECs and to indemnify members, particularly the lay members who, by definition, will not be employees or have any other legal relationship to the organisation. In some research projects it is the practice of sponsors to enter into indemnity arrangements with the institution, in order to protect them and HREC members from bearing the cost of compensating subjects who suffer harm in research.[507]

Functions and responsibilities

6.71 The primary function of an HREC is to protect the welfare and rights of participants in research.[508] 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. The guidelines require HRECs to maintain a record of all proposed research projects including specified information and to preserve the

506 *Kondis v State Transport Authority* (1984) 154 CLR 672; *Ellis v Wallsend District Hospital* (1989) 17 NSWLR 553. See also National Health and Medical Research Council, *Discussion Paper on Legal Liability, Insurance and Indemnity Arrangements for Institutional Ethics Committees*, (1993) Australian Government Printing Service, ch 6.2.

507 The issue of indemnification has been most prominent in relation to clinical trials of drugs: see R Day, *Report to the National Manager of the Therapeutic Goods Administration on the Review of the Clinical Trial Notification (CTN) Scheme* (1993), Therapeutic Goods Administration, Canberra. See also National Health and Medical Research Council, *Discussion Paper on Legal Liability, Insurance and Indemnity Arrangements for Institutional Ethics Committees*, (1993) Australian Government Printing Service, 33–36.

508 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.5.

protocols in their approved form. HRECs are to accept an obligation to provide information from their records to the NHMRC on request.[509]

6.72 Institutions and HRECs each have responsibilities to ensure that there is appropriate monitoring of the conduct of projects to their completion.[510] The frequency and type of monitoring determined by the HREC should reflect the degree of risk to participants and existing institutional mechanisms may be utilised.[511]

6.73 Regular reporting, at least annually, is a minimum procedure. Reports should address progress of the research, maintenance and security of records, compliance with the approved protocol and with any conditions of approval. Additional monitoring mechanisms may be employed by the HREC.[512] 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.[513] 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.[514]

6.74 Where an HREC is satisfied that a research project is not, or cannot be, conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not, or will not, be protected it may withdraw ethical approval, inform the researcher and institution of such withdrawal and recommend to the institution that the research be discontinued or suspended. A researcher is required to discontinue research if ethical approval is withdrawn.[515]

6.75 Institutions with HRECs are required to establish mechanisms for receiving and promptly handling complaints or concerns about the conduct of approved research projects. HRECs are to nominate a person to whom complaints may be made and make their identity known to the research participants. In the event of a dispute, the HREC must refer the complaint to the nominated person who will endeavour to resolve it. If not resolved, the HREC must refer the complaint to the person nominated by the institution to handle complaints. Institutions are also required to establish procedures for receiving and promptly

509 Ibid, para 1.16, para 2.30–2.31; para 2.47–2.48.
510 Ibid, para 2.20.
511 Ibid, para 2.33, para 2.34.
512 Ibid, para 2.35, 2.36.
513 Ibid, para 2.37.
514 Ibid, para 2.38.
515 Ibid, para 2.44–2.45.

handling complaints from researchers about considerations of research proposals by an HREC.[516]

6.76 Some HRECs perform other functions beyond those set out in the National Statement. These activities include providing advice on ethical issues in complex clinical decisions and in developing institutional policies on matters such as resuscitation decisions, palliative care and confidentiality.[517]

Membership

6.77 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.[518]

6.78 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.[519]

516 Ibid, para 2.39–2.43.
517 For a study of Australian practice, see P McNeill (1993).
518 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 2.6.
519 Ibid, para 2.7–2.9.

6.79 Institutions may recruit members in such manner and shall appoint them for such terms and on such conditions as it determines — although members are appointed for their expertise and not as representatives of any professional, political or social group. Members should receive a formal notice of appointment together with an assurance that the institution will provide legal protection in the event of claims arising from bona fide conduct of committee duties.[520]

Sanction for non-compliance

6.80 The National Statement provides that the NHMRC, through AHEC, will audit the activities of HRECs to ensure compliance with the National Statement[521] and requires institutions and HRECs to report annually on several matters 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;
- monitoring procedures in place and problems encountered; and
- complaints procedures and the number of complaints handled.[522]

6.81 In the event that this reporting reveals that an institution and its HREC have not complied with the National Statement, implementation of the NHMRC policy may result in that institution ceasing to be eligible to receive NHMRC funding for research.

Legal obligations

6.82 Researchers also have a range of relevant legal obligations, including those under the *Privacy Act 1988* (Cth), other legislation and at common law. Some of these obligations are discussed below.

520 Ibid, para 2.10–2.12.
521 Ibid, para 2.46.
522 Ibid, para 2.48.

Privacy Act research guidelines

6.83 From 21 December 2001, the new private sector provisions of the *Privacy Act* will, for the first time, make private sector medical and other research subject to enforceable privacy protections.

6.84 Under the *Privacy Act*, health information may only be collected without consent for research purposes if obtaining consent is impracticable, de-identified information would not be suitable, and the collection is carried out in accordance with guidelines issued by the NHMRC (or a prescribed authority) and approved by the Privacy Commissioner under s 95A of the *Privacy Act* (s 95A guidelines).[523]

6.85 As stated in Chapter 6, the s 95A guidelines have not yet been issued or approved but are under development by the NHMRC.[524] Existing research guidelines have been issued under s 95 of the *Privacy Act* (s 95 guidelines). These have a more limited operation than the proposed s 95A guidelines, applying only where it is proposed to use personal information held by a Commonwealth agency without the consent of the person to whom the information relates. However, because it is expected that the s 95A guidelines will establish similar ethical committee structures and cover many of the same issues, the s 95 guidelines are discussed in some detail below.

6.86 The s 95 guidelines must be read in conjunction with the National Statement. It is expected that the s 95A guidelines will also require that the guidelines be read in conjunction with the National Statement.[525]

6.87 When a proposal for medical research would, or might be thought to, involve a breach of an Information Privacy Principle (IPP), the s 95 guidelines require the proposal to contain a reference to the relevant principle, or principles, and reasons must be given for believing that the public interest in the research outweighs to a substantial degree the public interest in adhering to the IPPs.[526]

6.88 The s 95 guidelines specify other matters to be included in such a research proposal[527] and require the researcher to provide the HREC with the information necessary to enable it to weigh up the public interest considerations and to notify the agency from which the information is sought that the proposed research has been approved by the HREC.[528]

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523 *Privacy Act 1988* (Cth), National Privacy Principles 10.3(b)–(d).

524 See National Health and Medical Research Council, *Draft Guidelines under s 95A of the Privacy Act 1988*, (2001) NHMRC, Canberra.

525 The National Statement contains a general section on the protection of privacy in research and specific sections dealing with, among other things, epidemiological research and human genetic research.

526 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 2.3.

527 Ibid, para 2.4.

528 Ibid, para 2.3, para 2.5.

6.89 In assessing such a research proposal, the s 95 guidelines require that the HREC must assess whether it has sufficient information, expertise and understanding, either among its members or otherwise available, to take proper account of privacy.[529]

6.90 In making a decision, an HREC must identify and consider the Information Privacy Principle or Principles that might be breached and whether it is necessary for the research to use identified or potentially identifiable data and whether it is reasonable for the research to proceed without consent of those to whom the information relates. Second, it must ensure that it has the competence to determine whether or not the public interest in the proposed research outweighs to a substantial degree the public interest in the protection of privacy.[530]

6.91 The s 95 guidelines then require an HREC to weigh the public interest in medical research against the public interest in the privacy issues. If the HREC is of the opinion that the public interest in the research outweighs, to a substantial degree, the public interest in privacy, then the Commonwealth agency's actions in providing access to information for that research will not be in breach of the *Privacy Act 1988* (Cth).[531] 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.

6.92 In reaching this decision, the HREC is directed by the privacy guidelines to consider certain specified matters. These are:

- 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 an IPP and any scientific defects of the medical research not being conducted in the manner proposed;

- the financial costs of not proceeding with the research;

529 Ibid, para 3.1.
530 Ibid, para 3.2.
531 Ibid, para 3.2.

- the public importance of the medical research;
- the extent to which the data being sought is ordinarily available to the public from the Commonwealth agency;
- whether the medical research involves use of the data in a way inconsistent with the purpose for which they were made public;
- whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an IPP;
- whether the risk of harm to individuals is minimal;
- 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.[532]

6.93 The s 95 guidelines also require HRECs to maintain a register which records specified details of approved proposals and of decisions made under the guidelines.[533] In addition the s 95 guidelines:

- require HRECs to provide for regular surveillance of the conduct of approved research until completion to ensure that it conforms with the approval;[534] and
- provide that complaints may be made to HRECs concerning conduct of a research project that may interfere with the privacy of an individual and to the federal Privacy Commissioner concerning the use of personal information by Commonwealth agencies.[535]

6.94 The s 95 guidelines empower the NHMRC to obtain access, upon request, to information kept by HRECs. AHEC, as the responsible committee of the NHMRC, is required to report annually to the federal Privacy Commissioner

532 Ibid, para 3.3(a)–(h).
533 Ibid, para 3.4.
534 Ibid, para 3.5.
535 Ibid, para 6.

with details of medical research projects to which the guidelines have been applied, evaluating the operation of the guidelines and providing additional information at the request of the federal Privacy Commissioner. Where there has been a failure to comply with the s 95 guidelines, AHEC is directed to report details of the failure to the federal Privacy Commissioner and may name the researcher or HREC responsible. Where the failure involves the use of information disclosed by a Commonwealth agency, the agency may be informed about the failure.[536]

6.95 The effect of the s 95 guidelines is that an act done by an agency that would breach an IPP is to be regarded as not breaching that IPP if done in the course of medical research and approved by an HREC, in accordance with the guidelines.[537] The s 95 guidelines have a legislative status — they are issued by the NHMRC in the exercise of statutory powers contained in the *Privacy Act*. However, the only sanctions provided in the guidelines for non-compliance by a researcher are being named in the NHMRC's annual report or in a report to a Commonwealth agency or the federal Privacy Commissioner.[538] Where the conduct of an agency is in breach of the *Privacy Act*, affected individuals may complain to, and have their complaints investigated by, the federal Privacy Commissioner.[539]

Other statutory responsibilities

6.96 The *Therapeutic Goods Act 1989* (Cth) contains provisions that impose obligations on HRECs. However, these obligations arise only in research constituting clinical trials of unregistered therapeutic goods. In essence, this legislation makes statutory the duties of HRECs to conduct the review, approval and monitoring of such research in accordance with the National Statement. As these are unlikely to involve issues concerning the protection of genetic information, they are not discussed in detail.

Common law

6.97 Members of HRECs have common law duties to exercise reasonable care owed to those with whom the requisite relationship of sufficient proximity arises.[540] These include duties to participants in research, as discussed in more detail below.

6.98 Members of HRECs may also owe duties to the institutions to which they are attached and to researchers who submit applications for review, to take reasonable care in performing their functions. These duties may place some

536 Ibid, para 5.1–5.2.
537 *Privacy Act 1988* (Cth) s 95(4).
538 National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (2000), NHMRC, Canberra, para 4.3.
539 *Privacy Act 1988* (Cth), ss 36, 38, 40–51.
540 In accordance with the common law relating to the tort of negligence.

constraints on the research approval and monitoring system. For example, an HREC may owe a duty of care to give informed, fair and prompt consideration to research protocols and may be liable if delay or unjustified rejection causes harm.

6.99 HRECs constituted in conformity with the National Statement as committees of institutions will not be separate legal entities. Accordingly, such legal duties that may arise in the performance of their functions and any liabilities that may flow from that performance will be those of the individual members. The qualifications, expertise and experience of each individual member will be relevant to the precise determination of those duties and liabilities, if any, in the light of the relevant circumstances. Where boards or other instrumentalities of institutions adopt advice or decisions of HRECs, that adoption will usually result in the institution being legally accountable for the conduct of the research.

Duties to research participants

6.100 For HREC members to be subject to a legal duty to research participants to exercise reasonable care, there must be a relationship with a sufficient degree of proximity between the committee members and those participants.

6.101 Whether such relationships are sufficiently proximate has not been tested in Australia. The National Statement could be used to support the proposition that a duty of care is present.[541] On the other hand, if the HREC's role is confined to giving advice to an institution, the relationship between HREC members and participants in the research subsequently initiated by the institution may be insufficiently proximate to give rise to a duty of care. The imposition of a duty of care is, to a degree, a matter of policy in the sense that there will sometimes remain a question of whether a duty should be imposed, even where factual elements are present.

6.102 Even if HREC members owe a duty of care to research participants, the other elements necessary for a successful negligence claim remain problematic. It would be necessary for a participant to establish that the HREC members failed to conform to the relevant standard of care, that is, that a reasonably careful person with that member's expertise and experience would not have exercised reasonable care in acting as that member did. Such care would probably require an adequate consideration of relevant matters. The National Statement suggests relevant matters, for example, that the interests of subjects are protected[542] and that their free and informed consent to involvement will be obtained.[543]

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541 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra eg paragraphs 1.14 (implicit obligation on HRECs to ensure a balance of risks and benefits to participants) and 2.5 (the duty of HRECs is to protect the rights and welfare of participants).

542 Ibid, para 1.2.

543 Ibid, para 1.7.

6.103 The standard may vary from member to member, depending on his or her expertise and, although expert evidence from people with relevant experience will be useful, it is clear that the reasonableness of conduct is for the court, and not, for example, for a profession to decide.[544] Failure to ensure exclusion of subjects for whom involvement in the research is clinically contra-indicated or failure to require, in a consent form, disclosure of a risk of a kind that most other similarly qualified committee members would require be disclosed, might amount to evidence of negligent conduct.[545]

6.104 The participant would also have to establish that the conduct of the HREC member caused the harm, for example, that it was the materialisation of that undisclosed risk that caused the harm for which compensation is sought. Several acts occur between the HREC member's advice and the participant's harm, not the least of which is the decision by the institution to authorise the research to proceed and the actions of the researcher in recruiting the participant and conducting the research. Further, where risks have not been disclosed, causation depends on whether the subject would or would not have chosen to consent. Any one of these may amount to a sufficient break in the asserted chain of causation between the HREC member's advice and the participant's harm.

6.105 In addition, to succeed in an action for negligence the harm for which compensation can be sought must be of a type that could have been reasonably foreseen by an HREC member.

6.106 In the USA and Canada, some cases have arisen in which the liability of members of an HREC has been alleged or where HREC members have been joined as parties.[546] In most cases liability of HREC members has not resulted.[547] The particular circumstances involved and the different sources to which regard could be had in Australia to determine the relevant standard of care limit the force of these decisions in Australia.[548]

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544 *Rogers v Whitaker* (1992) 175 CLR 479.

545 For example, see *Weiss v Solomon* (1989) 48 CCLT 280 regarding liability for non-disclosure of risks to research subjects.

546 *Davis v Rodman* [1921] 227 SW 612; *Tarasoff v Regents of University of California*, 551 P2d 334 (1976); *Jones v Stanko*, 160 NE 456 (1928); *Weiss v Solomon* (1989) 48 CCLT 280. See also B Freedman and K Glass, 'Weiss v Solomon: A Case Study in Institutional Responsibility for Clinical Research' (1990) 18 *Law Medicine and Health Care* 395; L Bordas, 'Tort Liability of Institutional Review Boards' (1984–85) 87 *West Virginia Law Review* 137.

547 See A Holder, 'Liability and the IRB Member: The Legal Aspects' (1979) 1(3) *IRB: A Review of Human Subjects* 7.

548 For a valuable discussion of these issues and the weight of overseas authority, see National Health and Medical Research Council, *Discussion Paper on Legal Liability, Insurance and Indemnity Arrangements for Institutional Ethics Committees*, (1993) Australian Government Printing Service. In November 1994, the National Health and Medical Research Council (NHMRC) endorsed a revised version of the discussion paper. This revised version was published in April 1995: D Chalmers et al, *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.

Evaluation and criticism of the HREC system

6.107 Most published material that assesses the system of ethical review of research involving humans in Australia predates the present regulatory framework. The National Statement has, since June 1999, provided a comprehensive and more detailed set of principles and standards for HRECs than its predecessor. However, the effects of the National Statement on research practices and the degree to which it is complied with have not been examined systematically.

6.108 To some extent, the National Statement reflects the adoption of recommendations and the response to criticisms, made in earlier studies and submissions, to review of the research system. Between about 1990 and 1996, there were a number of independent studies and an important review commissioned by the federal Minister for Health (see below).

6.109 A recurrent focus of early work evaluating the system for research ethics approval was the membership of ethics committees. Drawing parallels with consumer participation in other health care contexts, arguments were advanced in support of lay membership being broadened to a representative role to provide better mechanisms for regular feedback and community input.[549] The capacity of lay members to be an effective voice, resist the domination of clinicians and medical researchers and be recognised as of equal importance to medical members was questioned.[550] Indeed, the different languages used by different categories of members may result in lay members being alienated or their views regarded as relatively unimportant.[551] Related concerns were the increased workload of committees, both in quantity and complexity, and the need for better training and resourcing.[552]

Review of institutional ethics committees

6.110 In 1994, the federal Minister for Health and Family Services commissioned a review of the then existing system, based on the operation of Institutional Ethics Committees (IECs). This report[553] made reference to submissions that expressed criticism or concern on a range of issues including:

549 S Laufer, 'The Regulation of Medical/Scientific Research Practices Involving Experimentation on Human Beings' (1990) 8(1) *Law in Context* 87; P McNeill (1993).

550 P McNeill, 'Institutional Ethics Committees: Survey Results' (1990) *Trends in Biomedical Regulation* 60; D Chalmers, 'IECs and the Management of Medical Research and Experimentation' (1995) 3(5) *Australian Health Law Bulletin* 57.

551 P McNeill, C Berglund and I Webster, 'How Much Influence do Various Members Have Within Research Ethics Committees?' (1996) 15(2) *Monash Bioethics Review* 20.

552 R Smallwood, 'Medical Ethics — Past and Future' (1993) 158 *The Medical Journal of Australia* 45 45; J Cooper, 'Facing Up to the Duty of Surveillance: An Ongoing Relationship Between Institutional Ethics Committees and Researchers' (1991) 10(4) *Bioethics News* 3; R Loblay and D Chalmers, 'Ethics Committees: Is Reform in Order?' (1999) 170 *Medical Journal of Australia* 9.

553 D Chalmers et al, *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.

- the risk of a conservative or 'chilling' effect on research of the power of IECs and a narrow view of ethics;[554]
- a lack of consistency between IEC decisions and administrative procedures;
- that IECs should focus on monitoring of research practice;
- that IECs should take care not to frustrate research and that current procedures sometimes alienate researchers and prevent prompt consideration of research protocols;[555]
- that review by IECs of social and behavioural research relying on a membership designed to review medical research was inappropriate and there needed to be changes in IEC membership;[556]
- the role of IECS in multicultural Australian society and the need for attention to confidentiality and the capacity of participants to understand and interpret research information and consent forms;[557]
- the delays and duplication involved in gaining approval of research conducted at several sites, usually referred to as multi-centre research, and proposals for shared or centralised processes to address these;[558]
- the need for increased training in and understanding of the clinical trial processes for pharmaceutical drugs;[559]
- concern about confidentiality and privacy raised by 'a small number of submissions' in epidemiological research, the use of medical records for purposes other than those for which they were created, the storage and destruction of confidential information and special concerns of minority groups including people with a disability;[560]

554 Ibid, 15, citing P Pettit, 'Instituting a Research Ethic: Chilling and Cautionary Tales' (1992) 6(2) *Bioethics*.

555 D Chalmers et al, *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, 15, 33.

556 Ibid, 18–19. Paragraph 2.6 of the National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra reflects a response to this criticism.

557 D Chalmers et al, *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, 19.

558 Ibid, 20–23.

559 Ibid, 24.

560 Ibid, 31.

- concerns about the difficulty research participants may have in understanding consent forms, especially where from non-English speaking backgrounds and Aboriginal and Torres Strait communities, and the need for information to be provided in plain and accessible language;[561]

- the need for expedited processes of review for projects needing 'only minimal ethics clearance';[562]

- concerns about appropriate categories of IEC membership, whether members acted as individuals or in a representative capacity, gender, institutional to non-institutional and science to non-science ratios of members, whether biomedically trained members may dominate the minority of lay members, the need for guidelines for selection of members;[563]

- the need for education of members;[564]

- the need for additional resources for IECs and to identify a minimum resource level;[565] and

- the need for increased public scrutiny of the IEC functioning and decision making, the improvement of current data gathering on IECs.[566]

6.111 The Report concluded that there was:

> no persuasive evidence of unsatisfactory or poor conduct in the current operation of IECs 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.[567]

6.112 The content of the National Statement reflects a response to many of these concerns and revision of existing guidelines was itself specifically recommended by the review.[568]

561 Ibid, 37.
562 Ibid, 38.
563 Ibid, 43.
564 Ibid, 49.
565 Ibid, 51.
566 Ibid, 54.
567 Ibid, 54.
568 Ibid, iv.

Inquiry into scientific, ethical and regulatory aspects of human cloning

6.113 In September 2001, the House of Representatives Standing Committee on Legal and Constitutional Affairs released the report of its inquiry into the scientific, ethical and regulatory aspects of human cloning and stem cell research.[569]

6.114 For present purposes, the report is interesting for what it had to say about the operation of the National Statement and other guidelines issued by the NHMRC. In particular, the Standing Committee observed that:

> NHMRC Guidelines are developed by people with considerable expertise and knowledge, but the public has little understanding of the process or the capacity to participate in it. 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.[570]

6.115 These observations may be just as relevant to the regulation of genetic research generally.

6.116 The Standing Committee heard a range of evidence criticising the structure and operation of HRECs (referred to in the report as IECs), including 'the lack of public accountability in the process and the in-house nature of committees' and the non-representative nature of their membership.[571] The Committee concluded that the current regulatory environment for medical research was 'deeply unsatisfactory'.

> The current framework of non-legislative guidelines and IECs are 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.[572]

6.117 The Committee noted that in the area of human cloning and human embryo research there is a heavy involvement of significant private sector funding and commercial pressures on public sector research, such as that conducted in universities. As discussed below this position may increasingly apply to research involving human genetics. The Committee observed that:

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569 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.

570 Ibid, 162–164.

571 eg Ibid, 163 (Queensland Bioethics Centre), 163–164 (Dr Tonti-Filippini).

572 Ibid, 167.

> this changing environment must reduce the capacity for IECs, composed largely of voluntary members and relying on non-legislative NHMRC guidelines, to be able to operate effectively … 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 and the private sector, where much of the research undertaken, is subject to limited regulation.[573]

6.118 The Committee stated that consistent regulation must be applied to both publicly and privately funded research. 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.[574] However, the Committee also expressed concerns about the structure and operation of IECs generally and about inadequacies in their transparency and accountability. It recommended that the federal government establish an independent review of the IEC system in Australia.

The commercialisation of genetic research

6.119 Application of the results of research involving human genetics has potential for the realisation of commercial profit. Examples include the development of genetic testing devices or processes, the refinement of the design of pharmaceutical drugs so that they will be effective in populations defined by identifiable genetic conditions (known as 'pharmacogenetics') [575] as well as applications of novel genetic therapy.

6.120 These developments have implications for the funding of research and research related intellectual property issues. The commercialisation of research results is usually based on the grant of patent rights in inventions and the resulting exclusive right to exploit that invention for the life of the patent. Involvement in, and funding of, research at an early stage may be necessary in order to secure patent rights.

6.121 Such 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. If so, the primary sanction for non-conformity to the existing Australian research standards, the denial of funding eligibility, may not be applicable to such institutions. Second, the interrelation between self-interest and scientific research

573 Ibid, 167.
574 Ibid, ch 12, recs 1–14.
575 See for example, 'Drugs of the Future', *Time*, 15 January 2001.

can lead to conflicts of interest that can compromise the validity and safety of research.[576]

Question 6–1. Are commercialisation arrangements posing any additional or different pressures on researchers and the system of ethical review of human research? If so:

- what is the nature of these pressures and their practical implications?
- how should these matters be addressed by the regulatory framework?

Question 6–2. Should the system of ethical review of research involving humans be subject to different mechanisms of accountability? For example:

- should there be more comprehensive reporting requirements applicable to researchers and to Human Research Ethics Committees (HRECs)?
- should there be more emphasis on the obligations of HRECs to monitor the ongoing conduct of research?
- what sanctions, if any, should be applicable to breaches of ethical requirements?

Question 6–3. With respect to research involving humans, are the current guidelines on privacy in the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*, together with the guidelines under s 95 and s 95A of the *Privacy Act 1988* (Cth), adequate for the purpose of protecting the privacy of genetic information?

Question 6–4. The NHMRC National Statement provides that HRECs may 'sometimes' waive consent after taking into account a number of factors, such as the extent to which it is 'impossible or difficult or intrusive' to obtain consent. Are these waiver principles operating satisfactorily in practice, or are other safeguards required?

576 See J Barker, 'Human Experimentation and the Double Facelessness of a Merciless Epoch' (1999) 25 *New York University Review of Law and Social Change* 603, for a discussion of a recent such conflict in gene therapy research.

7. Human genetic databases

Contents

Introduction

7.1 One particular context for the use or application of genetic samples and information relates to the establishment and maintenance of collections of human tissue. These collections are sometimes referred to as human genetic databases and have been defined 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.[577]

7.2 The privacy concerns raised by human genetic databases include questions about informed consent to the collection of genetic information and the extent of restrictions on the use and disclosure of the information.

7.3 Genetic registers, and genetic information and samples maintained in connection with newborn and other population screening programs, are also types of human genetic databases. These collections of samples and information are discussed in Chapter 9. DNA samples held by police forensic laboratories for criminal justice purposes are also a form of human genetic database. Issues concerning the regulation of criminal justice databases, including the national DNA database administered by CrimTrac under the *Crimes Act 1914* (Cth), are examined in detail in Chapter 13.

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577 House of Lords — Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2000–01), The Stationery Office Limited, London, para 3.3.

7.4 The focus of this chapter is on the collection, storage, use and disclosure of genetic samples and information held in human tissue banks[578] maintained by hospitals, public and private research organisations, and in the archives of pathology laboratories.

7.5 A large and increasing number of such samples are being stored. Some indication of the scale of this collection may be derived from the fact that one 'conservative estimate' of the number of stored tissue specimens in the US in 1999 was 282 million, with new samples being collected at the rate of 20 million per year.[579]

Archives of pathology laboratories

7.6 Every day Australian pathology laboratories receive many thousands of human tissue samples including samples of blood, body secretions or tissue. Most of these human tissue samples are taken by medical practitioners as part of a medical examination or treatment. Pathology laboratories carry out various tests on these human tissue samples. The results of these tests are interpreted by specialist pathologists in order to assist in understanding what is causing a condition or how it should be treated.

7.7 When tests are completed, reports are provided to the medical practitioner who has ordered the tests. However, the tissue samples are retained by the laboratory in an archive of samples, often for a considerable period of time. Retention of pathology samples is important for several reasons. Samples may need to be retested as part of routine laboratory quality assurance or on the request of clinicians managing the patient's health care. There may also be legal reasons for retaining samples.

7.8 An pathology archive is, therefore, comprised of residual tissue removed primarily for therapeutic and diagnostic purposes. An archive may include tissues held in a variety of forms and is not restricted to paraffin-embedded samples.

7.9 Boundaries between the clinical and research uses of pathology samples may be difficult to define. Where, for example, a sample is DNA-tested to determine if a patient has cancer or a metabolic genetic disease, this activity may be seen as involving both research and clinical practice. De-identification of pathology samples prior to use in research may be problematic since it is often necessary to re-examine specimens in the light of new information and knowledge and to go back to the patient or the family with new, relevant clinical information or a request for further samples.

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578 The term human tissue bank is sometimes used to refer to organisations that are licensed to process and supply human tissue for transplant and other purposes. See eg Therapeutic Goods Administration, *Australian Code of Good Manufacturing Practice — Human Blood and Tissue* (2000). This is not the meaning of the term intended by this paper.

579 K Barlow-Stewart (2001).

Human tissue banks

7.10 Human tissue banks are maintained by private and public hospitals and research institutes. Unlike the samples stored in the archives of pathology laboratories, samples in human tissue banks are stored solely for their possible use in research.

7.11 Different parts of the same sample may be sent for pathology testing and to a human tissue bank. A medical practitioner may remove, for example, a sample of cancerous tissue for biopsy. Part of the tissue will be sent to pathology and another part to a human tissue bank. Often the tissue destined for the tissue bank will be 'snap frozen' to better preserve m-RNA (messenger RNA) for future research.

Existing regulation of human genetic databases

7.12 Key elements of the existing regulatory framework that applies to the collection, storage, use and disclosure of genetic samples and information held by pathology laboratories and in human tissue banks include:

- General information privacy legislation, including the federal *Privacy Act* and state and territory information privacy and health privacy legislation, which require the collection, storage, use and disclosure of genetic samples and information to comply with information privacy principles (see Chapter 4).

- NHMRC guidelines for the conduct of research involving humans issued under the *National Health and Medical Research Council Act 1992* (Cth) as the *National Statement on Ethical Conduct in Research Involving Humans*[580] (the National Statement) (see Chapter 6).

- State and territory Human Tissue Acts which require written consent regarding the donation of certain types of tissue but not others.

- Common law property rights in human tissues.

- Standards and guidelines determined by the National Pathology Accreditation Advisory Council (NPAAC), applicable to pathology laboratories accredited in Australia and requirements for accreditation established by the National Association of Testing Authorities, Australia

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

(NATA). These standards prescribe retention periods for human tissue samples held by laboratories.[581]

- Professional ethical standards that apply to medical practitioners and pathologists. Breaches of such standards, including those relating to duties of confidentiality, may constitute unsatisfactory professional conduct or professional misconduct and lead to disciplinary proceedings before medical boards or tribunals (see Chapter 8).

Privacy and human genetic databases

Privacy legislation and guidelines

7.13 Privacy concerns may be raised if samples retained in the archives of pathology laboratories are used in human research or for other purposes not related to the clinical care of the person from whom the sample was collected.

7.14 From 21 December 2001, the federal *Privacy Act* will apply to all private sector pathology laboratories. The Act constrains secondary use of pathology samples and information for research purposes without the consent of the person from whom the sample has been taken. Chapter 6 examines privacy and ethical regulation of the use of genetic samples and information in human research in more detail.

7.15 Under the *Privacy Act*, if the primary purpose of collecting pathology samples and information derived from them was to provide a health service to the individual concerned (as would usually be the case with pathology laboratory samples), the sample may not generally be used or disclosed for a secondary purpose without consent.[582]

7.16 Even where samples are collected for research purposes, consent may be required for the samples to be used for a new research purpose, depending on the surrounding circumstances and, in particular, on whether the individual concerned

581 NPAAC standards for retention of laboratory records and diagnostic material provide for varying retention periods for samples ranging from two days for haematology blood samples up to 20 years for most anatomical pathology materials and indefinite retention for tissue and cell cultures used in genetic testing: National Pathology Accreditation Advisory Council, *Retention of Laboratory Records and Diagnostic Material* (1998), Commonwealth Department of Health and Family Services, Canberra. There are specific requirements for the retention of samples used in biochemical genetics, molecular genetics and newborn screening: National Pathology Accreditation Advisory Council, *Retention of Laboratory Records and Diagnostic Material* (1998), Commonwealth Department of Health and Family Services, Canberra, 11. NPAAC guidelines and NATA accreditation require newborn screening samples to be held for 50 years: NSW Newborn Screening Programme, *Newborn Screening in NSW: Storage of Samples*, (2000) NSW Department of Health.

582 Unless that secondary purpose is directly related to the primary purpose of collection and the individual would reasonably expect such use or disclosure: *Privacy Act 1988* (Cth) NPP 2.1(a). Where a pathology laboratory is part of a public hospital, state or territory information privacy or health privacy legislation may apply to similar effect.

would reasonably have expected the further research use. Where seeking consent is impracticable, the use of human genetic samples for research purposes may be permitted if carried out in accordance with guidelines to be issued under s 95A of the *Privacy Act*.[583]

7.17 The *Privacy Act* National Privacy Principles concerning the collection, use and disclosure of information only apply to information collected after 21 December 2001. Therefore, the *Privacy Act* does not constrain the use of existing samples stored in human tissue banks by private sector organisations, even where fully informed consent has not been obtained.[584]

Research guidelines

7.18 The NHMRC's National Statement contains specific provisions dealing with the use of human tissue samples in research.[585] The National Statement provides that consent for the use of tissue samples in new research should generally be obtained. However, a Human Research Ethics Committee (HREC) may sometimes waive the requirement for consent after taking into account, among other things:

- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver of consent including the extent to which it is impossible, difficult or intrusive to obtain specific consent;
- the extent to which the proposed research poses a risk to the privacy or well-being of the individual;
- the possibility of commercial exploitation of derivatives of the sample.[586]

Some privacy issues

7.19 Privacy concerns may be magnified by the volume of information that may come to be held in some human genetic databases and, therefore, the potential for interference with individual privacy. For example, in Iceland the government has authorised the collection and storage of genetic information about the entire population by a private biotechnology corporation, with rights to exploit the data as

583 Ibid NPP 2.1(d).
584 Ibid s 16C.
585 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 15.1–15.9.
586 Ibid, para 15.8.

a commercial resource.[587] Other human genetic database proposals also have focussed on genetically isolated populations such as Estonia, Newfoundland and Tonga.[588]

7.20 In the UK, the House of Lords Select Committee on Science and Technology recently conducted an inquiry into human genetic databases. In part this inquiry was commenced in response to a research project proposed by the Medical Research Council and The Wellcome Trust. This project would involve the collection of genetic information and linked longitudinal medical histories of 500 000 volunteering participants.[589]

7.21 The primary objective of the House of Lords inquiry was to investigate how 'issues of privacy, ownership, distribution and anonymisation of individuals' genetic and related health information were dealt with in relation to currently available and planned uses of human genetic databases'.[590] On privacy protection, the Committee concluded that the primary means of regulating human genetic databases should continue to be the Data Protection Act 1998 (UK)[591] and, with some exceptions,[592] no additional protection was required for personal genetic data.[593]

7.22 Given the value of such databases for genetic research, it is likely that similar comprehensive collections of genetic material may be established in Australia.

> Most pharmaceutical and biotechnology companies are building or buying access to genetic databases and DNA libraries, often formed around data from clinical trials.[594]

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587 See 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.

588 eg in November 2000, a small Australian biotechnology company, Autogen Ltd, said it had signed a deal with Tonga to set up a database of Tongan DNA so it could search for disease-causing genes: ABC News, *Clean Genes: Genetically Pure Polynesian Paradise Pegged for Research*, ABC News Online, <http://abcnews.go.com/sections/living/DailyNews/genes_tonga001122.html>, 22 November 2000.

589 See House of Lords — Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2000–01), The Stationery Office Limited, London, 8, Oral evidence 19.

590 Ibid, para 2.10.

591 ie the UK's information privacy legislation — the equivalent in general terms of the *Privacy Act 1988* (Cth) and similar state legislation.

592 The Committee recommended that the use of human genetic information for secondary uses (for purposes other than the specific purpose for which the information was collected from patients or participants in research projects) should require the approval of a new Medical Data Panel, where the research involved national or supra-regional secondary use of human genetic information. See House of Lords — Select Committee on Science and Technology, *Human Genetic Databases: Challenges and Opportunities* (2000–01), The Stationery Office Limited, London, para 7.50–7.60.

593 See Ibid, para 3.14–3.17.

594 W Lowrance, 'The Promise of Human Genetic Databases' (2001) 322 *British Medical Journal* 1009, 1010.

7.23 Some privacy protection could be extended to information held on genetic databases through requirements for coding of information. For example, the Icelandic legislation authorising its genetic database[595] provides for coding before entry on the database so that research staff work only with de-identified data. However, the legislation also contemplates that information will be added to a person's records after those records have been initially created, so linkage must be possible.[596]

7.24 Some of the privacy and ethical issues raised by such databases include the following:

- On what basis will individuals be asked to give their consent to the collection, use and disclosure of their genetic and other health information? Where large scale human genetic databases are intended to be used for multiple and ongoing research projects, will consent be sought only once or on multiple occasions? For example, where individuals have consented to the use of their information for health-related genetic research, should further consent be required before the information is used for research into links between genetic make-up and behaviour?

- In what circumstances, if any, will genetic information derived from research results be disclosed to individuals? As previously discussed, the National Statement requires research participants to 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.[597] Where precise nature of the research to be conducted is not known in advance, how can such consent be properly obtained?

7.25 In examining these issues there may be relevant distinctions between samples used primarily for clinical and diagnostic purposes and those used primarily in research; between stored tissue from living donors and from deceased or untraceable donors; and between identified, potentially identifiable and de-identified donors of tissue where research is conducted.[598]

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595 *Act on a Health Sector Database 1998* (Iceland). The Act does not refer specifically to a database of genetic material. Instead it regulates the creation and operation of a database of clinical medical information about Icelanders derived from their medical records. This database may be created or operated only by someone with a license from the Minister of Health — in this case deCODE Genetics Inc: H Greely, 'Iceland's Plan for Genomics Research: Facts and Implications' (2000) 40(2) *Jurimetrics* 153, 170.

596 H Greely, 'Iceland's Plan for Genomics Research: Facts and Implications' (2000) 40(2) *Jurimetrics* 153, 183–184.

597 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 16.10.

598 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 14.1–16.16.

7.26 In pathology research, ethical standards for research involving living and identified or potentially identifiable donors has been moving in the direction of obtaining consent. For example, the *Consensus Statement of Recommended Policies for Uses of Human Tissue in Research Education and Quality Control*[599] provides that consent is generally required for all genetic research using linkable samples, but consent is not generally required where samples are anonymous (referred to as 'de-identified' under the National Statement).[600]

7.27 A particular issue relating to the possible future regulation of human genetic databases involves the use of existing samples. The Association of Australian Medical Research Institutes (AAMRI) has noted that the Institutes and their affiliated hospitals hold many sample collections of tissue, cells or DNA from people, many of whom have died of serious diseases.[601] AAMRI states that:

> 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.
>
> It would be disastrous for research, as well as disrespectful to the donors to prevent research on such collections of samples or to insist on consent from relatives, many of whom may not even be aware of the circumstances of the donor or even that the donation occurred. In some cases, it would cause serious distress to living individuals, and bring no benefit to those who are deceased.[602]

7.28 AAMRI suggests that research should be allowed to continue on any historical collection of pathology samples provided that the individuals from whom the samples were collected cannot be identified, that the samples were collected in the course of diagnosis or treatment of a disease, and that approval from an HREC is obtained.

Question 7–1. In the specific context of human genetic databases, do federal, state and territory laws provide an adequate framework for protecting the privacy of human genetic samples and information? If not, why not, and how might the existing framework be improved?

599 Working Party of the Royal College of Pathologists and the Institute of Biomedical Science, *Consensus Statement of Recommended Policies for Uses of Human Tissue in Research Education and Quality Control* (1999), Royal College of Pathologists, London.

600 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), NHMRC, Canberra, para 14.1–14.13.

601 Association of Australian Medical Research Institutes, *Submission G7*, 27 April 2001.

602 Ibid.

Question 7–2. With respect to genetic information held in human genetic databases, are the current guidelines in the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*, together with the guidelines under s 95 and s 95A of the *Privacy Act 1988* (Cth), adequate to protect privacy?

Human Tissue Acts

7.29 The donation of human tissues is regulated in all States and Territories by human tissue legislation (the Human Tissue Acts).[603] If samples are intended to be used for research purposes, the Human Tissue Acts may impose legal requirements on the way samples are collected. The Human Tissue Acts require written consent for the donation of certain types of tissue and are an important legal constraint upon the use of human tissue samples for research purposes,[604] including genetic research.

7.30 The Human Tissue Acts are largely uniform and deal with:

- the donation of tissue by living persons;
- donations of blood and semen;
- the removal of tissue after death;
- post-mortem examinations; and
- trading in human tissue.

7.31 In general terms, the Human Tissue Acts restrict the kinds of tissue that may be donated for transplantation, other therapeutic purposes, or for medical or scientific purposes, and impose requirements for written consent to some donations. Removal of tissue other than in accordance with the requirements of the Acts may be punished by fines and imprisonment.[605]

7.32 Adults may donate regenerative tissue (including blood) although, with the exception of blood, a written consent is required. Children may donate blood for medical research but not other forms of regenerative tissue. Adults may donate

603 *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).

604 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, 396.

605 eg in NSW by a maximum penalty of 40 penalty units (ie, $4,040) or imprisonment for 6 months or both: *Human Tissue Act 1983* (NSW) s 36.

non-regenerative tissue (for example, kidneys) for transplantation but not for research purposes. The Acts authorise the removal of tissue from a deceased person subject to the previously expressed wishes of the deceased and the current wishes of his or her next of kin.[606] The Acts also remove potential liability flowing from the removal and use of tissue provided that the statutory requirements are complied with, and impose a prohibition on trading in tissue.

7.33 However, the Human Tissue Acts do not provide a comprehensive framework for deciding whether a valid consent has been given for a donation. Most importantly for present purposes, tissue that is originally removed for therapeutic purposes is not covered by the Human Tissue Acts.[607]

7.34 As the most frequent reason for the removal of tissue and blood from a living person is for therapeutic treatment of the person, the legal and ethical issues concerning control of tissue removed for therapeutic purposes may be of particular significance to the privacy of genetic samples.

7.35 The Human Tissue Acts do not prohibit the removal of tissue in the course of medical or surgical treatment or the use of tissue so removed.[608] What use may be made of tissue removed for therapeutic purposes is left to the operation of the law generally. Roger Magnusson has observed that:

> It would follow, for example, that human tissue legislation imposes no requirement upon researchers to obtain patient consent as a precondition to using — in research — cancer cells removed during surgery, or liver tissue removed from transplant patients and retained by an organ transplant unit. Indeed, it is the very absence of consent provisions here that has facilitated the development of tissue banks by hospitals and research institutes.[609]

7.36 Under the Human Tissue Acts, researchers who collect samples solely for research are obliged to seek consent to that use. However, if they use samples already collected in the archives of a pathology laboratory or parts of samples

606 See 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, 396–397.

607 Ibid , 397–399. Other limitations of the Human Tissue Acts identified by Magnusson are that: (i) the sections of the Acts that authorise the donation of tissue by living donors do not apply to semen, ova and foetal tissue (however, in some States the use of semen and ova in medical research is regulated by separate legislation); (ii) it is not clear whether the Human Tissue Acts apply to the donation of tissue from aborted foetuses and dead neonates; (iii) the Human Tissue Acts do not appear to have any application to tissue samples from infants and developmentally disabled adults who are not capable of understanding and consenting to the removal of tissue.

608 *Human Tissue Act 1983* (NSW) s 34; *Transplantation and Anatomy Act 1979* (Qld) s 47; *Transplantation and Anatomy Act 1983* (SA) s 37; *Human Tissue Act 1985* (Tas) s 28; *Human Tissue Act 1982* (Vic) s 42; *Human Tissue and Transplant Act 1982* (WA) s 32; *Transplantation and Anatomy Act 1978* (ACT) s 46; *Human Tissue Transplant Act 1979* (NT) s 26.

609 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, 399.

removed for pathology, but stored in a human tissue bank, the Human Tissue Acts consent requirements could be avoided.[610]

7.37 The Australian Law Reform Commission's 1977 report *Human Tissue Transplants* (ALRC 7),[611] which led to the enactment of the Human Tissue Acts, did not elaborate on the rationale for excluding tissue removed for therapeutic purposes from the consent requirements in the draft legislation. However, the current uses of tissue samples in genetic research and bio–prospecting were not envisaged at the time the Human Tissue Acts were enacted.

> These days … human cells are used by biotechnology companies in the production of novel cell lines, and in conjunction with recombinant DNA and gene splicing techniques, to produce synthetic hormones and enzymes.[612]

7.38 In view of new genetic technology and the increasing commercialisation of human research, it may be appropriate to ask whether this aspect of the Human Tissue Acts should be revisited. The Acts may 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.

7.39 The *Human Tissue Act 1983* (NSW) is under review by the NSW Health Department. One issue being considered is what legal rights a person should have in human tissue lawfully removed from his or her body for therapeutic purposes.[613] Ownership of human tissue is discussed in more detail below.

Question 7–3. In practice, what privacy concerns are raised by the use or potential use for research purposes of samples stored in the archives of pathology laboratories or in human tissue banks? For example:

- Is there any evidence that samples stored in the archives of pathology laboratories or in human tissue banks are being used for research without the consent of the individuals concerned or without proper oversight by HRECs?

610 However, if the human tissue sample is linked to an individual and may be considered as personal information, the *Privacy Act 1988* (Cth) or state or territory privacy laws may apply. That is, for example, NPP 2.1(a) of the *Privacy Act 1988* (Cth) may require the individual's consent to the use of the sample for research or research approval under the *Privacy Act 1988* (Cth) s 95A guidelines.

611 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), Australian Government Printing Service, Canberra.

612 R Magnusson (1998), 25.

613 See NSW Health Department, *Review of the Human Tissue Act: Organ and Tissue Donation and Use and Post Mortem Examination* (1999), NSW Health, Sydney, 41.

- Should there be additional sanctions against the unauthorised use of samples in this way?

Question 7–4. Should the Human Tissue Acts be amended to regulate the collection and use of human tissue samples for genetic research and, if so, in what way? For example, should the Human Tissue Acts require researchers to obtain patient consent as a precondition to using human tissue samples originally removed for therapeutic purposes?

Ownership of genetic samples

7.40 The ownership of genetic samples is an important background issue and is referred to in the inquiry's terms of reference. As discussed above, 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.

7.41 The exercise of information privacy rights need not conflict with property rights that may exist in genetic samples or genetic information. For example, the fact that a pathology laboratory may 'own' a genetic sample or genetic information (such as a report of genetic sequencing) does not necessarily prevent an individual from exercising information privacy rights to control the use or disclosure of that information, at least where the information remains identifiable. However, property rights involve broader rights of control than information privacy rights — for example, an owner may sell or commercially exploit genetic samples or information.

7.42 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 or hospital.[614] Historically, like dead bodies, human tissue samples were not regarded by the law as capable of becoming the 'property' of a person.[615] The Commission concluded that there was 'no reason to endow such tissue with the

614 Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (1977), Australian Government Printing Service, Canberra, para 13.

615 R Atherton, 'Claims on the Deceased: The Corpse as Property' (2000) 7 *Journal of Law and Medicine* 361.

attributes of property'. However, the 'no property' view has been criticised as creating a legal vacuum inappropriate to an age of biotechnology.[616]

> If the no "property view" were applied strictly by courts today, it would mean that neither patients, researchers nor research institutes would have a legal right to enforce their possession of human tissue samples … There is growing support for the view that courts will regard anatomical specimens as "property" where they have been "differentiated" from cadaveric specimens by the lawful exercise of work and skill. A wider and more suitable principle is that courts should embrace a property analysis at least in order to enforce possession of human tissue samples for socially worthwhile purposes, including medical research.[617]

7.43 A recent decision in the Supreme Court of Western Australia held that a surgical tissue sample held by a pathology laboratory was 'property'.[618] At issue was whether the Court could make an order for a deceased's tissue sample to be used for DNA testing to establish whether the plaintiff was the natural daughter of the deceased. In the decision Sanderson M referred to ALRC 7 and noted that:

> This report was completed 23 years ago. It makes no mention of DNA at all, let alone DNA testing. The world has moved on. This may be the first time that an application has been made allowing for testing of tissue held by a laboratory, but it is unlikely to be the last.[619]

7.44 Sanderson M concluded that it was proper to hold that the human tissue was property. There were compelling reasons, on the facts of the case, for holding the tissue samples to be property[620] and, in the wider sense, it would defy reason to not regard tissue samples as property.[621]

7.45 Property rights are a possible mechanism to protect the privacy of genetic samples and information. For example, s 104(a) of the model US Genetic Privacy Act (GPA) provided that 'an individually identifiable DNA sample is the property of the sample source'.[622] The authors of the GPA explained that:

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616 See eg R Magnusson (1998), 25–62; 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; R Atherton, 'Claims on the Deceased: The Corpse as Property' (2000) 7 *Journal of Law and Medicine* 361.

617 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.

618 *Roche v Douglas* [2000] 22 WAR 331 (Sanderson M). It was not necessary for the decision of the Court to determine whose property it was: 339.

619 Ibid, 338.

620 Testing would resolve paternity (a necessary element of the plaintiff's claim) and result in considerable savings in time and cost: Ibid, 338.

621 Ibid, 338–39.

622 G Annas, L Glantz and P Roche, *The Genetic Privacy Act and Commentary*, Oak Ridge National Laboratory, <http://www.ornl.gov/hgmis/resource/privacy>, 30 June 2001. A version of this model Act entitled the *Genetic Privacy and Non–discrimination Act of 1995* was introduced into the US Congress. However, this proposed legislation did not assign ownership of genetic information or DNA samples to anyone. See also Chapter 2 regarding the Australian Genetic Privacy and Non–discrimination Bill 1998.

> By establishing an individually identifiable sample as the property of the sample source, the GPA not only serves 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 DNA sample allows transfer of control in accordance with property law principles.[623]

7.46 In Australia, the Genetic Privacy and Non-discrimination Bill 1998 (Cth) was based in part on the GPA.[624] The Bill did not directly provide that individuals own their genetic material. However, it required individuals' authorisation for the commercial use of their genetic samples and that the form of authorisation must permit the individual to either waive or contract to receive economic benefits.[625] These provisions were intended to create 'a balance between the interest of complete ownership and promoting the opportunity of researchers to derive a commercial benefit from their endeavours'.[626]

7.47 The recognition or creation of donor property rights might allow donors to negotiate with researchers for the use of their genetic samples and contract to share in any resulting commercial benefits. Such property rights need not amount to full legal 'ownership'. Donor property rights in human tissue might be seen as creating an undesirable barrier to the conduct of medical research. On the other hand they may produce an incentive for people to participate in medical research[627] and have been suggested in the US as a means to remove some of the legal uncertainty resulting from cases involving legal ownership of human tissue used in medical research.[628]

Question 7–5. Should individuals have a form of property right (which need not amount to full 'ownership') in their own genetic material, in order to be able to better protect the privacy of this material? If so, how should such a right be defined and recognised?

623 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.

624 See 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, 38.

625 Genetic Privacy and Non-discrimination Bill 1998 (Cth), cl 16(1)(f). See also rights to order that samples or records be returned or destroyed: eg cl 14(b), cl 23(1), cl 15(f).

626 Commonwealth of Australia, *Parliamentary Debates*, Senate, 1 September 2000, 838 (Senator Stott Despoja), 840.

627 M Lin, 'Conferring a Federal Property Right in Genetic Material: Stepping into the Future With the Genetic Privacy Act' (1996) 22(1) *American Journal of Law and Medicine* 109, 133–34.

628 ie *Moore v Regents of the University of California, 793 P 2d 479 (1990)* and subsequent cases referred to in M Lin, 'Conferring a Federal Property Right in Genetic Material: Stepping into the Future With the Genetic Privacy Act' (1996) 22(1) *American Journal of Law and Medicine* 109.

8. Medical practitioners

Contents

Introduction

8.1 As genetic medicine develops, medical practitioners increasingly provide health services to individuals and families in connection with existing or predicted conditions that may have a genetic component. Medical practitioners provide advice on diagnostic and treatment options for genetic conditions, facilitate access to genetic testing, and provide advice and counselling on the implications and results of genetic tests.

8.2 As part of this role, medical practitioners collect genetic information and play a critical role as ‘gatekeepers’ of genetic information. At present, access to

genetic testing is almost exclusively through consultation with a medical practitioner.

8.3 Medical practitioners play a central role in deciding whether genetic testing is needed and the value of the possible results and therefore in determining whether tests are conducted and the relevant costs incurred. They collect and store genetic information and decide when and how genetic information should be used or disclosed and for what purposes.

8.4 This chapter will consider the existing regulatory framework that relates to how medical practitioners handle genetic information. This framework includes legislation, common law, guidelines and professional ethics.

The regulatory framework

8.5 The legal and voluntary systems that influence the conduct of medical practitioners are complex and interdependent. The elements of this framework include:

- medical educational requirements;
- professional registration authorities;
- health care complaints bodies;
- common law obligations;
- National Health and Medical Research Council (NHMRC) guidelines; and
- professional ethical obligations.

8.6 Undue emphasis on any one element can ignore the impact of others. The following is an overview of the components, some of which are discussed in more detail in later parts of this chapter.

Medical educational requirements

8.7 There are four phases through which professional medical education normally proceeds. The initial phase requires a degree from an Australian or New Zealand medical school accredited by the Australian Medical Council or, if educated elsewhere, a certificate from the Council. Following that initial education, medical graduates need to undertake pre-registration training in a hospital in a training program that is accredited with the state registration board. The third phase involves enrolment in a vocational training program conducted by one of the recognised specialist colleges, for example family practice, obstetrics, internal

medicine, radiology and so on. With the exception of general practice, these programs are also conducted in hospitals. The fourth phase comprises continuing medical education (CME) now required by the specialist colleges.

8.8 The Australian Medical Council was established in 1986 by Commonwealth, state and territory health ministers and accredits Australian medical schools and assesses overseas medical practitioners. The accreditation process can be important in promoting uniformity in standards and maintaining relevance in medical education to advancing science.

8.9 The specialist colleges are voluntary, self-governing bodies that follow a system developed in the United Kingdom. They provide education and supervised training for trainee specialists and conduct examinations prior to awarding fellowship (or membership) as well as continuing education programs. They are not established or regulated by legislation, although some States include specialist registration on the statutory register. A recognised specialist qualification is a prerequisite for patients of these professionals to recover the higher specialist rebate under the Medicare system.

8.10 The accreditation role of the Australian Medical Council and the training role of the specialist colleges could be important elements in any revision of existing regulatory frameworks to ensure genetic information is adequately protected in the course of medical professional practice.

Professional registration authorities

8.11 All Australian States and Territories have legislation regulating the medical profession.[629] These Acts establish registration boards typically comprised of government and professional appointees. The functions of registration boards include:

- setting the standards for education, admission and professional practice;
- conducting inquiries into complaints about the conduct of professionals;
- conducting, or referring to special tribunals, hearings to consider allegations of professional misconduct;
- determining, or having a specialist tribunal determine, responses to proven allegations of misconduct; and
- conducting research into the profession.

629 *Medical Act 1894* (WA); *Medical Practitioners Act 1930* (ACT); *Medical Practice Act 1992* (NSW); *Medical Act 1995* (NT); *Medical Act 1939* (Qld); *Medical Practitioners Act 1983* (SA); *Medical Practitioners Registration Act 1996* (Tas); *Medical Practice Act 1994* (Vic).

8.12 Boards maintain a register of those medical practitioners who have qualified for registration, either generally or for temporary purposes or on a provisional basis, for example, until further training or supervised practice is completed. Registration is usually renewed on an annual basis on continuing satisfaction of qualifications and payment of a fee. In addition to educational and experience qualifications it is common for applicants to establish that they are of 'good character'.

8.13 Medical practitioners who seek to qualify as specialists will need to satisfy the requirements of Specialist Recognition Advisory Committees, established under the *Health Insurance Act 1973* (Cth) — the legislation that establishes and is responsible for Australia's system of medical benefit payments for medical services (Medicare). Membership of the relevant Australian college of medical specialisation also will be relevant. However, not all state and territory registers include details of specialist qualification.

8.14 During the early 1990s the Commonwealth and all States and Territories passed mutual recognition legislation[630] that has the effect of allowing medical practitioners registered in one State or Territory to gain admission to practise in another simply by giving notice, including evidence of registration and the absence of restrictions or conditions, and paying the prescribed fee.

8.15 The function of registration boards to conduct inquiries into allegations about sub-standard conduct of professionals does not have the aim of punishment, or compensation to any citizens affected by the conduct. Rather, the primary intention of these processes is the protection of the public interest and the maintenance of the standards of the profession.

8.16 Although the wording of the legislation varies, the typical grounds for disciplinary action are:

- suspected mental or physical incapacity;
- professional misconduct;
- alcohol or drug addiction;
- ceasing to hold or having qualifications withdrawn;

630 *Mutual Recognition Act 1992* (Cth); *Mutual Recognition (Australian Capital Territory) Act 1992* (ACT); *Mutual Recognition (New South Wales) Act 1992* (NSW); *Mutual Recognition (Northern Territory) Act 1992* (NT); *Mutual Recognition (Queensland) Act 1992* (Qld); *Mutual Recognition (South Australia) Act 1993* (SA); *Mutual Recognition (Tasmania) Act 1993* (Tas); *Mutual Recognition (Victoria) Act 1998* (Vic); *Mutual Recognition (Western Australia) Act 1995* (WA).

- conviction for a serious offence;
- committing an offence against registration legislation;
- making a false statement to gain registration; and
- failing to comply with a lawful requirement of the registration board.

8.17 The boards or tribunals designated to perform the professional disciplinary task usually have a wide range of disciplinary actions available. These include:

- reprimand;
- suspension from practice for a period of time;
- cancellation of registration;
- fines;
- requiring undertakings; and
- directed retraining or counselling.

8.18 These disciplinary provisions form a significant part of the regulatory framework relating to the protection of genetic information handled by medical practitioners. For example, the disclosure of genetic information in a manner contrary to the accepted standards of the medical profession may lead to disciplinary action being taken against the practitioner.

Health care complaints bodies

8.19 All Australian States and Territories (except South Australia) have established statutory commissions to deal with complaints about the provision of health care by medical practitioners among a wide range of other providers.[631] These commissions typically have the following powers and functions:

- investigation and resolution of complaints, including those not amenable to conciliation or that are serious;

631 *Health Care Complaints Act 1993* (NSW); *Health and Community Services Complaints Act 1998* (NT); *Health Rights Commission Act 1991* (Qld); *Health Complaints Act 1995* (Tas); *Health Services (Conciliation and Review) Act 1995* (WA); *Health Services (Conciliation and Review) Act 1987* (Vic); *Community and Health Services Complaints Act 1997* (ACT).

- publication of information and education about the operation of the legislation;
- inquiries into issues in relation to the provision of health services and causes of complaints;
- advice to the relevant minister;
- powers to examine witnesses;
- powers to secure the production of documents and information;
- protection from reprisal against those involved in complaints; and
- immunity from legal action for making a complaint, statement or report for the function of the legislation.

8.20 Where conciliation is not appropriate or there are serious allegations involving professional misconduct there are often powers to investigate and refer matters to the state or territory registration boards for possible disciplinary action.

8.21 The availability of these alternative means for addressing complaints provides an accessible means for patients to address matters of difference in their relationships with medical practitioners and provides a mechanism by which complaints may be made about inappropriate use or disclosure of genetic information.

The common law

8.22 The relationship between medical practitioners and their patients has long been recognised as giving rise to important legal obligations. Of these, particularly relevant are the obligations to take reasonable care in the provision of advice, diagnosis and treatment and to observe confidentiality in relation to information provided by patients.

8.23 The fact that these duties have origins in general legal principles means that they are enforceable by legal action in courts, and remedies can be granted for their breach in situations where all of the necessary elements are established. Although this means of enforcement may loom large in the apprehension of medical practitioners, it is important to remember that non-fulfilment of these duties also may be the cause of complaints to a health care complaints commission or to a registration board.

NHRMC guidelines

8.24 Guidelines relevant to the collection, use and disclosure of genetic information on genetic registers have been issued by the NHMRC.[632] These guidelines are not themselves enforceable but may be influential in professional practice and peer recognition. Further, in the enforcement of common law duties such as that to exercise reasonable care, these guidelines may be relevant as evidence of the appropriate standard of care.

Professional ethics

8.25 The medical profession has a long tradition of self–regulation that was based on the expression of common values and ethical obligations to patients. Dating from as early as the Hippocratic oath in early Greece, these commitments remain influential in professional conduct and peer acceptance within the profession. The content of these codes will usually closely parallel that of the common law duties and will be relevant to professional disciplinary action in those States and Territories whose legislation includes unethical conduct within the meaning of unprofessional conduct.

8.26 How can ethics, by its principles and values, achieve good conduct in the provision of health care or research? The history of health professions can be used to show how ethical standards are adopted and observed. However, that same history can be used to show the contrary. That is, that the adoption by a profession of ethical principles and values has not, of itself, prevented individual members from failing to conform to those same principles and values. Similarly, the expression of some ethical principles in statutory regulatory systems can be used to show both compliant and non-compliant behaviour.

8.27 Ethics function to engender conforming behaviour through education and internalisation of principles and values and through peer influence. It remains an important influence on professional conduct, whether or not it is mirrored in regulatory frameworks that have the force of law.

8.28 Typical of the obligations of professional ethics are those of:

- maintaining the confidentiality of personal information about patients;
- giving highest priority to patients' interests; and
- avoiding conflicts of personal interests with personal duty and honesty.

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

Genetic counsellors

8.29 Genetic counselling is a communication process which involves making or discussing a diagnosis, providing accurate information about the disorder, presenting options available to the client and considering the impact the information has on clients and their families.[633] 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 allied health worker, as appropriate.

8.30 Genetic counselling itself is a relatively new discipline in Australia — the first genetic counsellor received certification from the Human Genetics Society of Australasia (HGSA) in 1991. Genetic counsellors have tertiary qualifications in a variety of fields, for example, nursing, science, psychology, social work and education. Certification as an associate genetic counsellor requires a post-graduate qualification in both genetics and counselling. Certification as an HGSA certified genetic counsellor requires two years full-time equivalent supervised practice.

8.31 In September 1999, the HGSA issued *Guidelines for the Practice of Genetic Counselling*.[634] Many genetic counsellors are members of the Australasian Society of Genetic Counsellors (ASGC), a group of the HGSA. The ASGC has issued a Code of Ethics, which deals with matters including genetic counsellors' obligations of confidentiality. There are no formal sanctions for breach. 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.

Summary

8.32 This brief outline of the elements in the existing regulatory framework of medical practitioners shows their complex and interdependent processes and principles. Recommendations for change will need to take careful account of all of the elements and the efficacy of their interaction.

Collection of genetic information

8.33 Medical practitioners may collect genetic information from many sources. This may be family history information or information derived from genetic registers or from genetic testing. Information may be collected from or in connection with:

633 See K Barlow-Stewart, 'New Genetics: Benefits and Burdens for Families' (2001) 79 *Reform*.

634 Human Genetics Society of Australasia, *Guidelines for the Practice of Genetic Counselling*, Human Genetics Society of Australasia, <http://www.hgsa.com.au>, 1 September 1999.

- patients who have experienced symptoms and who are aware that similar conditions have been experienced in previous generations of their families;
- patients who have no such symptoms but who know, through the existence of a genetic register, their family history of a disorder or illness that is now known or suspected to have genetic components;
- patients contemplating reproduction who seek testing to establish their respective carrier states for any genetic conditions that, when combined with that of their partner, may involve a risk that any children will be affected by a disorder; and
- individuals who have produced an embryo by in vitro fertilisation and who are anxious to establish whether the embryo has any diagnosable genetic condition that might be deleterious.

8.34 Where medical practitioners collect genetic information in the form of patients' family histories they generally do this in the same way that they collect other health information from patients — directly, with implied consent and on the understanding that the information is subject to confidentiality obligations. The use of genetic registers and genetic testing may raise additional considerations.

Genetic registers

8.35 The purpose of genetic registers is to operate as an effective way of identifying members of families who are at significantly increased risk of developing an inherited disorder or of having affected children.[635] The information on the register can include genetic information about many genetically related people and may also contain tissue samples. It can ensure that family members have an opportunity to become aware of their risk and have access to genetic counselling. The register can facilitate clinical diagnosis (including prenatal diagnosis, pre-symptomatic diagnosis and carrier detection). Genetic registers may also be used for research purposes.

8.36 The NHMRC has issued *Guidelines for Genetic Registers and Associated Use of Genetic Material*.[636] These 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. 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.

635 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 7.
636 Ibid.

8.37 Where medical practitioners are or become the keepers of such a register, the guidelines direct their attention to the need for an advisory committee, written guidelines addressing privacy, confidentiality and cultural sensitivity and the need for definition of staff roles.[637] The guidelines deal in detail with consent to inclusion of genetic information on a register. They list the information to be provided to a person before they choose to participate:

- that participation is voluntary;
- 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.[638]

8.38 There are detailed provisions relating to consent from other related persons to an initial registrant and consent in relation to deceased persons,[639] the protection of confidentiality[640] and contacting other family members.[641]

8.39 The guidelines recognise that medical practitioners responsible for a genetic register have duties at law to gain consent and to protect the confidentiality of the information contained on the register. They provide a detailed guide on compliance with those duties.

637 Ibid, 11–12.
638 Ibid, 17–19.
639 Ibid, 20–22.
640 Ibid, 23–27.
641 Ibid, 29–32.

8.40 As discussed in Chapter 9, the collection, use and disclosure of genetic information on genetic registers may be subject to general information privacy legislation or specific health information privacy legislation.

Genetic testing

8.41 A list of genetic disorders for which there are established tests appears in Chapter 2. It can be assumed that this list will expand rapidly as genetic research links further disorders or susceptibility to them to identifiable and testable genes.

8.42 It seems likely that medical practitioners will continue to have a vital role in counselling, advising about the taking of tests and interpreting results. The typical pathway for a genetic test (see Table 8–1) shows this role as well as indicating the links to the other uses of genetic tests results.

Ethical guidelines

8.43 In 2000, the NHMRC issued *Ethical Aspects of Human Genetic Testing: An Information Paper*.[642] The paper does not set out guidelines and is not capable of being enforced. However, some of the information is of value, particularly the categorisation of genetic tests and advice about consent for testing, privacy and confidentiality of results. The categorisation of tests shows how different information may affect different people and thus the scope of relevant common law duties of confidentiality. The detailed advice about information to be provided before consent to testing is sought will also assist in fulfilling the common law duty to exercise reasonable care in providing information and advice.

8.44 The paper identifies the different types of genetic test based on the reasons a test is being sought. These include diagnostic tests, pre-symptomatic or predictive tests; susceptibility tests; carrier tests; prenatal tests; pre-implantation tests and screening tests (see Chapter 2).

8.45 The paper notes the importance of establishing the reasons that a person has sought a test, his or her level of understanding of what information that test can provide and the need for time to consider all the implications. Counselling will be important prior to all tests even before the process of providing full information commences. The paper contains an extended description of the information to be provided, the recommended process to be followed and some advice about situations of disagreement.[643]

642 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra.
643 Ibid, 32–44.

8.46 Informing patients about the consequences of undergoing genetic tests could be equated with the obligations of medical practitioners to inform patients of material risks of proposed treatment before they choose whether to undergo it.[644] This is a specific application of the general common law duty to exercise reasonable care noted above, but relates to the information that should be given in seeking consent. A risk is material if:

> in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.[645]

8.47 In the context of genetic testing, the application of this test may prove complex. Known family history may well suggest that certain results of genetic tests will be material in the sense used in the quotation. However, the question whether the 'risks' can include the emotional impact of discovering tests results will need to be determined.

8.48 The roles of medical practitioners, however well guided, will call for increasing knowledge of genetic contributions to disorders, the availability of tests and skill in providing counselling relating to genetic tests.

8.49 Community knowledge may not be as well informed and may promote an ill founded belief in the amount and value of knowledge to be gained from tests, confronting medical practitioners with potential conflicts between patients' desires, their understanding, the limits of what can be learned by testing, the impact on other family members and the need to preserve limited financial resources. These developments are characteristic of the application of new scientific knowledge into the practice of health care.

Question 8–1. Is there a need to educate health professionals better about ethical principles involved in genetic testing and information? Should medical practitioners be required to undergo specific training before being able to order genetic testing or interpret the results for patients?

Over the counter and mail order testing

8.50 A related issue concerns the development and availability of over the counter genetic test kits and mail order genetic testing. As discussed in Chapter 14, concerns have been raised in Australia about ethical and privacy issues related to the availability of mail order paternity testing by private laboratories (see Chapter 14).

644 *Rogers v Whitaker* (1992) 175 CLR 479.
645 Ibid, 634.

8.51 For ethical reasons, it is important that all persons undergoing testing provide their informed consent to genetic testing. If genetic testing may be conducted, for example, from hair follicles alone, it may be possible to collect samples without the knowledge or consent of the individual being tested. Access to proper post-test counselling upon receipt of the results also needs to be ensured as does a proper chain of custody of the test samples, from collection through to analysis, and to ensure generally that test results are as accurate as possible. These concerns may be addressed by accredited laboratories, but may not be addressed as well by others.

8.52 These concerns may become more important if more types of testing become available over the counter, at pharmacies, or via the internet. Genetic testing kits have become available in other countries, such as the Netherlands, for testing, among other things, for the presence of the most common mutations for cystic fibrosis.

8.53 It is to be expected that, as the technology progresses, the development of easy to use DIY tests will rapidly become technically feasible for more and more disorders. This development, in conjunction with non-professional information, use and counselling may entail significant risks to the health of users (and possibly their families).

Question 8–2. Should the public availability of genetic testing be regulated so that it may be conducted only on the request of a medical practitioner and by an accredited laboratory?

Access to genetic information

8.54 As discussed in Chapter 4, from 21 December 2001, National Privacy Principle 6 of the federal *Privacy Act* will provide individuals with a right to access genetic and other health information and to correct it if it is not accurate, complete and up-to-date. The principle provides for some limited circumstances in which health providers may withhold genetic and other health information, including where providing access would:

- pose a serious threat to the life or health of any individual;
- have an unreasonable impact upon the privacy of other individuals; or

- be unlawful or prejudice various law enforcement interests.[646]

8.55 This provision will have a significant effect on existing legal standards in relation to access to medical records. The High Court of Australia in *Breen v Williams*,[647] confirmed that medical practitioners have a proprietary right in the records that they create and that patients had no common law right of access to these records. However, where records contain documents that arise from the practitioner acting as agent of the patient, as in the case of an X-ray result or a pathology test (including a genetic test), these may be the property of the patient.

8.56 Therefore, while patients may have had rights to obtain access to the results of genetic tests conducted by a laboratory, they had no right to access genetic information in the form of family histories recorded by a medical practitioner.

8.57 The operation of NPP 6 may have rendered this distinction academic. However, there may still be difficult decisions for a medical practitioner to make in relation to test results or family histories because of the effect that these may have on the privacy of family members. The meaning of such histories may have an increased significance when the results of new genetic tests are added.

Question 8–3. Do medical practitioners require more guidance on the rights of individuals to obtain access to genetic information held in medical records (for example, on the application of National Privacy Principle 6 of the federal *Privacy Act*)?

Storage of genetic information

8.58 Medical practitioners' obligations with regard to the storage of genetic information will depend on the kind of information and the way that it has been obtained. For instance, if it is contained on a genetic register, there will be specific protocols for its secure storage.[648] Where the genetic information comprises family histories that have accumulated over generations, they will be stored as any other record kept by a medical practitioner. As the attached pathway for genetic tests shows, it will be usual for medical practitioners to retain the records of genetic tests.

646 *Privacy Act 1988* (Cth) NPP 6.1.
647 *Breen v Williams* (1996) 186 CLR 71.
648 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 33–34.

8.59 Increasingly, the statutory protection of privacy is likely to be the source of standards of security for medical records containing genetic information.[649] The increasing reliance on electronic health records is also relevant to storage and data security issues.

8.60 The duties of medical practitioners in relation to storage and security of medical records with genetic information may be affected by the corporatisation of medical practices. The legal effect of such incorporation may be that it is the corporation (and not any of the individual medical practitioners), which is the owner of the genetic information held by the practice.[650]

Question 8–4. What practical implications does the corporatisation of medical practice have in relation to patients' abilities to control the collection, storage, use and disclosure of information about them? For example, how are the duties of medical practitioners under the federal *Privacy Act* affected where personal ownership of medical records is replaced by ownership by a corporation (of which the medical practitioner may be a director and shareholder)?

Use and disclosure of genetic information

8.61 The use and disclosure of genetic information by medical practitioners is regulated by legislation, including the federal *Privacy Act*, common law, guidelines and professional ethics.

8.62 The following material focuses on the important common law duties to exercise reasonable care and to protect the confidentiality of patient information. These duties reflect long established conceptions of the ethical and professional responsibilities of medical practitioners.

8.63 Conduct that offends either duty may be the basis of a complaint either to a health care complaints body or a professional registration authority.[651] Those agencies will exercise their powers to fulfil their statutory goals and functions, namely, the resolution of complaints and disputes or the public interest in receiving good quality health care.

649 eg *Privacy Act 1988* (Cth) NPP 4.

650 *Health Services for Men Pty Ltd v D'Souza* (2000) 48 NSWLR 448.

651 Depending on the circumstances, breaches of medical confidentiality may also constitute a breach of the federal *Privacy Act* and constitute grounds for a complaint to the Federal Privacy Commissioner, or under other state and territory privacy legislation.

8.64 Civil litigation, based on these common law duties, focuses on the interests of the individual patient, rather than on any broader public interest concerns. Litigation is generally aimed at providing compensation for harm alleged to have been suffered as a result of a failure to exercise reasonable care, an order restraining a breach of confidentiality or, less commonly, compensation for harm suffered by reason of the breach of confidentiality.

Duty of care in medical treatment

8.65 Medical practitioners have long been held to owe to their patients duties to exercise reasonable care in the conduct of their professional care. The duty is regarded as requiring that reasonable care be taken in all phases of the relationship, whether advice, diagnosis or treatment.[652]

8.66 In the present context, the most likely situations to arise are those in which a medical practitioner is asked to advise a patient concerning the effect on him or her of existing genetic information (of any kind) or the considerations relevant to a prospective genetic test. It may also be important to consider to what extent a medical practitioner owes any duty to take reasonable care in relation to genetic information to a person related to a patient, but who is not a patient. In the current situation, genetic tests themselves are likely to be performed by pathology laboratories and not by medical practitioners. Accordingly, the exercise of duty to take reasonable care in performing such tests is not discussed in this chapter.

8.67 Such a duty of care is one of the essential components of what is commonly referred to as a negligence claim. Where the defendant in such a claim is a professional, it also may be called a claim for professional malpractice. Either way, the claimant will be successful only if he or she can establish all of the following:

- that the defendant owed the claimant a duty to exercise reasonable care;
- that the defendant failed to exercise reasonable care to an appropriate standard;
- that the claimant suffered harm; and
- that the harm was caused by the defendant's failure to exercise reasonable care.

8.68 Some explanation follows on each of these elements.

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652 *Rogers v Whitaker* (1992) 175 CLR 479.

8.69 A duty to exercise reasonable care arises in a relationship in which a person should realise that if he or she does not take reasonable care in his or her conduct, harm may be caused to the other person in that relationship. Such relationships are of infinite variety and are characterised by two essential elements: proximity and reasonable foreseeability. The relationship must have a sufficient degree of proximity: a requirement that can be satisfied by a simple physical proximity, the closeness in space or time between the parties; circumstantial proximity, the extension of physical proximity to others closely emotionally related to the events, or causal proximity, or the closeness or directness of the relationship between an act and injury. Examples of what has been held to amount to a proximate relationship are those between a car driver who injured a man and that man's emotionally shocked wife;[653] and a medical practitioner and a nearby child, not his patient, in need of urgent treatment.[654] There would be little doubt that such a relationship exists between a medical practitioner and his or her patient. There might also exist such a relationship between a medical practitioner and a family member of a patient known to the medical practitioner to have, or be at risk of having, a genetic disorder that could lead to impairment if remedial treatment was not advised and undertaken.

8.70 The requirement of reasonable foreseeability is satisfied if the harm foreseen is probable (if reasonable care is not taken) and not merely possible or conceivable. Further, what is to be foreseen does not need to be the precise harm that eventuated but the general nature of that harm, for example the foreseeability of some harm to the brain was sufficient even if the precise harm, a rupture of cerebral artery, was not.[655]

8.71 Whether a duty to take reasonable care arises in a given relationship is a matter of law to be determined by a court, usually when resolving a claim for compensation for harm. Whether a duty is found is to some extent a matter of judgment — whether in the relationship at hand a duty of care *should* be found. Thus, although there is little doubt that such a duty arises between a medical practitioner and a patient, there cannot be a definitive conclusion as to relationships with family members genetically related to that patient. The details of the circumstances will be relevant. The finding that there is a duty to a patient's partner to warn the patient of the risk of a serious infectious disease suggest that similar duties may be asserted in favour of genetically related family members at risk of treatable conditions.[656]

8.72 Clarification of the application of these common law duties to disclosure of genetic information will follow contested and decided cases. As noted above, for such a claim to be mounted, let alone be successful, there will need to be sufficient

653 *Jaensch v Coffey* (1984) 155 CLR 549.
654 *Lowns v Woods* [1996] Aust Torts Reports ¶81–376.
655 *Richards v State of Victoria* [1969] VR 136.
656 *BT v Oei* (Unreported, Supreme Court of NSW, Bell J, 5 November 1999).

evidence of the other two essential elements, namely, harm and causation. Harm for which compensation can be awarded does include recognised psychiatric illnesses flowing from exposure to traumatic events[657] or of close relatives on hearing news of them.[658] Emotional reactions of stress or shock that are immediate emotional responses to a distressing experience have not been recognised as a ground for compensation. The effect of learning of some genetic disorders, especially those single gene dominant disorders, such as Huntington's disease, that have severe and inevitable effects for which there is no cure may lead to psychiatric conditions for which compensation would be awarded. The development of psychiatric classifications such as post–traumatic stress disorder may also increase these possibilities.[659]

8.73 Causation is the other essential element for a claim to enforce the common duty to exercise reasonable care. Often a difficult issue in cases involving medical treatment, it may not prove as complex where the event leading to the alleged harm is disclosure of genetic information. Indirect discovery of disclosed information may add complications, although there is authority that where a medical practitioner should have known that information concerning a patient's mental state released to her husband would be likely to become known to her, liability followed when she suffered from her discovery of the report.[660]

Duties of confidentiality

8.74 It has long been recognised that medical practitioners owe their patients a common law duty to maintain confidential information provided by that patient. In general terms, the duty is not to use the information provided by a patient for purposes other than those for which it was provided. Accordingly, where information is provided for the purpose of medical treatment, its use to obtain specialist advice or genetic tests will not normally involve a breach of the duty.

8.75 Duties of confidentiality may also arise as a term of the contractual relationship between medical practitioner and patient[661] or as an incident of the fiduciary character of that relationship.[662] Similar duties can be imposed directly by legislation governing the use of medical information in publicly funded health services,[663] or by the application of statutory disciplinary standards of unethical

657 *Mt Isa Mines Ltd v Pusey* (1970) 125 CLR 383.

658 *Jaensch v Coffey* (1984) 155 CLR 549; *Petrie v Dowling* (1992) 1 Qd R 284; *Harrington v Macquarie Pathology Services Pty Ltd (No 3)* [1998] Aust Torts Reports ¶81–489.

659 I Freckelton, 'Post Traumatic Stress Disorder: A Challenge for Public and Private Health' (1998) 5 *Journal of Law and Medicine* 252.

660 *Furniss v Fitchett* [1958] NZLR 396.

661 *Parry-Jones v Law Society* [1969] 1 Ch 1.

662 *Breen v Williams* (1996) 186 CLR 71, 81 (per Brennan CJ).

663 *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).

conduct.[664] Duties of confidentiality are also expressed in codes of professional ethics.

8.76 The common law duty of confidentiality is subject to exceptions. These permit disclosure of the information in ways that would otherwise infringe the duty. The most relevant exception is where a patient consents to the disclosure. It is to the patient that the duty is owed and so he or she can choose to permit information to be released. However, in the potentially sensitive climate of genetic information within a family, there may be heightened obligations for a medical practitioner to be satisfied that such a patient is aware of the risks of that disclosure.

8.77 The second exception is where there is lawful obligation to disclose information. This is regularly exercised in the compulsory disclosure of certain notifiable or infectious 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 confidentiality does not generally give a medical practitioner a justification for refusing to disclose such information. In the Northern Territory, Victoria and Tasmania, there are limited privileges in some types of proceedings.

8.78 The third exception permits the release of confidential information where to do so is in the public interest. This will be satisfied where there is a clear public interest in knowing of the dangerous propensity of a person who may be released from custody.[665]

8.79 There have been situations involving predictable risks of significant harm to identified individuals. In California, it has been held that medical practitioners have a duty to warn those people, even if doing so would infringe the duty of confidentiality.[666] There is no legal authority for the same extent of such a duty in Australia. As noted above, it has been held that there is a duty of care owed to a patient's partner to exercise reasonable care in advising the patient to warn the partner of the risk of infection carried by the patient.[667] 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'.[668]

664 *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513.
665 *W v Edgell* [1990] 1 All ER 835.
666 *Tarasoff v Regents of University of California*, 551 P2d 334 (1976).
667 *BT v Oei* (Unreported, Supreme Court of NSW, Bell J, 5 November 1999).
668 Australian Medical Association (NSW), *Code of Ethics*, (1996) AMA, para 1.3.4.

Example 8–1. Although it is not the intention of such procedures, genetic testing for medical or research purposes also may serve to identify parentage. If parentage has been misattributed (eg, in cases of non-paternity, donated ova, adoption) this creates an ethical dilemma for the medical practitioner or researcher — namely, whether or not to inform the child and the 'parents' of the results. This raises important questions about the ownership of the information (ie, whether members of the family have a right to be informed of an individual's test results where they are affected), doctor-patient confidentiality, and post-test counselling.

Enforcing compliance with duties of confidentiality

8.80 The common law duty of confidentiality is rarely enforced by court proceedings. Other elements of the regulatory framework tend to be more important than civil litigation in ensuring compliance with duties of confidentiality, such as statutory provisions for discipline of medical practitioners and the obligations contained in privacy legislation.

8.81 The state and territory regulatory legislation varies in the language used to define unsatisfactory professional conduct that may lead to disciplinary action. Nevertheless, the language used may be broad enough to be relevant to a range of conduct involving the use and disclosure of genetic information. For example, state and territory health registration legislation commonly defines 'unsatisfactory professional conduct' as including any 'improper or unethical conduct in the practice of medicine'.[669] Registration boards or tribunals generally determine unsatisfactory professional conduct by reference to standards commonly accepted by the medical profession.

Conclusion

8.82 There may be increasing commercial and other incentives for medical practitioners to use genetic and other health information for purposes other than for which the information was originally provided.

8.83 These incentives may include those arising from the corporatisation of medical practice — which may mean that medical practitioners face pressures to fully exploit the assets of a medical practice, including the genetic and other health information it controls. The commercialisation of medical research may provide financial incentives to share clinical information with pharmaceutical or other organisations involved in medical research. Genetic information is an increasingly valuable commodity.

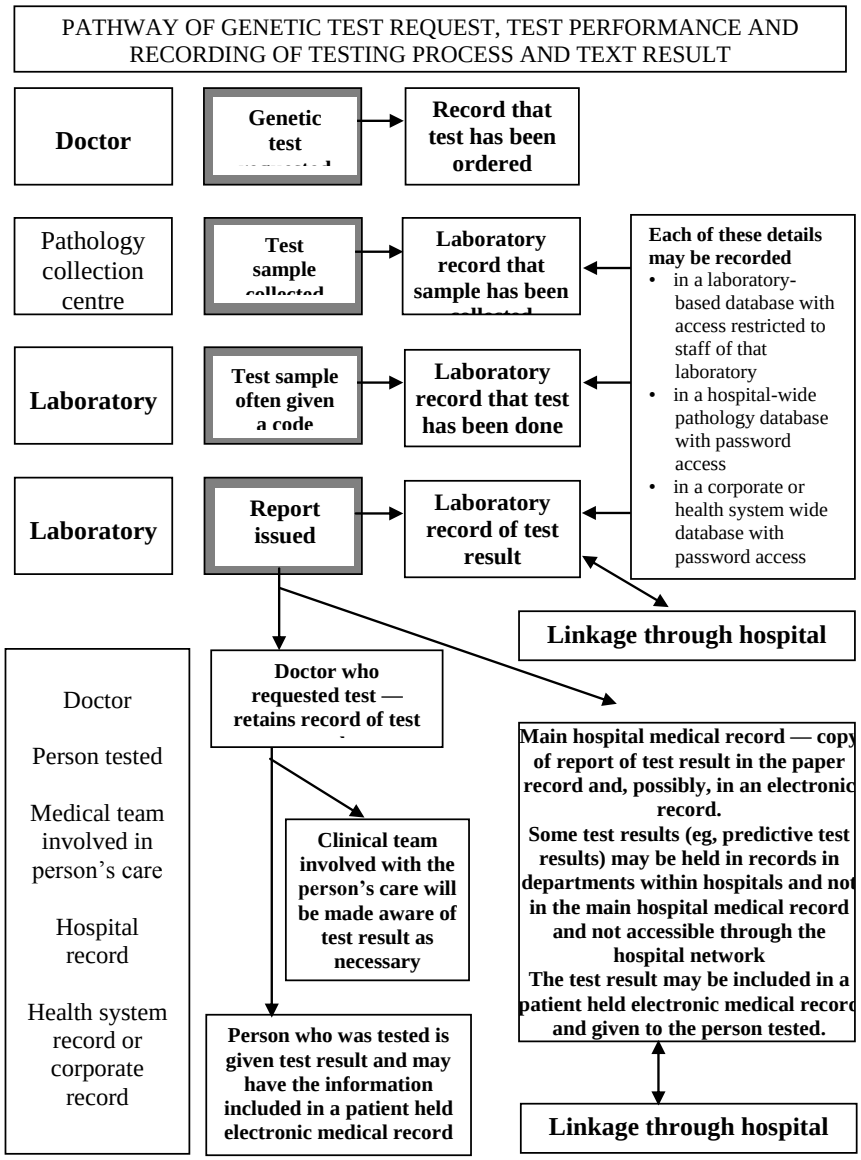
669 eg *Medical Practitioners Act 1930* (ACT) s. 35(1)(m); *Medical Practice Act 1992* (NSW) s. 36(1)(m); *Medical Practitioners Act 1983* (SA) s.5.

8.84 The inquiry is interested in comments on whether any changes to the regulatory framework for protecting the privacy of information should give special recognition to the important 'gatekeeper' role played by medical practitioners.

Question 8–5. In relation to the way medical practitioners handle genetic information and samples, does the existing ethical and legal regulatory framework provide adequate protection? If not, why not, and how might the existing framework be improved?

Question 8–6. Should the content of the duty of confidentiality, reflected in ethical codes applying to the medical profession, be revised to take account of the specific characteristics of the genetic information?

Table 8–1


PATHWAY OF GENETIC TEST REQUEST, TEST PERFORMANCE AND RECORDING OF TESTING PROCESS AND TEXT RESULT
Doctor
Genetic test
Record that test has been ordered
Pathology collection centre
Test sample
Laboratory record that sample has been
Each of these details may be recorded
• in a laboratory-based database with access restricted to staff of that laboratory
• in a hospital-wide pathology database with password access
• in a corporate or health system wide database with password access
Laboratory
Test sample often given a code
Laboratory record that test has been done
Laboratory
Report issued
Laboratory record of test result
Linkage through hospital
Doctor
Person tested
Medical team involved in person's care
Hospital record
Health system record or corporate record
Doctor who requested test — retains record of test
Clinical team involved with the person's care will be made aware of test result as necessary
Person who was tested is given test result and may have the information included in a patient held electronic medical record
Main hospital medical record — copy of report of test result in the paper record and, possibly, in an electronic record.
Some test results (eg, predictive test results) may be held in records in departments within hospitals and not in the main hospital medical record and not accessible through the hospital network
The test result may be included in a patient held electronic medical record and given to the person tested.
Linkage through hospital

9. Health administration

Contents

Introduction

9.1 Advances in human genetic technology and in the scientific and medical applications of genetic information have broad implications for the administration of the Australian health care system. Some diverse issues are discussed in this Chapter, including:

- Allocation of health care resources. The increasing availability and potential use of genetic testing may raise debates about health care resource allocation, and in particular, about what tests should be publicly funded.

- Population screening programs. Currently, a number of private and publicly funded population screening programs are being conducted in Australia. These programs may raise ethical, privacy and other concerns.

- Genetic registers. Similar concerns are raised by genetic registers, which are maintained to help identify members of genetic families who are at significantly increased risk of developing an inherited disorder or of having affected children.

- Electronic health record systems. Government initiatives aimed at the development of a national health information network raise concerns associated with the potential for breaches of privacy and present challenges for proper information storage, transfer and data integrity.

Allocation of health care resources

9.2 The application of genetic testing technology has the potential to improve health through improved diagnosis and treatment and through programs to screen for susceptibility to a disorder and early implementation of effective preventative interventions.[670] The increasing availability and potential use of genetic testing may raise debates about health resource allocation, and in particular, about what tests should be publicly funded.[671]

9.3 At present most diagnostic testing is carried out, on referral by medical practitioners, by a small number of public hospital laboratories funded by the States and Territories, each of which specialises in certain tests. For example, in New South Wales a laboratory at the Royal Prince Alfred Hospital conducts all testing for Huntington's disease.[672]

9.4 Genetic testing must compete with other technologies and services for public funding. In this context, the National Health and Medical Research Council (NHMRC) has expressed the view that:

> It is therefore vital that genetic testing is provided in the most cost-effective way and without unnecessary duplication and this may entail the establishment of national referral centres for certain tests. [673]

9.5 At present, with two exceptions,[674] genetic tests are not included on the Medicare Benefits Schedule. As genetic testing becomes an increasing part of the medical mainstream there may be pressure to include other tests associated with a beneficial medical intervention on the Schedule.[675]

9.6 Concerns about resource allocation are not unique to genetic technology. Comparisons have been made between genetic technology and the advent of non-invasive and highly informative diagnostic procedures such as Computed Tomography (CT) and Positron Emission Tomography (PET). These technologies also brought with them concerns about where the technology should be provided and to whom, and questions about who should pay.[676]

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670 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 27.

671 Including in relation to population screening programs.

672 R Trent, *Consultation*, Sydney, 4 April 2001.

673 National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 27.

674 Testing for haemochromatosis and Factor V Leiden.

675 D Allan, 'Ethical Boundaries in Genetic Testing' (1996) 154 *Canadian Medical Association Journal* 241, 241.

676 S Leeder, *Resource Allocation and the Genetic Revolution*, Online Opinion, <www.onlineopinion.com.au/2000/Oct00/Leeder.html>, 14 August 2001.

9.7 The privacy and ethical concerns raised by genetic testing may provide additional reason to discourage the availability of genetic testing outside the public hospital system and the resulting potential for necessary and unreasonable testing.[677]

9.8 Such concerns may be highlighted by the use of DNA microarrays (or gene chips) that allow scientists to look for the presence, expression or sequence of thousands of genes at a time.[678] Testing for multiple genetic conditions, and for multiple purposes (for example, involving both predictive and carrier testing) may compound the ethical complexities involved in obtaining informed consent and providing appropriate counselling.

> Not only does each type of test require different, unique information backgrounds, the tests trigger different social or personal concerns. For instance, different susceptibility tests have different implications for patients, and the information required for meaningful interpretation of the results may vary substantially.[679]

9.9 The need to provide increasingly complex genetic counselling may raise significant resource implications. In 1998, the Council on Ethical and Judicial Affairs of the American Medical Association observed that:

> Incentives currently in place often have the intended or secondary effect of requiring physicians to see more patients in the course of their practice rather than fewer. In this environment, it is unlikely that physicians will be able to meet the counseling requirements presented by multiplex testing. Even if the burden of conveying strictly genetic information is shifted to non-physicians, the process of counseling must include the consideration of clinical implications that can only be conveyed by physicians.[680]

9.10 The inquiry would be interested in comments about similar concerns that arise in the context of Australian clinical practice.

9.11 Another resource related issue concerns intellectual property rights and the costs associated with licensing fees for the use of genetic testing technology. In particular, concerns have been expressed that patent monopolies may reduce access to genetic testing services.[681] Although the inquiry accepts the critical and growing importance of issues relating to gene patenting, for the reasons set out earlier, the ALRC and AHEC take the view that these issues are not appropriate for resolution by this inquiry.

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677 R Trent, *Correspondence*, 16 May 2001.
678 S Moore, 'Making Chips to Probe Genes', *IEEE Spectrum*, 1 March 2001, 54.
679 Council on Ethical and Judicial Affairs — American Medical Association, 'Multiplex genetic testing' (1998) 28(4) *Hastings Center Report* 15, 17.
680 Ibid, 17.
681 See eg G Chin, 'Is Gene Patenting in the Interests of Public Health?' (1999) *ALSA Academic Journal* 1, 6; The Royal College of Pathologists of Australasia, *Submission G4*, 5 April 2001.

Population screening programs

9.12 Genetic population screening programs vary in their objectives, and in the size of the population groups to which they are applied. They include:

- Selective screening programs — 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.

- Mass screening programs — involving the testing of entire population groups, in order to identify a disorder or disorders suitable for treatment or prevention.[682]

9.13 Currently, a number of private and publicly funded population screening programs are being conducted in Australia. These include newborn screening programs conducted in each of the States and Territories to identify whether a baby has any of a number of genetic conditions that may respond to early treatment and screening programs conducted in schools and workplaces. Some of these programs are discussed below.

Genetic screening of newborns

9.14 Specific privacy issues are raised by the collection and use of genetic information and samples in testing newborn infants for a number of serious genetic conditions, including phenylketonuria (PKU) and cystic fibrosis.[683]

9.15 The purpose of screening is to enable the early diagnosis and treatment of the conditions tested for. Shortly before newborns leave hospital, a few drops of blood are taken from the infant's heel and collected onto special absorbent papers. These blood samples are commonly referred to as Guthrie cards.

9.16 Laboratories in each State and Territory conduct this testing. For example, infants born in New South Wales and the ACT are tested by the NSW Newborn Screening Programme based at Westmead Children's Hospital. In Victoria, testing is conducted by the Murdoch Institute and the Royal Children's Hospital. These laboratories are also responsible for storing the cards after testing.

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682 R Trent (1997), 193.

683 In NSW infants are tested for PKU, primary congenital hypothyroidism, cystic fibrosis, galactosaemia and more than 20 rarer metabolic disorders, involving fatty acid, amino acid and organic acid defects: NSW Health Department, *Guidelines for Newborn Screening*, 2001/45 (2001).

9.17 While practices may vary from state to state and hospital to hospital, concerns have been expressed about the extent to which parental consent to testing is fully informed.[684] However, at least in New South Wales, NSW Health Department policy is that before the newborn screening test is carried out, staff must ensure that parents or guardians are properly informed about the test and its importance and that consent is obtained. Information for parents is included in a pamphlet, the contents of which must be discussed with parents or guardians.[685]

9.18 There is no legislation expressly mandating the collection and testing of blood for newborn screening. Suggestions have been made that testing blood for PKU and some other genetic conditions should be mandated under legislation and parents told that the test is compulsory.[686]

9.19 Concerns have been raised about the extent to which the storage, use and disclosure of Guthrie cards is regulated,[687] although privacy legislation has been enacted in NSW, Victoria and the ACT that has application to the genetic information and samples associated with newborn screening.[688] Where such collections are maintained other than in state public hospitals, the *Privacy Act* may apply to them.

9.20 These concerns may be heightened because of the scale of Guthrie card collections — newborn screening programs in Australia have operated since the 1960s and some programs store cards indefinitely. These collections constitute major DNA databases relating to significant numbers of the Australian population. The existence of these collections raises questions about the purposes for which these samples may be used or disclosed.

9.21 Laboratories retain Guthrie cards. Currently, the six screening programs in New Zealand and Australia store their sample cards for times varying from two years to indefinitely.[689] The purposes of retaining the cards are said to include:

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684 See eg L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 138. Skene concluded that 'in view of the benefits of children being tested as soon as possible after birth for serious and treatable genetic abnormalities, the legal requirements for information-giving should be dispensed with': 142.

685 See NSW Health Department, *Guidelines for Newborn Screening*, 2001/45 (2001); NSW Health Department, *Test to Protect Your Baby* (2000).

686 See L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137.

687 See Ibid.

688 *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT).

689 Human Genetics Society of Australasia, *Draft Policy Statement on the Retention, Storage and Use of Sample Cards for Newborn Screening Programs*, Human Genetics Society of Australasia, <http://www.hgsa.com.au/policy>, 7 June 2001.

- screening program audit;
- confirmation of laboratory normal ranges;
- modification of existing screening tests;
- development of new screening tests;
- epidemiology or public health research;
- testing of deceased members of a family if a specific disorder is suspected or known; and
- assisting in coronial or forensic investigations.[690]

9.22 Some of these secondary uses may raise privacy concerns, at least to the extent that identifiable rather than de-identified samples are used.

9.23 Where the samples are covered by information privacy legislation some privacy protection will be extended to the genetic information and samples. For example, medical research using identifiable samples should take place only with consent of the individuals concerned or with ethics committee approval.

9.24 The *Privacy Act* and state information privacy legislation enables personal information to be disclosed for law enforcement purposes.[691] Guthrie cards are sometimes used for coronial or forensic investigations by coroners or the police. DNA evidence from Guthrie cards has been used in NSW criminal court proceedings.[692] Most often the disclosure of samples for this purpose will relate to the identification of deceased or missing persons, where the Guthrie card is the only available sample to assist identification.[693]

9.25 Concerns over police access to Guthrie cards in Western Australia led to the destruction of cards more than three years old. However, police powers to require suspects to provide samples for forensic procedures, including under the *Crimes Act 1914* (Cth) (see Chapter 13) may mean police have little practical need for access to Guthrie cards.

690 Ibid.
691 See eg *Privacy Act 1988* (Cth) NPP 2.1(h); *Privacy and Personal Information Protection Act 1998* (NSW) s 23(5).
692 See *R v McIntyre* (Unreported, NSW Supreme Court, Bell J, 11 April 2001).
693 NSW Newborn Screening Programme, *Newborn Screening in NSW: Storage of Samples*, (2000) NSW Department of Health.

Genetic screening programs in schools

9.26 A voluntary, privately funded screening program is currently conducted in a number of private Jewish schools in Sydney, to identify students who are 'carriers' of Tay Sachs disease (TSD).[694] A carrier will not in fact develop the disease him or herself, but if he or she has a child with another carrier, the child will inherit the disease. Therefore, knowledge of carrier status will be useful in family planning decisions.

9.27 Year 11 students must attend a genetics education session about the disease and the implications of being a carrier, and may then choose whether or not to consent to the screening; parental consent is not required if the student is 16 years or over. The screening is conducted about one week after the information session.

9.28 The student may choose to receive the results when they become available, or may opt for a deferred results scheme. If the student is a carrier of the condition, he or she will be telephoned at home; if he or she is not a carrier, the results will be mailed to his or her home. If the student opts for the deferred scheme, the results will be held confidentially by a third party 'gene broker' until the student requests access to them.[695]

9.29 In 1997, the Institute of Community Genetics (ICG) was established to oversee the implementation of genetic carrier testing programs in Australia. In conjunction with the NSW Genetics Education Program (GEP), the ICG began a research program to examine the effectiveness of various strategies of carrier genetic screening in 10 secondary schools in Sydney. The research program considered the following screening programs:

- TSD screening in the four Jewish private secondary schools, since 1995;
- TSD and cystic fibrosis (CF) screening in an additional six public secondary schools during 1997-2000; and
- TSD, CF and thalassaemia screening in all 10 secondary schools during 2000.[696]

694 The Murdoch Children's Research Institute is also conducting a similar, privately funded program in Melbourne schools.

695 The process for delayed access to the results is as follows: the student is given a code number linked to his or her identifying details; the link between the code number and identifier is held by an independent third-party gene broker, established by the ICG; the link can only be activated by the student's written request to the gene broker; the gene broker then provides the laboratory with the student's identifying details so that the result can be released from the databank: H Aizenberg and others, *The Gene Broker: A Generic Model for DNA Databanking (Poster)* (2001).

696 Ibid.

9.30 In all, 5 906 students participated in the mandatory education sessions regarding screening, and 3 400 students voluntarily underwent screening for one or more of the disorders. Students were surveyed prior to the education session, immediately after, and 12 months later to determine their understanding and level of satisfaction with the program.[697] The results have not yet been published.

Other population screening programs

9.31 The Murdoch Children's Research Institute is currently conducting a population screening program, known as 'HaemScreen', in a number of Melbourne workplaces, to identify individuals with a predisposition to the genetic disease, haemochromatosis.[698]

9.32 The Institute plans to conduct voluntary genetic testing on about 30 000 individuals in the 18–35 year age bracket. The program will be conducted at large workplaces, including the National Australia Bank and Telstra.[699] It is understood that the reason for conducting the screening in workplaces is that those at highest risk of developing the condition are in the demographic which may be least likely to attend their medical practitioner on a regular basis.

9.33 The screening program involves members of the Institute attending nominated workplaces, providing information sessions to employees about haemochromatosis, the screening program, and action that may be taken to prevent the onset of the condition, where necessary. If individuals choose to undergo screening, they must give their written consent, and will then be tested by way of a cheek swab. The individual may choose whether the swab — containing the genetic sample — will be destroyed after testing, or retained by the Institute for possible further use.[700] If the sample is retained, it will only be used for further testing with further specific written consent from the individual.

9.34 Individuals who are not predisposed to the condition will have their results mailed to them at home; individuals who are predisposed, or who have in fact developed the symptoms of the condition, will be contacted by telephone as well as by mail to their home address. The results will not be disclosed to the employer.[701] However, the individual will be required to disclose the results in applications for certain types of insurance, particularly life insurance.

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697 Ibid.

698 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', (Melbourne), 10 September 2001.

699 Dr Martin Delatycki, Murdoch Children's Research Institute, *Communication*, 27 August 2001.

700 Ibid.

701 Ibid.

Issues raised by population screening programs

9.35 As with other forms of genetic testing, any genetic population screening program may raise a number of ethical concerns, including: that individuals should only be tested with their informed consent (and if they are of an age where they are capable of giving that consent); that adequate counselling is available before testing, and upon receipt of the test results; that the testing procedure is reliable and provides accurate results; and the test results, as well as any genetic samples taken from the individual, remain confidential.

9.36 Professional ethical standards that apply to medical practitioners may be of relevance to the conduct of screening programs, particularly those standards that apply to obtaining informed consent and to duties of confidentiality.

9.37 There are generally agreed criteria that should be considered in making decisions about allocating health resources to population screening programs. These include criteria concerning the accuracy of the tests, cost-benefit ratios and the availability of effective prevention or therapy.[702]

9.38 Where screening programs are conducted for medical research purposes they will be subject to the *National Statement on Ethical Conduct in Research Involving Humans*[703] and other regulation relevant to research involving humans (see Chapter 6). However, it may not be entirely clear whether screening programs, including those referred to above, should be considered as being primarily aimed towards the treatment or prevention of genetic disease or as including research components in relation to which Human Research Ethics Committee approval should be sought.

9.39 Finally, general information privacy legislation, including the federal *Privacy Act* and state and territory information privacy and health privacy legislation, may apply to the collection, storage, use and disclosure of genetic samples and information in conjunction with population screening programs (see Chapter 4).

9.40 Population screening programs, both public and private, may become more prevalent as human genetic technology develops. The inquiry is interested in comments on whether specific regulation of population screening programs, such as newborn screening, is needed.

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702 eg J Collier and M Sherman, ' 'Screening for Hepatocellular Carcinoma'' (1998) 27 *Hepatology* 273.

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

Question 9–1. In the specific context of population screening programs, do federal, state and territory privacy laws provide an adequate framework for protecting the privacy of genetic samples and information? If not, why not, and how might the existing framework be improved?

Genetic registers

9.41 Genetic registers raise particular privacy issues. Such registers contain genetic information about many genetically related people and may also contain body samples.

9.42 The purpose of genetic registers is to operate as an effective way of identifying members of families who are at significantly increased risk of developing an inherited disorder or of having affected children.[704] The information on the register can ensure that family members have an opportunity to become aware of their risk and access genetic counselling, and to facilitate clinical diagnosis. Genetic registers may also be used for research purposes.

9.43 The collection, use and disclosure of genetic information on genetic registers may be subject to general information privacy legislation or specific health information 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.

9.44 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 *Privacy and Personal Information Protection Act 1998* (NSW) or *Health Records Act 2001* (Vic).

9.45 Genetic registers maintained by community based organisations, such as disease support groups, will 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. 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*[705] but may be covered by state legislation.

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704 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 7.

705 *Privacy Act 1988* (Cth) s 6C(1); s 6C(3)(c).

9.46 Some particular issues are raised by the application of the NPPs (or similar state legislative privacy principles) to genetic information included on genetic registers. For example, the collection of information on genetic registers raises privacy concerns. Potential registrants are identified in different ways.[706] 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. Such collection will be without the consent of the individual, at least initially, and may breach NPP 10.[707]

9.47 The National Health and Medical Research Council (NHMRC) has issued *Guidelines for Genetic Registers and Associated Use of Genetic Material*.[708] However, these guidelines have no direct legal effect and do not provide any formal sanction for non-compliance.

Question 9–2. In the specific context of genetic registers, do federal, state and territory privacy laws provide an adequate framework for protecting the privacy of genetic samples and information? If not, why not, and how might the existing framework be improved?

Electronic health records

9.48 Regulatory responses to health information privacy concerns, including those relating to genetic information, will need to take into account new possibilities for the sharing and transfer of health information opened up by information technology.

9.49 Moves towards electronic health record systems, including those that may include genetic information, are important background factors in considering privacy issues relevant to this inquiry. An electronic health record has been defined as:

706 National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (2000), NHMRC, Canberra, 13–14.

707 The NHMRC's *Guidelines for Genetic Registers and Associated Use of Genetic Material* recognise that the collection and recording of family information in a genetic register may involve a breach of the privacy of those family members. The guidelines state that registers should distinguish information that identifies people who are not registrants and not disclose it in identifiable form without the consent of the identified person and provide that, 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: Ibid, 21–22.

708 Ibid.

> An electronic longitudinal collection of personal health information usually based on the individual, entered or accepted by health care providers, which can be distributed over a number of sites or aggregated at a particular source.[709]

9.50 Systems to support the sharing of electronic health records are being promoted as capable of helping to achieve better health outcomes, quality of care and consumer safety, through better consumer and health care provider access to health information.[710] At the same time electronic health records may increase concerns associated with breaches of privacy and present challenges for proper information storage, transfer and data integrity.

A National Health Information Network

9.51 The terms of reference specifically require the inquiry to have regard to the implications of the July 2000 decision by Australian health ministers to develop a national health information network. This decision endorsed proposals made by the National Electronic Health Records Taskforce in its report *A Health Information Network for Australia*.[711]

9.52 The proposal to develop a national health information network, now known as Health*Connect*, would allow health information to be stored and exchanged on-line. The Health*Connect* initiative is currently in an initial two-year phase of research and development being undertaken by a joint State, Territory and Commonwealth Program Office. The work of the Program Office will be guided by the Health*Connect* Board, made up of representatives from all States and Territories, as well as health care provider, consumer and health informatics representatives.[712]

9.53 Under Health*Connect*, health information about individuals would be collected and held in a standard electronic format at the point of health service delivery (hospital, medical practitioner's surgery and so on). The information held would take the form of standardised event summaries and, with the consumer's consent, these summaries would then be exchanged via a secure network among health care providers authorised by consumers to access the information.

The need for privacy protection

9.54 The complex and fragmented nature of national regulation of heath information privacy may be highlighted by a national electronic health information network such as that set out in the Health*Connect* proposals, under which the same information may be accessed on-line or downloaded by many different health care providers and health system organisations.

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709 National Electronic Health Records Taskforce, *A Health Information Network for Australia* (2000), 21.
710 See Ibid, xiii.
711 See Ibid.
712 See Department of Health and Aged Care, *HealthConnect June 2001 Update*, Commonwealth of Australia, <http://www.health.gov.au/healthonline/update0106.htm>, 14 August 2001.

9.55 As discussed in Chapter 4, health information is subject to different protection depending on whether it is held by a Commonwealth agency, state agency or private sector organisation. For example:

- Information held by a Commonwealth agency (such as the Health Insurance Commission) would be subject to the Information Privacy Principles in the federal *Privacy Act* and other federal legislation, including the *Health Insurance Commission Act 1973* (Cth);

- Information held by public hospitals and other state government organisations would be subject to state privacy legislation and Freedom of Information Acts;

- Information held by private hospitals and health care providers, such as medial practitioners and pharmacists, would be subject to the National Privacy Principles in the federal *Privacy Act*;

- Information held in both the public and private sector will also be subject to relevant state and territory legislation. The ACT and Victoria have existing health information privacy legislation covering health information wherever it is held. New South Wales and the Northern Territory have signalled their intention to introduce similar legislation in the near future.

9.56 Telecommunications privacy and computer crime legislation also forms part of the existing framework of privacy protection that would apply to a national electronic health information network. For example, the *Telecommunications (Interception) Act 1979* (Cth) creates offences relating to the interception of communications passing over a telecommunications system and the *Crimes Act 1914* (Cth) provides for a range of criminal offences relating to telecommunications services and computers, some of which indirectly protect privacy interests.[713]

9.57 The National Electronic Health Records Taskforce recognised that privacy protection is critical to the success of initiatives aimed at greater sharing of health information by electronic means.

> These initiatives can only successfully proceed within an environment in which consumers can be confident that their privacy is protected and where they can understand and maintain a reasonable level of control over how their personal health information is handled.[714]

713 eg *Crimes Act 1914 (Cth)* s 85ZD dealing with 'wrongful delivery of communications'.

714 National Electronic Health Records Taskforce, *A Health Information Network for Australia* (2000), 132.

9.58 Unless health consumers and health care providers are confident that health information is adequately protected, they may not be willing to participate in electronic record systems such as Health*Connect*.[715] In this context, the Commonwealth, States and Territories are working towards a National Health Privacy Code to support health information initiatives generally and ensure consistency across the public and private sectors. The focus of this work is the Australian Health Ministers' Advisory Council's (AHMAC) Health Information Privacy Working Group.

9.59 It is anticipated that health care providers participating in Health*Connect* will be bound by the National Health Privacy Code and that additional, specific legislation for Health*Connect* will also be developed before any national roll-out of the network.[716]

Better Medication Management System

9.60 One model for specific legislation related to electronic health records systems is draft legislation to govern the operation of the proposed Better Medication Management System (BMMS).

9.61 The BMMS is a program that is related to the Health*Connect* initiative in that it will make possible the creation of an electronic patient medication record through linking prescriptions written by different medical practitioners and dispensed by different pharmacists. It is anticipated that the BMMS will be extended to include other health service providers (such as hospitals).[717] Implementation of the BMMS is not expected before 1 July 2002.[718]

9.62 As Health*Connect* is developed over time, the BMMS is expected to become the medication part of the Health*Connect* electronic record. The privacy protections and governance arrangements for BMMS would then be absorbed into the overarching arrangements for Health*Connect.*[719]

9.63 An exposure draft Better Medical Management System Bill released in May 2001 (the BMMS draft legislation) contained a range of provisions intended to protect the privacy of participating consumers whose medication information is recorded on the system and held by the Health Insurance Commission.

9.64 The BMMS draft legislation may, if enacted, provide a higher level of privacy protection to medication information on the BMMS than is provided to other kinds of health information under the *Privacy Act*. The main elements of the

715 See Department of Health and Aged Care, *HealthConnect June 2001 Update*, Commonwealth of Australia, <http://www.health.gov.au/healthonline/update0106.htm>, 14 August 2001.
716 See Ibid.
717 Summary of the Better Medication Management System — Legislative Components May 2001.
718 Senate Estimates Committee Discussion, 29 May 2001.
719 See <http://www.health.gov.au/bmms/legislation.htm>.

privacy protection provided by the BMMS draft legislation are as follows (these provisions may be substantially changed before the legislation is introduced into Parliament):

- The express consent of participating consumers is required before the consumer's record may be included on the BMMS and before each participating doctor or pharmacist may have access to the consumer's record or enter information on it.[720]

- The *Privacy Act* would apply of its own force to breaches of privacy connected with the BMMS. Such breaches include a participating doctor's failure to obtain consent to interact with a participating consumer's BMMS record or failure to comply with a consumer's request for suppression of medication information.[721]

- Breaches of BMMS privacy may constitute grounds for the imposition of administrative sanctions by the BMMS Board, including the cancellation of doctors' or pharmacists' participation in the system.[722]

- There are extensive offence provisions related to mishandling of information on the BMMS record that attract maximum penalties of two years imprisonment, or 120 penalty units, or both.[723] For example, it is an offence for any person to access or enter information on a BMMS record without authority[724] or to make it a condition of the insurance or employment of any person that a participant must provide BMMS information.[725]

Question 9–3. What are the implications of moves towards a national system of linked electronic health records for the national regulation of health and genetic information privacy? Do these developments suggest a need for a single regulatory framework for health information privacy?

Question 9–4. Does effective protection of health information privacy, including genetic information, require the use of a wider range of sanctions for breach (for example, enhanced criminal or administrative penalties)?

720 *Exposure Draft Better Medication Management System Bill 2001* (Cth), Pt 5, s 36.
721 Ibid s 6 — definition of 'breach of BMMS privacy' and proposed consequential amendments to the *Privacy Act*.
722 Ibid, Pt 11, s 116.
723 Ibid, Pt 12, ss 128–144.
724 Ibid, Pt 12, ss 130–131.
725 Ibid, Pt 12, s 144.

10. Employment and workplace issues

Contents

Introduction

10.1 Basic medical and psychological testing of applicants is becoming commonplace in Australian workplaces; some employers have also sought to impose mandatory drug testing. In future, employers may wish to access genetic test results of job applicants or employees derived from earlier medical testing, or they may seek to conduct their own genetic testing.

10.2 The use of genetic information in the employment context is still largely only of theoretical concern in Australia. Surveys to date have found only a small number of cases in which individuals believe they have been the subject of genetic screening or discrimination by employers.[726] However, as the testing technology grows in sophistication, it is possible that employers will seek to rely on genetic information to a greater degree when making employment decisions.

10.3 There is some indication of community fear regarding the potential misuse of genetic information by employers. In June 2001, a *Sydney Morning Herald* internet poll found that 93.5% of respondents thought the government should ban the use of genetic testing in insurance, employment and borrowing until a detailed policy was worked out.[727] In a US national survey conducted in 1998, 85% of those surveyed thought that employers should be prohibited from obtaining information about an individual's genetic condition, risks and predispositions; 36% would probably not take genetic tests; and 27% would definitely not take the tests if health insurers and employers could gain access to them.[728]

10.4 At present, there is no legislation in Australia that deals specifically with the use of genetic testing by employers. Whatever limitations exist on employers requiring employees or job applicants to undergo genetic or other medical testing, or to disclose the results of previous medical tests undertaken when applying for jobs, are to be found in the general anti-discrimination, workplace safety and privacy regimes noted below.

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726 A recent study of genetic discrimination by Dr Kristine Barlow-Stewart and David Keays identified three cases of alleged discrimination by employers against individuals who were asymptomatic with positive gene tests for late-onset neurological conditions: K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 254. Another case of reported discrimination involved an individual with a family history of Huntington's disease who was initially refused a position with the public service when he refused to undergo HD testing to confirm that he did not have the gene: S Taylor, 'A Case Study of Genetic Discrimination: Social Work and Advocacy Within a New Context' (1998) 51(4) *Australian Social Work* 51, 53.

727 *The Sydney Morning Herald — Online Poll*, <http://www.smh.com.au/>, 1 June 2001.

728 The survey was undertaken by the US federally funded National Center for Genome Resources. Among the groups surveyed were primary care physicians, leaders of health care organisations, scientists, religious leaders and the media. A similar study conducted by Georgetown University researchers in 1995 found that over 85% of the 332 people surveyed were very concerned or somewhat concerned about insurers and employers gaining access to, and using, genetic information in a discriminatory manner: 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, 232–33.

The use of genetic information in employment

10.5 An employer may seek access to an individual's genetic information for the purpose of genetic screening or genetic monitoring. Genetic screening will usually be conducted prior to an offer of employment, while genetic monitoring may be conducted on an ongoing basis throughout the employment period.

Genetic screening

10.6 Genetic screening involves the genetic testing of an employee or job applicant by an employer in order to exclude 'high risk' individuals from the workforce. The testing may take the form of susceptibility screening, to identify whether an individual who is currently asymptomatic has a gene or genes that increase the likelihood that he or she will develop a disorder as a result of the workplace environment; or screening for genes or disorders that are unrelated to the workplace, but which nevertheless render the individual undesirable to the employer.[729]

10.7 It has been suggested that employers in some industries have been using a form of genetic screening for many years, by screening job applicants on the basis of visible inherited characteristics. After it was established in the 19th century that workers exposed to tar, creosote and other petroleum products were at a higher risk of developing skin cancer — and pale skinned workers appeared to be at an even higher risk — it was common for job applications from pale skinned people to be rejected on that basis alone.[730]

10.8 One recently reported case of genetic screening involved a US laboratory that, for more than a decade, tested its administrative and clerical employees for the presence of sickle cell anaemia, as well as pregnancy and syphilis, without their knowledge or consent. It is unclear what use the laboratory made of the genetic test results, but the testing was held to be in violation of the employees' constitutional right of privacy.[731]

Genetic monitoring

10.9 Health monitoring is an established practice in workplaces involving exposure to hazardous substances. This monitoring involves the periodic examination of employees to identify whether there has been any modification in their genetic material during the course of employment, as a result of exposure to a

729 M Otlowski (2001), para 2.1; see also US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 5.

730 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney, 46.

731 *Norman-Bloodsaw v Lawrence Berkeley Laboratory*, 135 F 3rd 1260 (9th circuit, 1998).

toxic substance or its by-products. These modifications may include chromosomal damage or molecular mutations.[732] If such modifications have occurred, the employer may take action to prevent further damage by moving the employee within the workplace or removing him or her from the workplace altogether.

10.10 An example of the genetic mutations that may result from exposure to harmful workplace agents is found in the program for 'cleaning up' the Chernobyl nuclear disaster. Researchers have recently conducted genetic tests on the children of workers used in the clean up program. They found that these children suffer seven times the mutation rate of those whose parents were not exposed to radiation.[733] Subsequent monitoring of these children and their offspring may indicate further mutations, and the health implications of these for the descendants of those workers.

10.11 The main issues relating to genetic screening and monitoring are dealt with below. Briefly, they include the implementation of genetic tests in the workplace and the use of genetic test results; the storage and disclosure of genetic test results; and the role of genetic counselling for both employers and employees in these monitoring and screening programs.[734]

Anti-discrimination legislation

10.12 The anti-discrimination legislation enacted at the Commonwealth, state and territory levels are examined in greater detail in Chapter 5.

10.13 At the federal level, the *Disability Discrimination Act 1992* (Cth) (DDA) and the *Human Rights and Equal Opportunity Commission Act* 1986 (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) also may have some application, depending on the nature of the genetic information.

732 US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 4.

733 P Brown, 'Chernobyl Raised Mutations 600%', *The Guardian* (London), 9 May 2001. Another example of genetic monitoring is the pilot program of cytogenetic monitoring initiated by the American company Dow Chemicals in the 1960s. The company monitored the chromosomes of employees involved in the chemical production process; it also tested employees at the pre-employment stage. These analyses provided a baseline of the future cytogenetic analysis of an individual. The program was criticised for its failure to consider the effects of environmental factors on chromosomal change, and its failure to properly inform the employees as to the implications of the results. The validity, reliability and interpretation of the results were also questioned: US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 44.

734 US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 17.

Anti- discrimination legislation also has been enacted by each of the States and Territories.[735]

10.14 As noted in Chapter 5, in some circumstances the federal, state and territory anti-discrimination laws will overlap. In those circumstances, an individual may choose whether to seek redress under the federal or the applicable state or territory legislation. However, as this inquiry is primarily concerned with federal law, the following discussion focuses on the application of federal anti-discrimination legislation.

Disability discrimination

10.15 To date, it has been claimed that employers in Australia have attempted to discriminate against employees and job applicants in relation to a number of disabilities, including colour blindness,[736] back conditions,[737] psychiatric conditions,[738] neurological conditions,[739] epilepsy,[740] occupational overuse syndrome (also known as repetitive strain injury),[741] susceptibility to certain chemicals,[742] prosthetic limbs,[743] and HIV/AIDS status.[744]

10.16 As the employment provisions of the DDA are 'limited application provisions' (see Chapter 5 for more detail), they apply to: all Commonwealth employees and applicants;[745] other employees in specified areas;[746] and other employees to the extent that the provisions give effect to the *International Labour Organisation Convention*, the *International Covenant on Civil and Political Rights*, the *International Covenant on Economic Social and Cultural Rights*, or otherwise relate to matters external to Australia or of international concern.[747] As a result,

735 The application to employment is not uniform across discrimination legislation in Australia. While all of the legislation covers full-time, part-time and temporary employment, which is wider than the common law definition of 'employment' in that it applies to contracts for services, it generally does not apply to work done in a private household. Four jurisdictions (Queensland, South Australia, Tasmania and the ACT) specifically include unpaid and voluntary work, while New South Wales and Victoria exempt all employers with fewer than five full-time employees.

736 *Eyden v Commonwealth* (1999) EOC ¶93-000; *MacDonald v Queensland Rail* (1999) EOC ¶92-995; *Davies v State of Victoria (Victoria Police)* (2000) EOC ¶93-058.

737 *Logan v State of Western Australia (Ministry of Justice)* (2000) EOC ¶93-108.

738 *Y v Australia Post* (1996) EOC ¶92-865.

739 *McDonald v Hospital Superannuation Board* (1999) EOC ¶93-025, in relation to an employee with multiple sclerosis.

740 *Stevens v Queensland Police Service* (1998) EOC ¶92-933.

741 *Rees v Australian Agency for International Development* (1999) EOC ¶93-005.

742 *Cramer & Ors v Smithkline Beecham* (1997) 73 IR 470.

743 *Woodhouse v Wood Coffill Funerals Pty Ltd* (1998) EOC ¶92-942.

744 *X v Commonwealth* (1999) 200 CLR 177.

745 *Disability Discrimination Act 1992* (Cth) s 12(5). See generally, M Otlowski (2001), para 2.6, regarding the application of the 'limited application' provisions.

746 That is, in relation to discrimination by foreign, trading or financial corporations, or in the course of carrying on the business of banking or insurance, or in the course of interstate or international trade or commerce: *Disability Discrimination Act 1992* (Cth) ss 12(9)–(12).

747 Ibid s 12(8).

even though the employment provisions are of limited application, most private and public sector employees would seem to be covered by the DDA.

'Materially different'

10.17 The DDA provides that individuals should be treated alike except where their circumstances are so 'materially different' that they justify different treatment.[748] As a result of genetic testing, it is increasingly possible to differentiate between individuals on the basis of their genetic information.[749]

10.18 The question is whether currently asymptomatic individuals who are genetically predisposed to, or who are presymptomatic of, genetic conditions will be regarded as 'materially different' to other members of society. If so, they may not share the protection of the DDA in areas such as employment even though they may be currently healthy and, indeed, may never develop the particular genetic condition.

10.19 Margaret Otlowski has suggested that, on the basis of case law decided in other contexts, an individual's situation may only be construed as materially different if his or her condition indicates a current inability to perform the required tasks.[750] Therefore, an employee or job applicant should be entitled to be assessed on the basis of his or her actual *current* abilities — rather than his or her predisposition to *future* conditions that may result in impairment. Indeed, she suggests that, even in the case of monogenic, mature-onset disorders, knowledge that an individual will at some future time develop a disease that may impair his or her ability to work is not evidence of a current inability to fulfil the requirements of the position.[751] However, due to the lack of case law dealing with genetic information under the DDA, this important issue is still uncertain.

The 'inherent requirements' exemption

10.20 The DDA protects an individual from employment discrimination on the basis of his or her predisposition to a genetic condition — unless the employer can show that the individual is unable to comply with the 'inherent requirements' of the position, and it would be an 'unjustifiable hardship' on the employer to make the necessary accommodations so that the employee would be able to comply with these requirements.[752]

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748 Ibid s 5.
749 M Otlowski (2001), para 2.7.1.
750 Ibid.
751 Ibid.
27 *Disability* Discrimination *Act 1992* (Cth) s 15(4); see also *X v Commonwealth* (1999) 200 CLR 177, in which McHugh J (with whom the majority agreed) held that the two arms of s 15(4) must be read as a whole.

10.21 This raises questions as to the scope of the 'inherent requirements' exemption. First, what are the inherent requirements of a particular employment position, and should an employer have the right to determine these requirements in line with its own business interests? Second, it raises the question of material differentiation. Is it legitimate for an employer to assess an individual's ability to comply with these inherent requirements over the whole period of employment? Put another way, should an employer have the right to treat the employee as 'materially different' on the basis that, while he or she is currently fit for work, this may not be the case in the future?

10.22 As noted above, there are no reported cases of genetic discrimination under the DDA. However, the Human Rights and Equal Opportunity Commission's (HREOC) Deputy Disability Discrimination Commissioner has advised that the use of genetic test results to discriminate against employees or applicants would be unlawful under the DDA because this would amount to discrimination on the basis of an actual disability, or a propensity to a disability.[753]

10.23 A recent High Court case provides some guidance as to the way in which the courts may treat genetic information under the DDA. In *X v Commonwealth*, 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. The ADF successfully argued that X was unable to carry out an inherent requirement of employment, being deployment, because of his inability to bleed safely.[754]

10.24 The High Court interpreted the 'inherent requirements' exemption broadly, finding that these are not restricted to the performance of the physical tasks involved in a position. The inherent requirements are the characteristics or essential requirements of the employment,[755] including the surrounding context of the employment. This includes the ability to work safely, in a way that does not pose a risk to the health or safety of the individual or other employees.[756] In this case, the soldier was unable to bleed safely in the field without risking the infection of his fellow soldiers. However, the majority indicated that this approach would

753 *HREOC Issues Warning on Genetic Testing*, Workplace Express, <http://www.workplaceexpress.com.au/wpredirect?in_id=27709>, 8 May 2001.

754 *X v Commonwealth* (1999) 200 CLR 177.

755 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.

756 *X v Commonwealth* (1999) 200 CLR 177, 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.

not allow an employer to frame the terms of the contract, or the nature of its business, to allow unlawful discrimination.[757]

10.25 In *Logan v State of Western Australia (Ministry of Justice)*, HREOC considered a case of alleged discrimination as a result of a prison officer's apparent inability to 'work safely'. The prison officer complained that she had been improperly dismissed from her position, and had not been considered for an alternative position of stores/laundry officer, as a result of her degenerative back disease. The Disability Discrimination Commissioner considered that an inherent requirement of the position of prison officer was an ability to restrain prisoners without undue risk to her own safety or that of others. The dismissal was therefore lawful under the DDA because the complainant's back condition rendered her unable to fulfil this requirement.[758]

10.26 The Commissioner considered the employer's legal obligations to the complainant under both occupational health and safety legislation and the common law:

> In my view, an employer who is aware that a particular employee has an existing medical condition which makes that employee particularly vulnerable to exacerbating that condition by performing what I have found to be an inherent requirement of the position is entitled to view the prospect of the employee suffering substantial pain and a significant period off work as amounting to an undue, unreasonable or unacceptable level of risk. It seems to me that to come to any other conclusion would be to require the employer to expose itself to the prospect of a claim in negligence by the employee … an employer who is aware of a special vulnerability on the part of a particular employee might later be subject to a claim by a fellow employee in such circumstances, and is entitled to take that prospect into account in determining whether the risk arising from an employee's disability is an undue or unreasonable risk.[759]

'Unjustifiable hardship'

10.27 An employer may lawfully discriminate under the DDA only if it can show that the employee or job applicant is unable to perform the inherent requirements of the position and that it would be an unjustifiable hardship on the

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757 G Bernardi, 'X v Commonwealth' (2000) 7 *Medical Law Reporter* 355, 358. However, note the recent case of *State of Victoria v Schou* (Unreported, Supreme Court of Victoria, Harper J, 31 August 2001), in which the Supreme Court of Victoria considered a complaint brought under the *Equal Opportunity Act 1995* (Vic). A parliamentary sub-editor of Hansard alleged that her employer had indirectly discriminated against her on the grounds of her status as a parent and carer. The employee had unsuccessfully requested a networked computer modem so that she could work from home in order to care for her sickly child. The Court considered that the reasonableness of a requirement imposed by an employer must be assessed by reference to the interests of the employer and all affected employees, as well as the interests of the employee claiming to have been subjected to indirect discrimination.

758 *Logan v State of Western Australia (Ministry of Justice)* (2000) EOC ¶93-108, 13. However, this was not an inherent requirement of the other position and the failure to consider her for that position was unlawful discrimination under the *Disability Discrimination Act 1992* (Cth).

759 *Logan v State of Western Australia (Ministry of Justice)* (2000) EOC ¶93-108, 16.

employer to make any adjustments that would be required for the employee or job applicant to be able to perform those requirements. In *Woodhouse v Wood Coffill Funerals Pty Ltd*,[760] HREOC accepted evidence that a pallbearer could not carry coffins safely because of his prosthetic foot. However, it found that his dismissal was unlawful discrimination under the DDA because he would have been able to perform this inherent requirement of the position if he had been given a small amount of training, and the provision of such training would not have been an unjustifiable hardship on his employer.

10.28 These cases provide some indication of the way in which the courts will consider genetic information under the DDA. In circumstances where an individual suffers from a genetic disease, or has a predisposition to a genetic disease with a sudden and unpredictable onset — and this disease would pose a threat to the safety of the employee or others in the workplace — the employee may be considered unable to fulfil the inherent requirements of the position. Although these circumstances would be very rare, they could result in the exclusion of some asymptomatic individuals from the protection of the DDA. The remaining question is whether an individual who is currently able to perform these inherent requirements may lawfully be considered unable to do so on the basis of a possible future inability to do so.

Exemptions

10.29 The DDA provides that HREOC may grant exemptions to the prohibition against disability discrimination in employment. As noted in Chapter 5, an employer may apply to HREOC for a temporary exemption from the operation of the DDA. Such an exemption may be granted for periods up to five years, provided that it is not inconsistent with the objects of the DDA.[761]

Disability standards

10.30 Finally, as is also noted in Chapter 5, the Minister may formulate disability standards in relation to employment; once tabled before Parliament for a certain period, these standards gain the force of law.[762] Currently, there are no standards in force in relation to employment. However, draft standards have been prepared by the Disability Standards Sub-Committee of the National Committee on Discrimination in Employment and Occupation.[763]

760 *Woodhouse v Wood Coffill Funerals Pty Ltd* (1998) EOC ¶92-942.
761 *Disability Discrimination Act 1992* (Cth) s 55.
762 Ibid ss 31, 32.
763 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>.

10.31 Otlowski suggests that the draft standards adopt an expansive approach to the 'inherent requirements' exemption to the DDA, providing that external factors such as market and customer requirements and industrial circumstances are relevant.[764] If these are given the force of law in light of the recent High Court cases of *X v Commonwealth*[765] and *Christie*,[766] they may result in an undermining of the current DDA protections.

Sex discrimination

10.32 The SDA is outlined in Chapter 5. The SDA prohibits an employer from discriminating against an employee or applicant on the ground of his or her sex, a characteristic relating to his or her sex, or a characteristic that is generally believed to be so related. The employer cannot discriminate in the job selection process or in the terms or conditions offered.[767]

10.33 In certain circumstances, an asymptomatic individual with a predisposition to a genetic disease may also be protected from unlawful discrimination under the SDA. For example, if a genetic condition manifests in individuals of only one sex, any discrimination based on that condition might be considered unlawful sex discrimination. Therefore, a woman with a predisposition to cervical cancer, or a man with a predisposition to prostate cancer, may be protected from employment discrimination under the SDA.

Racial discrimination

10.34 The RDA is outlined in Chapter 5. The RDA prohibits an employer from discriminating against an employee or applicant on the ground of his or her race, colour, descent, or national or ethnic origin. Discrimination in the decision to employ or terminate an individual, in the terms or conditions of work, and in the training and promotion opportunities provided, is prohibited.[768]

10.35 There are examples of genetic discrimination against particular racial groups in the United States. Throughout the 1970s, the US Department of Defence and certain industrial companies routinely tested employees to determine whether they had the sickle cell trait or disease; some of these employees were then screened from employment. Sickle cell trait and disease is found mainly in people of African descent and, to a lesser extent, in people of Middle Eastern and

764 M Otlowski (2001), para 2.7.2; see also 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>, 9 October 2001.

765 *X v Commonwealth* (1999) 200 CLR 177.

766 *Qantas Airways Limited v Christie* (1998) 193 CLR 280.

767 *Sex Discrimination Act 1984* (Cth) ss 5(1), 14(1).

768 *Racial Discrimination Act 1975* (Cth) ss 9, 15.

Mediterranean descent; however, only African Americans were tested, and therefore screened.[769]

10.36 As noted in Chapter 5, many genetic traits are more prevalent in some races and nationalities than in others.[770] If Australian employers begin to discriminate on the basis of racially specific genetic conditions, it is possible that such discrimination will be prohibited under the RDA.

Human Rights and Equal Opportunities Commission Act

10.37 The *HREOC Act* is outlined in Chapter 5. The *HREOC Act* applies to all public and private sector employment. An employee is protected from certain types of discrimination in employment, such as discrimination on the basis of his or her medical record, race, nationality, national extraction, colour, impairment, or mental or physical disability. 'Impairment' is defined to include the presence in the body of organisms causing disease, and it may be sufficiently broad to include the presence of genetic disorders.

Employment regulation

Workplace Relations Act

10.38 The *Workplace Relations Act 1996* (Cth) (WRA) provides that an employer must not terminate an individual's employment as a result of his or her race, colour, sex, physical or mental disability, national extraction or social origin.[771] The employer may do so, however, when this factor renders the employee unable to fulfil the 'inherent requirements' of the particular position.[772]

10.39 This is a broader exemption than under the DDA, because there is no specific requirement that the employer attempt to accommodate the employee in spite of his or her disability. However, the courts will generally consider whether the employer has acted reasonably in the circumstances, and any attempt to accommodate the employee (or the failure to do so) may be considered in this context. In any case, the protection may be stronger under this legislation than under the DDA because, once disability is raised as an issue, the onus is on the

769 J Seltzer, 'The Cassandra Complex: An Employer's Dilemma in the Genetic Workplace' (1998) 27 *Hofstra Law Review* 411, 418–20.

770 For example, Tay Sach's disease is found primarily in the Ashkenazi Jewish population, and SAT deficiency occurs mainly among people of northern European descent: Ibid, 421. Indeed, a survey of ethnic genetic variations has indicated that: African people are more prone to milk intolerance; Armenian people to inflammation and fever; Chinese people to thalassemia; Mediterranean people to liver disease; and Irish people to spina bifida: 'Patchwork of Genes: A Survey of Global Genetic Diversity', *The New York Times*, 22 May 2001.

771 *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.

772 Ibid s 170CK(3).

employer to establish that it had a valid reason for dismissal, and that disability was not one of those reasons. By contrast, under the DDA the onus is on the complainant.[773]

10.40 In *Cramer & Ors v Smithkline Beecham*,[774] two employees of a chemical plant were dismissed because of their ongoing sensitivity to penicillin, to which they were exposed at work. The Court decided that penicillin tolerance was an inherent requirement of working in the chemical plant and therefore the dismissal of the two employees was not unfair.

10.41 In *Qantas Airways Ltd v Christie*,[775] the High Court considerably expanded the scope of the 'inherent requirements' exemption. The Court considered whether the employment of an international airline pilot, who had been dismissed by Qantas on the basis of his age, had been unfairly terminated. In deciding whether the pilot could fulfil the inherent requirements of his position, the 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 of the countries to, or over which, an international airline pilot would fly 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 he was not able to do so.

Summary

10.42 In summary, an employee who is not experiencing any symptoms but who is dismissed from a position on the basis of a predisposition to a genetic disease could bring a claim against the employer under the federal anti-discrimination legislation, the *HREOC Act* or the WRA, depending on the grounds for dismissal. However, each of these statutory frameworks allows an employer to lawfully terminate an employee where he or she cannot fulfil the inherent requirements of the position. As a result of *X v Commonwealth*[776] and *Christie*,[777] even if the employee is physically able to fulfil these requirements, the 'surrounding context' of the position — including the risk to workplace safety — may mean that the termination is lawful.

Question 10–1. Do federal anti-discrimination and workplace relations laws adequately protect a person with a predisposition to a genetic illness, but no symptoms, from unfair discrimination in the employment context?

773 See M Otlowski (2001), para 2.10.
774 *Cramer & Ors v Smithkline Beecham* (1997) 73 IR 470.
775 *Qantas Airways Limited v Christie* (1998) 193 CLR 280.
776 *X v Commonwealth* (1999) 200 CLR 177.
777 *Qantas Airways Limited v Christie* (1998) 193 CLR 280.

Question 10–2. How should a genetic predisposition be considered in relation to an individual's ability to fulfil the 'inherent requirements' of a particular position?

Occupational health and safety legislation

10.43 The health and safety of employees in the workplace is regulated at the federal, state and territory level by occupational health and safety legislation.[778] These statutes generally place a duty on employers to take reasonable care for the health, safety and welfare of all employees, as well as for members of the public. An employer who breaches this duty may be prosecuted under this legislation.

10.44 At the federal level, the *Occupational Health and Safety (Commonwealth Employment) Act 1991* (Cth) applies to employees of the Commonwealth in government departments or government business enterprises. An employer must take all steps reasonably practicable to protect the health and safety of its employees in the workplace. This includes a duty to provide and maintain a safe workplace, to monitor employees' health and safety at work, and to maintain health and safety records.[779]

10.45 At the same time, an employee has a duty to take steps to ensure that he or she does not create or add to any risk to his or her own health or safety, or that of other employees or third persons at or near the workplace.[780] The employer also has a duty to third parties, such as the members of the general public, to the extent that it must take all reasonably practicable steps to ensure that the health or safety of any person at or near a workplace under its control is not put at risk.[781]

Industry standards and codes of practice

10.46 The National Occupational Health and Safety Commission (NOHSC) drafts national standards and codes of practice that are intended to create uniform health and safety standards in each State and Territory.[782] The national codes of practice advise employers and workers of an acceptable way of meeting the

778 See the *Occupational Health and Safety (Commonwealth Employment) Act 1991* (Cth); *Occupational Health and Safety Act 1989* (ACT); *Occupational Health and Safety Act 2000* (NSW); *Work Health Act 1986* (NT); *Workplace Health and Safety Act 1995* (Qld); *Occupational Health, Safety and Welfare Act 1986* (SA); *Workplace Health and Safety Act 1995* (Qld); *Occupational Health and Safety Act 1985* (Vic); *Occupational Safety and Health Act 1984* (WA).

779 *National Occupational Health and Safety Commission Act 1985* (Cth) ss 16(1), (2) and (5).

780 Ibid s 21.

781 Ibid s 17.

782 Ibid s 38(1).

national standards.[783] These are advisory only unless they are enacted into legislation or made under delegated authority.[784]

10.47 In drafting its national standards and codes, the NOHSC must consider relevant anti-discrimination legislation. For example, in *HREOC v Mt Isa Mines*,[785] the High Court considered a non-discriminatory standard and draft code of practice for the lead industry prepared by the NOHSC. The draft standard and code provided for the exclusion of pregnant and breastfeeding women from lead-risk jobs in the lead industry (see Chapter 5 for more detail). The Court considered that the NOHSC should have clearly advised employers that adoption of the standard and code could involve a breach of the SDA, unless temporary exemptions were obtained under that legislation.

10.48 The NOHSC's national *Guidelines for Health Surveillance* set the minimum requirements for health surveillance and monitoring in the workplace.[786] Under these guidelines, an employer must assess the health risks created by work involving potential exposure to hazardous substances.[787] If a risk is identified, the employer must ensure that exposure to these substances is either prevented or adequately controlled so as to minimise the health risks to its employees.[788]

10.49 The Guidelines provide for the monitoring of workplaces and surveillance of individual employees. Generally, the results must be recorded and provided to 'at risk' employees. In certain circumstances, the employer must take 'appropriate remedial action'.[789] However, the Guidelines do not specify what is the appropriate remedial action in the circumstances.

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783 National Occupational Health and Safety Commission, *The National Standards Guide — Final Draft*, Commonwealth of Australia, <http://www.nohsc.gov.au/OHSInformation/NOHSCPublications/f.../03297-01.html>, 15 May 2001.

784 For example, the *Occupational Health and Safety (Commonwealth Employment) (National Standards) Regulations 1994* (Cth) incorporates national codes, including National Occupational Health and Safety Commission, *National Codes of Practice for the Control of Workplace Hazardous Substances [NOHSC: 2007 (1994)]* (1994), and other guidance material, including the National Occupational Health and Safety Commission, *Guidelines for Health Surveillance [NOHSC: 7039 (1995)]* (1995), Commonwealth of Australia.

785 *Human Rights and Equal Opportunity Commission v Mount Isa Mines Ltd* (1993) 118 ALR 80.

786 National Occupational Health and Safety Commission, *Guidelines for Health Surveillance [NOHSC: 7039 (1995)]* (1995), Commonwealth of Australia. These are complemented by National Occupational Health and Safety Commission, *National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)]* (1995) and the National Occupational Health and Safety Commission, *National Codes of Practice for the Control of Workplace Hazardous Substances [NOHSC: 2007 (1994)]* (1994).

787 National Occupational Health and Safety Commission, *Guidelines for Health Surveillance [NOHSC: 7039 (1995)]* (1995), Commonwealth of Australia, r 11(1).

788 Ibid r 12(1).

789 Ibid rr 13, 14.

10.50 This surveillance must be performed under the supervision of a medical practitioner, who has a duty to maintain the confidentiality of the records. If the medical records identify an employee, they must not be disclosed to any third party (who is not covered by professional confidentiality) without the individual's informed written consent.[790]

Workers compensation

10.51 Workers compensation schemes are a form of accident compensation for employees who suffer work-related injuries and diseases, and their dependants. The compensation is paid on a 'no fault' basis. An employer cannot contract out of its liability, and the compensation schemes are generally funded by compulsory insurance or self-insurance. Workers compensation is regulated on a federal,[791] state and territory basis.

10.52 In future, employers may seek access to an employee's or applicant's personal genetic information in order to minimise their workers compensation premiums.[792] For example, in NSW part of the employer's yearly insurance premium is based on its claims history and safety record.[793] An employer who wishes to minimise its premium may seek to screen out of its workforce individuals who are more susceptible to workplace injuries or diseases, including employees who have genetic predispositions to certain conditions that may be caused or contributed to by the workplace environment. Alternatively, in future employers may seek to obtain waivers of liability from employees identified as susceptible to particular genetic injuries or diseases, or may argue that such liability was impliedly waived when employees who knew they were susceptible chose to work regardless.[794]

10.53 It is also possible that, in future, insurers providing workers compensation coverage may pressure employers to screen susceptible individuals from employment.

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790 Ibid.

791 See *Safety, Rehabilitation and Compensation Act 1988* (Cth).

792 If they do so, the organisation disclosing an individual's personal information to an employer will have to comply with the *Privacy Act* unless that organisation is not subject to the *Privacy Act*, or unless it has previously employed the individual, and the disclosure is directly related to the employment relationship.

793 See *Workers Compensation Act 1987* (NSW)*; Workers Compensation (Insurance Premiums) Regulation 1995* (NSW).

794 See M Rothstein, 'Genetics and the Work Force of the Next Hundred Years' (2000) 3 *Columbia Business Law Review* 371, 401, and 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, 312.

Common law duties

10.54 An employer also has a common law duty — in both contract and tort — to take reasonable care for the safety of an employee. The contractual duty is implied into the contract of employment.[795] The duty in tort is more extensive than a duty to take reasonable care; it is a duty to ensure that reasonable care is taken.[796] In each case, the court will consider whether it was foreseeable that an employee would be injured or harmed as a result of a specific work practice in order to decide whether an employer has been negligent.[797] However, while an employee may have the right to bring a common law suit against an employer, the introduction of workers compensation legislation in each jurisdiction has meant that claims under these schemes have generally replaced common law claims.

10.55 Another implied contractual term is the implied duty of confidence and trust that is owed by an employer to his or her employees.[798] The courts may interpret the use of genetic testing as a means of excluding susceptible, and potentially expensive, individuals from the workforce as a breach of this implied term.

The Genetic Privacy and Non-discrimination Bill 1998

10.56 The Genetic Privacy and Non-discrimination Bill 1998 is considered in Chapters 2, 4 and 5. The Bill is an example of a specific piece of legislation regulating the use of genetic information in all contexts, and providing specific exemptions in relation to employment and insurance.

10.57 As noted in above, the Senate Legal and Constitutional Legislation Committee recommended that the Bill not be enacted.

The interpretation of genetic information

10.58 There are a number of potential concerns with the interpretation of genetic test results by employers. First, the test results must be accurate and reliable; second, employers or their medical consultants must interpret them

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795 See *Wilsons v Clyde Coal Co Ltd v English* [1938] AC 157; *Hamilton v Nuroof (WA) Pty Ltd* (1956) 96 CLR 18.

796 *Kondis v State Transport Authority* (1984) 154 CLR 672.

797 In one case, an employee was injured by exposure to noise of over 85 decibels. The Court decided that, because 3% of the population is susceptible to hearing impairment at that noise range, it was foreseeable that there would be employees with that susceptibility within the employer's workforce. If the employer had adapted the noise levels in the workplace, it could have avoided the injury. It was therefore found to be negligent: *Zanardo v Continental Check Point Pty Ltd* (Unreported, NSW Court of Appeal, 19 June 1986). In *Paris v Stepney Borough Council* [1951] AC 367, an employee was blinded by a fragment of metal that flew into his only sighted eye. The Court held that, as the employer knew that the employee was blind in one eye, a reasonable employer would have provided goggles to employees with only one sighted eye in order to prevent such foreseeable injury.

798 For example, see *Blaikie v SA Superannuation Board* (1995) 65 SASR 85; *Brackenridge v Toyota Motor Corporation Australia Ltd* (1996) 142 ALR 99.

properly; and third, if they are to be used in deciding whether to employ or dismiss an individual the results must be relevant to an employee's ability to perform in a particular position.

10.59 As discussed earlier in this paper, genetic testing is not always a precise science. A test may result in a false positive or a false negative for a number of reasons such as degradation or contamination of the sample, improper laboratory handling procedures, or misinterpretation of the test results by the analyst.[799] All of these factors may undermine the accuracy or reliability of genetic test results.

10.60 An employer's ignorance of genetic science may lead it to misinterpret the true nature of genetic test results and make an employment decision based on an incorrect assessment of an individual's state of health. In the short term, it is likely that there will be a degree of ignorance regarding the nature of genetic science and genetic test results within the community. If employers use genetic test results but remain ignorant of their true predictive nature, this may have significant implications for currently healthy individuals.[800] That is, although genetic tests for multifactorial conditions can only ever predict the probability of a disease, there is a concern that employers will misinterpret these results as capable of determining whether an individual has, or will develop, the disease.[801]

10.61 An example is the 'breast cancer genes', known as BRCA1 and BRCA2. As noted in Chapter 2, only 60-85% of women with the BRCA1 or BRCA2 gene will develop breast cancer during their lifetimes. It has been suggested that this probability will depend on whether there is a clear family history of this cancer; if there is no family history, the risk is unknown.[802] Therefore, the employer could not make an accurate decision as to susceptibility on the basis of the genetic test results alone.

10.62 Employers also may misunderstand the difference between a person who is a *carrier* of a particular disease, and a person who *has* that disease. As noted above, for a number of years the US armed forces and airline industry tested pilots and other airline crew for the sickle cell trait and screened these individuals out of employment in the belief that the trait could cause health problems at high

799 Levitt states, 'Whilst the employer with access to a large pool of labour can simply employ someone else, the individual concerned has been given false medical information and excluded from employment': M Levitt (2000), 33.

800 K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 254; see also K Brokaw, 'Genetic Screening in the Workplace and Employers' Liability' (1990) 23 *Columbia Journal of Law and Social Problems* 317, 325, and M Otlowski (2001), para 3.2.1.

801 K van Damme (2000), 15; J K Brokaw, 'Genetic Screening in the Workplace and Employers' Liability' (1990) 23 *Columbia Journal of Law and Social Problems* 317, 325.

802 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, 231.

altitudes.[803] In fact, individuals with sickle cell trait are merely carriers of the condition and will not develop the condition themselves.[804]

10.63 Finally, genetic test results may simply be irrelevant in a particular employment context. In light of changing employment trends within the Australian labour market, specifically the move to shorter term employment, it may not be reasonable for an employer to consider genetic test results if it is unlikely that the symptoms will manifest during the term of employment, if at all.[805]

Question 10–3. Where employers are permitted to conduct genetic testing, what measures should be put in place to establish the reliability, accuracy and proper interpretation of any genetic testing before making decisions based on that information?

Genetic testing and discrimination

10.64 The UK Human Genetics Commission has stated that employers may be interested in obtaining genetic information in relation to employees and applicants, in order to identify which employees:

- may put others at risk in the workplace;
- have an increased susceptibility to occupational disease; or
- are likely to experience long periods of absence from work as a result of their genetic conditions.[806]

803 J Seltzer, 'The Cassandra Complex: An Employer's Dilemma in the Genetic Workplace' (1998) 27 *Hofstra Law Review* 411, 419.

804 J Crespin, 'Genetic Screening in the Workplace for Sickle Cell Trait: A Dangerous Tool' (1992) 30 *Medical Trial Technique Quarterly* 91, 95–96. In the UK, the Ministry of Defence still tests all applicants for aircrew training for sickle cell trait and disease, and screens those who test positive from certain positions. The Ministry is currently re-examining this policy in relation to the sickle cell trait because of uncertainty about whether such a risk actually exists for those with the carrier status only: see generally, Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London, 38; see also the Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, 59–60; US Congress — Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990), US Government Printing Office, Washington, 41–43; and the Human Genetics Advisory Committee, *The Implications of Genetic Testing for Employment* (1999), Human Genetics Advisory Committee, London, para 3.3.

805 See generally, R Johnstone, 'Paradigm Crossed? The Statutory Occupational Health and Safety Obligations of the Business Undertaking' (1999) 12 *Australian Journal of Labour Law* 73, 73–75.

806 Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London, 39.

Risk in the workplace

10.65 Employers may argue that they have a duty to screen out of employment those individuals whose genetic or other medical conditions pose a risk to the health and safety of the individual employee, other employees or the general public.

10.66 An example that is often used to support this argument is the case of an airline pilot or a bus driver. Both of these positions involve responsibility for the safety of others. If a pilot or a bus driver suffers a sudden heart attack while at work, this could result in the death or injury of large numbers of the public as well as other employees.[807]

10.67 Indeed, in the light of the recent scientific suggestions that there may be a genetic component to the condition known as deep vein thrombosis (commonly referred to as 'economy class syndrome'), it is possible that the airline industry could in future introduce programs to identify those employees who have a genetic predisposition to the condition, in order to screen them from employment.[808]

10.68 The courts already have been willing to accept mandatory drug testing in workplaces involving dangerous work activities.[809] For example, in *Kay v Cargill Foods Australia*,[810] the court held that an employer was justified in imposing drug and alcohol tests on its employees who worked as meat boners on the basis that they could pose a risk to their own and others' safety if they were 'under the influence' at work. In *Denbo v Transadelaide*,[811] an employer's policy of drug testing its train driver employees was considered justified in light of the employer's duty to ensure public safety.

10.69 More recently, the Professional Boxing and Martial Arts Board (Vic) has 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 may make them more susceptible to 'punch drunk syndrome'. Concerns have been

807 Otlowski has reported that Qantas presently does not have an official policy on genetic testing for Huntington's disease, but does ask standard employment questions in relation to family history that would indicate whether a person is at risk of developing the condition: M Otlowski (2001), para 3.1.2, fn 123.

808 'Rare Gene May Cause Fatal Clots on Flights', *The Sydney Morning Herald*, 10 July 2001.

809 J Butler and R McCallum (2001), 9. Rothstein has commented as follows on the US position: 'In trying to make hiring and placement decisions, most employers have shown an insatiable appetite for tests, including intelligence tests, aptitude tests, personality tests, 'honesty' tests, drug tests, and various medical tests': M Rothstein, 'Genetics and the Work Force of the Next Hundred Years' (2000) 3 *Columbia Business Law Review* 371, 382.

810 *Kay v Cargill Foods Australia* (Unreported, Industrial Relations Court of Australia, 6 September 1996), cited by J Butler and R McCallum (2001), 9–10.

811 *Denbo v Transadelaide* (Unreported, Australian Industrial Relations Commission, 7 September 1999), cited by J Butler and R McCallum (2001), 10–11.

raised that the Board could be legally liable if it allowed boxers with this genetic predisposition to fight, and they subsequently developed the syndrome.[812]

10.70 As noted above, the ADF has already successfully argued that, due to the risk of infecting other soldiers in the field, an HIV positive soldier is unable to fulfil an 'inherent requirement' of his position, being the ability to bleed safely in deployment.[813] This principle could be extended to employees whose genetic condition poses a health or safety risk to their fellow employees, or the general public. However, at this stage of our understanding of genetic science and in the present state of testing technology, it is not possible to predict with any certainty whether an individual with a genetic predisposition to a multifactorial disorder will actually develop that disorder or when its onset will occur. Therefore, many individuals may be screened from employment even though they will never experience the disorder to which they are predisposed.

10.71 As a result, it has been suggested that an individual should be protected from employment screening unless his or her condition poses a 'direct and substantial risk' to the public.[814] Very few positions will involve such a risk to public safety, but pilots and professional drivers may be among them. Recent cases have suggested that where there is reliable evidence of a direct risk to public safety, it is likely that the individual could be lawfully dismissed under the DDA or WRA as being unable to fulfil the inherent requirements of the position.

10.72 The difficulty could be in deciding where to 'draw the line'.[815] For example, should a bus driver with a genetic predisposition to heart disease, but who is currently asymptomatic, be dismissed from employment merely because of this predisposition? Or, should the employer be required to consider additional factors

812 J Robotham, 'Pro Boxers Face Going Down for the Gene Count', *The Sydney Morning Herald*, 1 June 2001. The boxers would be tested for the genetic variation called apolipopoprotein E (ApoE) 4. US research has shown that people with two copies of this gene, inherited from both parents, are more susceptible to this syndrome, being brain damage from head injuries received in the boxing ring.

813 *X v Commonwealth* (1999) 200 CLR 177.

814 See D Keays, 'The Legal Implications of Genetic Testing: Insurance, Employment and Privacy' (1999) 6(4) *Journal of Law and Medicine* 357, 369. The UK House of Commons Science and Technology Committee has made a similar recommendation that legislation to protect the privacy of genetic information should be so drafted as to forbid employers from testing for genetic traits other than those which might put the public at direct and substantial risk: House of Commons Science and Technology Committee, *Human Genetics: The Science and its Consequences* (1995), House of Commons, London, paras 232–233.

815 W Murry, J Wimbush and D Dalton, 'Genetic Screening in the Workplace: Legislative and Ethical Implications' (2001) 29(4) *Journal of Business Ethics* 365. See also Keays, who states 'if testing is to be permitted where it is consistent with business necessity, where does one draw the line? While the example of a pilot with sickle cell anaemia is a potent argument in favour of genetic testing in such instances, presumably truck drivers should be screened for predispositions to alcoholism and counsellors screened for predispositions to depression. To draw distinctions between occupations and the relative degree of necessity of a genetic test would create nothing more than a quagmire of complex artificial distinctions': D Keays, 'The Legal Implications of Genetic Testing: Insurance, Employment and Privacy' (1999) 6(4) *Journal of Law and Medicine* 357, 369.

that may lead to the onset of the disorder, such as the driver's diet, stress levels and general level of fitness?

10.73 Essentially, the question may be whether an employer should be allowed to shift the burden of workplace risk or hazards from management to its workers. At the same time, should an employer have the power to make the employment decision itself, or should it be required to first seek expert medical advice in relation to the genetic risk? In any case, in order to comply with the DDA, an employer will need to show that some form of accommodation, such as regular performance monitoring, is unreasonable or insufficient in the circumstances.[816]

Question 10–4. Should employees in positions involving significant safety risks to the public and/or other employees (eg airline pilots and professional drivers) be required to undertake genetic testing? If so, how should this testing be regulated?

Susceptibility to occupational disease

10.74 As noted above, employers have a duty to take reasonable care for the health and safety of their employees. If an employee with a genetic susceptibility to a multifactorial disease is exposed to substances in the workplace that cause or contribute to the onset of the disease, the employer may be liable for breach of this duty.

10.75 Therefore, in certain industries, an employer may seek to limit its potential liability by seeking information about an individual's genetic susceptibilities before deciding whether or not to employ him or her. Professor Karel Van Damme notes two broad employment approaches in relation to occupational health — the health and employment protection approach and the standardisation approach.[817]

Health and employment protection approach

10.76 An employer may take a 'health and employment protection' approach, which aims to employ every job candidate while protecting his or her total health by ongoing medical surveillance.[818] The guiding principle of this approach is that the employer should contribute to improving workplaces and adapting tasks so that almost any worker who has the skill can perform the job safely without

816 M Otlowski, *Discussion Paper No 2 — Implications of the Human Genome Project for Australian Employment Law and Practice*, (1997) Centre for Genetics and the Law, 10.
817 K van Damme (2000).
818 Ibid, 5–6.

endangering his or her health, as well as increasing the opportunity of every worker to be offered a proper job (unless the job would certainly be detrimental to his or her health).[819]

10.77 This approach reflects the objects of Australian anti-discrimination and occupational health and safety legislation. Anti-discrimination legislation attempts to protect employment prospects by protecting individuals from unfair discrimination on the basis of their sex, race or disabilities. Occupational health and safety legislation seeks to prevent workplace injuries and disease by ensuring that employers take measures to provide a safe workplace.

Standardisation approach

10.78 The second approach is the 'standardisation' approach, which focuses on selecting out those persons who are more vulnerable than the average at the pre-employment stage, or following any indication of a possible increased risk to an exposure-related health effect. The purpose of this approach is to minimise absenteeism and employer costs and to increase productivity.[820]

10.79 The UK Nuffield Council on Bioethics has suggested that susceptibility screening ought to be contemplated only where there is strong evidence of a clear connection between the working environment and the development of the particular condition; the condition is one which seriously endangers the health of the employee, or may result in a serious danger to third parties; or the condition is one, the dangers of which cannot be eliminated or significantly reduced by reasonable measures by the employer. It also suggested that a genetic screening program only be introduced if accompanied by safeguards for employees and after appropriate consultation.[821]

10.80 The UK Human Genetics Advisory Commission has subsequently recommended that employers should offer a genetic test (where available) if it is known that a specific working environment or practice (although meeting health and safety requirements) might pose specific risks to individuals with particular genetic variations.[822]

10.81 The federal Privacy Commissioner has also noted possible criteria for deciding which tests might appropriately be applied in the workplace, including:

- the condition tested for should be of relatively high prevalence;

819 Ibid, 6.
820 Ibid, 5–6.
821 Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, quoted in M Otlowski (2001), para 4.3.3.
822 Human Genetics Advisory Committee, *The Implications of Genetic Testing for Employment* (1999), Human Genetics Advisory Committee, London, para 3.19.

- the condition must be compatible with a normal life (in health terms) until an environmental factor is encountered;
- there should be a scientifically established link between the condition and potential occupational exposures; and
- there should be proven, reliable and affordable testing procedures available.[823]

10.82 The Commissioner noted that if the approach to susceptibility testing is determined on an individual-case basis, the following factors may be relevant in determining a policy response: the degree of susceptibility, the seriousness of the adverse effects, and other that inferences may be drawn from the results of the genetic testing.[824]

10.83 At present in Australia, the extent of an employer's duty to employees with genetic susceptibilities is unclear. The basic question for an employer is whether it may lawfully screen from employment those individuals with a susceptibility to a particular harm that may be found in the workplace. If it does so, will this be considered a legitimate exercise of its duty to care for the safety of its employees, or will it be considered unlawful discrimination?[825] Indeed, will courts in future consider that employers should take positive steps to determine such genetic susceptibility to exclude such individuals from potentially hazardous environments?

10.84 In certain situations, it may be possible for the employer to obtain a temporary exemption from the prohibition against discrimination under the DDA (see Chapter 5 for more detail about exemptions). However, in light of the fact that most genetic test results cannot determine with certainty whether an individual will develop a particular disease or condition, dismissal could be unnecessarily harsh and unfair to the individual. Additionally, employers could use dismissal as an alternative to providing other measures to ensure a safe workplace. According to Van Damme:

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823 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney, 48; see also M Otlowski (2001), 59–60.

824 Ibid.

825 The South Australian and Victorian legislation both provide that an employer will not be in breach of the relevant anti-discrimination legislation if the person suffering from the impairment would not be able to perform the work required adequately without endangering him or herself or other persons: *Equal Opportunity Act 1995* (Vic) s 80; *Equal Opportunity Act 1984* (SA) s 71(2)(a). In other jurisdictions, anti-discrimination legislation includes a provision permitting discriminatory conduct where it is necessary to comply with other laws. Depending on the nature of the health risk involved, this may be sufficient grounds to permit discrimination by an employer seeking to comply with its duties arising under occupational health and safety legislation: see M Otlowski (2001), para 2.8.

> [T]he 'outcome predictive value' of a test should not be confused with the preventive action needed to protect an individual's health. In pre-employment testing, for example, the career of an employee might be jeopardised if he or she were identified in a susceptibility test as being at increased risk for disease and therefore denied the job … However, the tested person might be exposed for only a few months, as the first step in a long career in other departments of the same company ... the relevance of a series of pre-employment testing practices for an individual may differ with future exposures and dose variables, and the outcome predictive value of a susceptibility test may vary with duration of exposure.[826]

10.85 The alternative position could be for an employer to conduct ongoing health monitoring and surveillance of employees involved in dangerous work activities or exposed to hazardous substances — as is recommended by the NOHSC Guidelines. If any changes in an employee's health appear (for example the onset of the early symptoms of a disorder or genetic mutations as a result of exposure to certain chemicals), the employer then may take appropriate action. This approach would be consistent with the employer's duty to ensure a safe workplace as well as its duty to make attempts to accommodate the employee under anti-discrimination legislation.

Question 10–5. Should an employer have access to an employee or job applicant's genetic information for occupational health and safety reasons (such as to determine which employees have a genetic susceptibility to a disease that may triggered by specific environmental factors or substances present in the workplace)? If so, how should access to, and use of, such information be regulated?

Costs associated with absence from work

10.86 Employers might seek access to genetic information as a means of screening out of employment those individuals with a higher likelihood of experiencing long absences from work, reduced productivity or who may claim workers compensation or other entitlements arising out of their genetic disorders.[827]

10.87 The issue is whether it is appropriate for an employer to base discriminatory employment decisions on the financial costs to the business. For example, it has been suggested that some employers currently screen applicants by checking their workers compensation records. Increasingly, instead of screening

826 K van Damme (2000), 14–15.

827 'Healthy workers cost less: they are less often absent through illness, there are lower costs for hiring temporary replacements or for training permanent replacements, and there are fewer precautions which would need to be taken to deal with health and safety risks': Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London, 56.

out applicants whose injury history demonstrates they are unable to perform the inherent requirements of the job, some employers exclude anyone with a background of workers compensation claims on the basis that the very existence of such a history indicates a condition that may pose a risk to the employer.[828]

10.88 In any case, asymptomatic individuals screened from employment on this basis will generally be protected by the WRA or the DDA unless the employer can show that it would be an unjustifiable hardship for it to accommodate the employee.

Example 10–1. A recent report of genetic testing by employers involved the US Burlington Northern and Santa Fe Railway Company, which had genetically tested employees who filed claims for a wrist condition known as 'carpal tunnel syndrome'.[829]

The company required blood tests from all employees who filed claims for the syndrome and then genetically tested the samples without the informed consent of the employees. When one employee refused to provide a blood sample after filing an injury claim, he was threatened with dismissal.

A number of employees complained to the US Equal Employment Opportunity Commission (EEOC) that they had been subjected to genetic testing without their consent. The company had been conducting the tests to determine whether the employees had a predisposition to carpal tunnel syndrome. According to evidence before the EEOC, some experts believe that a genetic defect on chromosome 17 may predispose a person to forms of the syndrome.

The company stated that it was not trying to reduce its claim costs. Rather, it argued that the testing was for safety purposes, to determine whether work practices needed to be changed. However, if the company could prove that an employee had a predisposition to the syndrome prior to commencing work, this could limit the company's liability for those injuries.

The company agreed to stop the testing after the EEOC filed a lawsuit against it, alleging that the policy violated the *Americans with Disabilities Act* (ADA), which is similar to the Australian DDA.[830]

828 M Otlowski (2001), para 3.2.1, citing a submission from the Queensland Anti-Discrimination Commissioner.

829 This is a musculoskeletal disorder that causes pain and numbness in the hand or wrist: 'Genetic Testing Lands Employer in Court', *The Sunday Times*, 11 February 2001.

830 R Ceniceros, 'Genetic Screening Faces Lawsuits' (2001) 35(8) *Business Insurance* 1, 42. See also S Gottlieb, 'US Employer Agrees to Stop Genetic Testing' (2001) 322(7284) *British Medical Journal* 449.

Question 10–6. Are there any other circumstances in which it would be justifiable for the genetic information of an employee or job applicant to be required by, or made available to, an employer?

Privacy of genetic information

10.89 Existing contractual and equitable principles will generally offer some protection to individuals in a contract of employment. Employers have an implied duty of confidence and trust toward their employees.[831] This may include a duty to respect the confidentiality of genetic information they have obtained about an employee and may preclude the employer from disclosing that information to third parties, such as insurance companies.[832] While contractual duties will not apply to job applicants who do not in fact enter into an employment relationship with the employer, the employer may instead have an equitable duty to maintain the confidence of any genetic information given.[833]

10.90 The employer's right to collect, use, store and disclose personal information is also regulated by privacy laws, including voluntary industry codes of practice and workplace relations legislation. The framework for privacy protection in Australia is detailed in Chapter 4.

10.91 In relation to Commonwealth and ACT public sector employment, the employer will be constrained by the Information Privacy Principles (IPPs) set out in the *Privacy Act*. A public sector employer may obtain existing personal information — such as genetic test results — about a job applicant or an employee only in limited circumstances. The employer may request the information from the individual directly, or may collect it by other lawful and fair means, provided that the information is necessary for, or directly related to, the employer's function or activities.

10.92 Alternatively, an employer could ask a job applicant or employee to consent to genetic testing and to the disclosure of the test results by the medical practitioner. The IPPs regulate the use, storage and disclosure of personal information held by the public sector employer.

10.93 Generally, a private sector employer's right to collect, use, store and disclose an employee's 'personal information' is regulated by the NPPs. However, s 7B(3) of the *Privacy Act* provides that an act done, or practice engaged in, by an

831 For example, see *Blaikie v SA Superannuation Board* (1995) 65 SASR 85; *Brackenridge v Toyota Motor Corporation Australia Ltd* (1996) 142 ALR 99.
832 See M Otlowski (2001), para 4.4.1.
833 Ibid.

employer organisation is exempt from the Act if the act or practice is directly related to a current or former employment relationship and an 'employee record' held by the organisation and relating to the individual. An 'employee record' is a record of personal information relating to the individual's employment by the organisation; it includes health information such as information relating to a disability, a medical condition or family medical history.[834]

10.94 This is a broad exemption to the *Privacy Act* protections. A private sector employer organisation need not comply with the *Privacy Act* in its collection, use, storage and disclosure of an individual's health information provided that its act or practice in relation to the information directly relates to a current or former employment relationship with a particular individual and that individual's employee record.

10.95 For example, if a private sector manufacturer conducts health monitoring or surveillance of its employees as a result of their exposure to hazardous substances in the workplace, these medical records will be exempt from the protection of the *Privacy Act* to the extent that they are held in an employee record (by the individual's current or former employer). Subject to any other regulation, they could potentially be disclosed to other employers or agencies without breaching Commonwealth privacy law.

10.96 However, personal information collected in relation to a job applicant is *not* exempt from the *Privacy Act* because it does not relate to a current or former employment relationship. If the applicant is unsuccessful, this information will continue to be protected. But if he or she is employed by the private sector employer, the information will become part of the 'employee record' and will be exempt from the privacy protection for the term of that employment, and after it has ceased.

10.97 Private sector employee records were exempted from the *Privacy Act* protections because the federal government considered that this was more properly a matter for workplace relations legislation.[835] However, serious concerns have been raised that current legislation does not provide the same level of protection as would be provided under the *Privacy Act*.

10.98 For example, s 353A of the WRA provides that the government may make regulations relating to employee records. Regulations 131K and 131L of the WRA permit employees to access, copy and correct employee records — but these have been described as 'time and wages' records. They do not cover the broad

834 *Privacy Act 1988* (Cth) s 6(1).

835 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 12 April 2000, 15077 (The Hon Daryl Williams, Attorney-General).

range of information that may be collected as an 'employee record' under the *Privacy Act*.[836]

10.99 Additionally, as privacy protection is not an 'allowable matter' listed under s 89A(2) of the WRA, it is not a matter over which the Industrial Relations Commission has jurisdiction to make an award.[837] Finally, the Australian Council of Trade Unions (ACTU) has suggested that, while privacy issues could be included in agreements made under the WRA, in practice this is not generally the case.[838]

10.100 Margaret Otlowski has commented on current regulation under workplace relations legislation as follows:

> Viewed objectively … 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 …[839]

10.101 By contrast, the Australian Chamber of Commerce and Industry (ACCI) has argued that the exemption of 'employee records' is appropriate. In its submission to the House of Representatives Standing Committee on Legal and Constitutional Affairs, it argued that employment records are almost always maintained by employers to comply with statutory requirements, the objects of which are to protect employees. The maintenance of employee records does not involve any invasion of privacy and should be understood as a precondition of employment. They argued that these records are maintained to protect the interests of both the employers and employees, and privacy regulation of these records is already covered under workplace legislation.[840]

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836 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.

837 M Otlowski (2001), para 4.4.3.

838 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, 28.

839 M Otlowski (2001), para 4.4.3.

840 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; see also Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), Parliament of the Commonwealth of Australia, 19, quoting Australian Chamber of Commerce and Industry, *Submission to*

10.102 The ACTU argued that significant areas of employee records should be protected, including information relating to health. It argued that the WRA does not deal adequately with privacy issues, and the regulations provide no protection against disclosure of employee information.[841] As a result of the exemption, employers would be virtually free to disclose information about sensitive issues relating to employees to other persons, so long as such disclosures were directly related to a current or former employment relationship (between the employer and the individual). Employees could then be disadvantaged by the collection of such sensitive, and possibly inaccurate, information about them.[842] The Australian Privacy Charter Council (APCC) and the federal Privacy Commissioner also opposed the exemption of employee records from the *Privacy Act*.[843]

10.103 The House of Representatives Standing Committee on Legal and Constitutional Affairs concluded that it was not satisfied that existing workplace relations legislation provides adequate protection for the privacy of private sector 'employee records'. It considered that the terms of the exemption were unnecessarily broad, allowing an employer to provide a great deal of potentially very sensitive information to other people, particularly other employers.[844] In relation to 'health information' in particular, the Committee concluded:

> The Committee is also strongly of the view that 'health information' should be removed from the definition of 'employee record'. Given the nature of much health information, it is inappropriate for inclusion in such an exemption and inconsistent with the more specific protection given to health information and sensitive information elsewhere in the Bill.[845]

10.104 As noted in Chapter 4, a federal government review of existing Commonwealth, state and territory laws is currently being conducted to consider the extent of privacy protection for employee records, and whether there is a need for further measures.[846]

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the Senate Legal and Constitutional References Committee Inquiry into Privacy Issues Including the Privacy Amendment Bill 1998.

841 Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), Parliament of the Commonwealth of Australia, 20.

842 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, 30.

843 Senate Legal and Constitutional References Committee, *Privacy in the Private Sector: Inquiry into Privacy Issues Including the Privacy Amendment Bill 1998* (1999), Parliament of the Commonwealth of Australia, Canberra, 20.

844 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, 34.

845 Ibid.

846 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', 29 November 2000.

10.105 Finally, it is important to note that an employer may ask an employee or applicant to consent to undergo a genetic test; alternatively, an employer may seek an individual's consent to the disclosure of existing information, for example, from a medical practitioner.[847] In light of the considerable power imbalance inherent in the employment context, it is likely that employees and applicants will feel bound to provide such consent to protect their job and career prospects.[848]

Question 10–7. In relation to privacy protection for employees under the federal *Privacy Act*, with respect to genetic information:

- Are Commonwealth public sector employees adequately protected?
- Are private sector employees adequately protected, in light of the 'employee records' exemption?
- Is there a need for uniform privacy regulation across public and private sector employment?

Public interest issues

Employee's right 'not to know'

10.106 An important issue in genetic testing is whether the individual has a right 'not to know' that he or she has a genetic condition. This issue was highlighted in an Australian case involving a young man with a family history of Huntington's disease (HD) who applied for a position in the public sector. He had decided not to undergo a genetic test for the HD gene on the basis that, as there is no known cure for the disease, he did not wish to know whether he had it. He was reportedly informed that he would only be employed if he undertook a genetic test.[849] This approach interferes with the man's right not to know that he has the condition — a right that is all the more important in relation to conditions for which there is no cure.[850]

847 J Butler and R McCallum (2001), 5; however, several States and Territories have prohibited requests for information on which unlawful discrimination could be based: see *Anti-Discrimination Act 1991* (Qld) s 124; *Equal Opportunity Act 1984* (SA) s 66O; *Anti-Discrimination Act 1992* (NT) s 26.

848 See M Otlowski (2001), paras 2.5, 3.2.1; see also Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney, 77.

849 S Taylor, 'A Case Study of Genetic Discrimination: Social Work and Advocacy Within a New Context' (1998) 51(4) *Australian Social Work* 51, 53.

850 Indeed, the UK Human Genetics Advisory Committee recently recommended that employers not have the right to require individuals to take genetic tests in the employment context because this would interfere with their 'right not to know': Human Genetics Advisory Committee, *The Implications of Genetic Testing for Employment* (1999), Human Genetics Advisory Committee, London, para 3.19.

Deterrence from undergoing testing

10.107 Concerns have been raised that, if there is a legal duty to disclose the results of a genetic test to an employer (or insurer), this may in fact deter an individual from undergoing the test in the first place. The concern is that individuals may refuse to undergo genetic testing even though it may identify a condition or predisposition that will be responsive to treatment. Indeed, Otlowski has commented that a number of health care providers had advised that they already see people refusing to take health-related genetic tests because they are worried about the impact the results may have on insurance and employment.[851]

Genetic underclass

10.108 Finally, there may be a public interest in protecting society against the development of a 'genetic underclass'. This is a class of people who are asymptomatic but have tested positive to susceptibility to monogenic or multifactorial diseases. While they are capable of working, they may be routinely excluded from any form of meaningful employment on the basis that they may in future be unfit to perform certain work activities. The public policy questions include whether it is acceptable to the Australian community to allow such discrimination in employment, and whether the social welfare system can support a new class of individuals who are thus rendered unable to support themselves financially.[852]

Regulation in other jurisdictions

10.109 Overseas jurisdictions have taken differing approaches to regulating the use of genetic information in the employment context.

Europe

10.110 In Norway and France, genetic testing for employment purposes is illegal. In Austria, employers are prohibited from requesting, collecting or using information derived from genetic tests.[853] In the Netherlands, Spain and Denmark, genetic tests can be used by employers where there is an unambiguous health requirement for the job or where the test is required for the protection of the employee's health in the workplace.[854]

851 M Otlowski (2001), para 3.2.1.
852 Ibid, para 3.2.1.
853 Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London, 40.
854 Ibid.

10.111 The United Kingdom does not have any specific legislative prohibition on the use of genetic information in employment. While discrimination on the basis of an existing disability of genetic origin is prohibited by the *Disability Discrimination Act 1995*, there is no protection for asymptomatic employees.[855] This area is currently under review by the UK Human Genetics Commission.

The United States

10.112 In the absence of comprehensive public health insurance schemes, the majority of Americans rely on employer-provided health insurance to meet their health care needs. Thus, issues of workplace discrimination have an unfortunate double effect in the US. The potential costs of providing health care coverage for employees provides a considerable incentive for employers to seek to rely on genetic information in order to screen out persons susceptible to genetic disorders.

10.113 At the federal level, the *Americans with Disabilities Act 1990* (ADA) provides limited protection against employment discrimination. Under the ADA, employers may inquire as to the applicant's ability to perform job-related duties, but may not conduct a medical examination or make inquiries as to whether an applicant has a disability, or as to its nature. However, after a conditional offer of employment has been made, employers may require applicants to undergo examinations and may make employment subject to these results.

10.114 An Executive Order signed by President Bill Clinton prohibits federal departments and agencies from using genetic information in any action involving hiring or promoting.[856]

10.115 By the end of 2000, 23 American States had enacted legislation relating to the use of genetic information in employment. These statutes vary considerably in the scope and in the protection they provide; however, the clear trend of recent legislation is toward the provision of more comprehensive protection against discrimination on the basis of genetic information.[857]

855 Ibid, 39.

856 President Clinton signed this in February 2000. The *Genetic Non Discrimination in Health Insurance and Employment Act 1999* (US) is a Bill which has been introduced into Congress to extend the protections provided by the Executive Order to the private sector.

857 D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London at 47.

11. Insurance

Contents

Introduction

11.1 The terms of reference ask the inquiry to consider the current and potential uses of genetic information in the insurance and superannuation industries.

11.2 The purpose of insurance is risk distribution — that is, to spread risk across a large pool of individuals.[858] People who want to avoid or spread risk use insurance as a means of protecting against potential future loss. Insurance provides a mechanism by which individuals who pay an agreed sum, known as a 'premium', can be indemnified against or compensated financially for future events that may cause loss.

11.3 The Australian insurance industry is a major market. General insurers managed 37.6 million policies during 2000, with $14.6 billion collected in premiums and $12.2 billion paid in claims.[859] During the 1999–2000 financial year life insurers operating in Australia received $41.9 billion in premiums and paid $33.4 billion in claims.[860]

11.4 The Commonwealth's power to regulate insurance, expressly conferred by s 51(xiv) of the Constitution, supports a comprehensive system of regulation of the insurance industry. In practice, insurance law is a large and complex area, governed by a patchwork of federal, state and territory statutes, industry codes, standards and guidelines.[861] In the case of most personal insurance contracts, the *Life Insurance Act 1945* (Cth) (now superseded by the *Life Insurance Act 1995* (Cth) (LIA)) was interpreted to 'cover the field' of insurance regulation over

858 J Outreville (1998), 147.

859 Australian Prudential Regulation Authority, *General Insurance Trends December Quarter 2000* (2001), Australian Prudential Regulation Authority, Sydney.

860 Note, 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), Australian Prudential Regulation Authority, Sydney.

861 This chapter does not restate the law and practice governing all types of insurance in Australia but is limited to those areas of personal insurance and superannuation that currently, or may in future, collect and use genetic information.

certain matters, such as the establishment of life insurance companies, actuarial investigation and rate of premiums charged.[862] Because inconsistent state (and effectively territory) legislation is invalid where a federal law is said to cover the field, state anti-discrimination legislation has relatively little role in regulating insurance.[863]

11.5 At the federal level, major legislation affecting this area includes:

- the *Insurance Contracts Act 1984* (Cth);
- the *Life Insurance Act 1995* (Cth);
- the *Insurance (Agents and Brokers) Act 1984* (Cth) and the *Financial Services Reform Act 2001* (Cth) (due to commence on 11 March 2002);
- privacy laws, especially with its extension to the private sector from 21 December 2001[864] (see chapter 4, above); and
- anti-discrimination laws, including the *Disability Discrimination Act 1992* (Cth) (see chapter 5, above).

11.6 Insurance in Australia is commonly divided into three categories: life, health, and general insurance. Life insurance encompasses contracts that provide payment upon death, continuous disability or trauma. 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 — for example, product liability, travel insurance and professional indemnity insurance.

11.7 Collection and use of genetic information is likely to have the greatest impact on 'personal insurance policies' — that is, policies in those areas that already collect or use other health information, are mutually rated, and use predictive health information as a component of the underwriting process.[865]

11.8 Personal insurance policies that may collect or use genetic information include:

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862 *Australian Mutual Provident Society v Goulden* (1986) 160 CLR 330. See also *Hope v NIB Health Funds* (1995) EOC 92–716, 78,390.

863 See the Constitution, s 109.

864 See the *Privacy Act 1988* (Cth) and the *Privacy Amendment (Private Sector) Act 2000* (Cth).

865 'Underwriting' is the process of assessing whether to accept an insurance proposal (application) and, if so, on what terms. Underwriting is often referred to as rating. 'Mutually rated' insurance describes a method adopted by insurers to underwrite. Mutually rated personal insurance contracts are characterised by the use of mortality risk (death) and morbidity risk (disability and other health risks) information.

- life insurance;
- income protection insurance, including sickness and accident insurance;
- total or permanent disability insurance;
- critical illness insurance;
- health insurance;[866]
- travel insurance;
- annuities; and
- superannuation, to the extent that a plan includes an insurance component that is mutually rated.

11.9 Insurance companies, especially life insurers, have collected and used family medical histories for well over a century.[867] In recent times, however, the development of the potential to use information derived from the direct analysis of DNA sequence (genetic testing) has placed a greater spotlight on the collection and use of genetic information by the insurance industry in Australia, and overseas.[868]

866 Public (Medicare) and private health insurers collect health information from insureds. However, for underwriting purposes, community rating restricts insurers' use of this information.

867 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London 81 (Memorandum submitted by S Raeburn).

868 A number of national and international inquiries have considered issues arising from the use of genetic information in insurance: 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) ; House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London; Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London; Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance* (1997), Human Genetics Advisory Commission, London; Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney; Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (1993), Nuffield Council on Bioethics, London. Much scholarly discussion has been published about the use of new genetic test information in insurance: See, particularly, T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347; D Keays, 'The Legal Implications of Genetic Testing: Insurance, Employment and Privacy' (1999) 6(4) *Journal of Law and Medicine* 357; K Barlow-Stewart (2000); M Otlowski, 'Resolving the Conundrum: Should Insurers be Entitled to Access to Genetic Test Information' (2000) 11 *Insurance Law Journal* 193.

11.10 It does not appear that the collection and use of DNA test information is currently widespread in the Australian insurance industry[869] and steps have been taken by life insurers to clarify the industry's position regarding its use.[870] However, recent studies conducted in Australia by Kristine Barlow-Stewart and David Keays presented anecdotal evidence of alleged acts of discrimination in insurance and superannuation based on genetic information,[871] which highlighted public concern about current and future practice in this area.

Insurance concepts

11.11 An understanding of the nature of the insurance industry, terminology and underwriting practice is essential to appreciate fully the likely consequences of incorporating or excluding genetic information from insurance practice.

Insurance contracts (policies)

11.12 Insurance companies (insurers) provide the service of risk distribution. A person who transfers risk to an insurer is referred to as 'an insured'. An insurance policy is the embodiment of the contract between the insurer and insured. In law, the nature of the insurance contract is one of 'utmost good faith', which in part means that the insured has a special duty at common law[872] and under legislation[873] to disclose all information that is or which the insured knows, or ought to know, to be relevant to the insurer. In practice, disclosure occurs when applicants for insurance answer questions posed by insurers in an insurance application form or proposal.

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869 IFSA, *Consultation*, Sydney, 23 April 2001. See T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347 351, which suggests that insurers have been cautious in adopting the use of new genetic test information for numerous reasons, including: fear of negative reaction, prohibitive cost of genetic testing and complexity of the information gained from genetic testing. See also R Braun, 'Keeping Life Insurance Affordable in the Era of Genetic Medicine' (1999) 53 *Journal of Financial Service Professionals* 46.

870 In Australia, the peak body representing life insurers, the Investment and Financial Services Association (IFSA), has produced a voluntary industry policy on genetic testing in life insurance: see Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999). IFSA has commissioned the Institute of Actuaries of Australia (IAAust) to collect data on the number of genetic tests that all life companies writing retail risk business in Australia collect and use. Of the 25 life offices surveyed, 17 offices reported that 54 applications had been received where genetic test information was disclosed and analysed. Fifty of the applications received had used genetic information to underwrite. Of these, 23 were accepted on standard terms, 14 were accepted on non-standard terms, three were deferred, six declined and four partially declined: Institute of Actuaries of Australia, *Final Draft of IFSA Report [IFSA Genetic Test Survey]* (2001), Investment and Financial Services Association, Sydney.

871 See K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, 253, which identifies 45 cases of alleged discrimination in life insurance, income protection insurance, trauma insurance, superannuation, loan insurance, travel insurance and health insurance. See ch 2 for a discussion of the Barlow-Stewart and Keays studies and ch 4 for a discussion of discrimination law as it applies to genetic information.

872 *Carter v Boehm* (1766) 3 Burr 1905, 1909 (Mansfield LJ).

873 *Insurance Contracts Act 1984* (Cth), s 21. Disclosure, an element of the duty of utmost good faith, is discussed below. See also, Australian Law Reform Commission, *Review of the Marine Insurance Act 1909*, Report 91 (2001), Commonwealth of Australia, Sydney, ch 10.

Agents and brokers

11.13 In completing an insurance proposal, insureds often receive advice from an insurance agent or broker. An insurance agent acts exclusively on behalf of an insurer, marketing and selling insurance policies to insureds.[874] A broker acts on behalf of insureds, providing advice on which products from a range of insurers (and sometimes from other financial services providers) best suit their clients' needs.[875]

11.14 The *Insurance (Agents And Brokers) Act 1984* (Cth) (IABA) currently regulates most of the practices adopted by insurance advisers. The federal Parliament has recently passed the *Financial Services Reform Act 2001* (Cth) (FSRA), which will replace the IABA, commencing 11 March 2002. The FSRA is aimed at providing for the uniform regulation of all financial products; a single licensing framework for all providers of financial advice, including insurance brokers and agents; and minimum standards of conduct for all such financial advisers.

11.15 Advisers provide insurance applicants with guidance on matters relating to the proposal, including the choice of insurance policy and the interpretation of questions in the proposal. Advisers also assist insurers by providing a report about the insurance applicant.[876] When advising applicants about underwriting matters, advisers usually rely on information provided by the insurer. Insurers generally provide advisers with guidelines to provide applicants with information and advice about the effects that some risk factors may have for insurance underwriting. For example, if an applicant has experienced clinical depression, agents generally consult an 'advisers guide' to give the applicant an idea of the type of premium loading or exclusions that might apply to different types of insurance.

11.16 The primary role of advisers is to explain to applicants how to fill in the proposal forms correctly. While advisers are not expected to provide specific interpretation or counselling about genetic test information, they have a positive legal duty to ensure that they do not mislead the insured.[877] Thus, they must ensure

874 Agency is not strictly limited to natural persons. Banks or building societies often act as 'tied agents', finding customers through the ordinary course of business and only recommending one particular insurer: R Brackenridge and W Elder (1998), 183–4.

875 Ibid. Note that, under new legislation, the terms 'agent' and 'broker' will disappear and will be replaced by the label 'authorised representative': *Financial Services Reform Act 2001* (Cth).

876 B Speering, *Consultation*, Sydney, 21 May 2001.

877 See generally *Rocco Pezzano v Unity Insurance Brokers* (1995) 8 ANZ Ins Cases ¶61-288. See also IABA s 13, which provides that intermediaries shall not intentionally mislead the insured.

that they are familiar with how insurance companies deal with genetic risk factors.[878]

11.17 Advisers will need to keep up to date with developments in genetic testing and information. For example, a life insurance applicant may ask an agent about the insurance implications of a genetic test that reveals carrier status for the sickle cell anaemia gene.[879] In such a case, advisers have a responsibility to advise applicants adequately about the disclosure requirements.

11.18 The agent or broker also should be able to advise the applicant generally on the impact that carrier status may have on the acceptance of the insurance proposal or the possibility of premium loading. Although the advice that the insurance agent or broker provides does not necessarily reflect the final underwriting judgment, it may nevertheless impact upon the applicant's decision whether or not to continue with the proposal, even before it reaches the insurer.[880] There is a suggestion that some of the instances of alleged discrimination against insureds found in the Barlow-Stewart and Keays studies may have resulted from the failure of some agents and brokers to understand the nature of genetic information and thus to advise clients properly about their insurance prospects and options.

11.19 Agents, brokers and other significant participants in the insurance industry would no doubt benefit from a better understanding of the different types and implications of genetic information. Providing education about new technologies in genetics and their effects on insurance is primarily a matter for the insurance industry itself, but it may be seen as a responsibility shared with government. For example, the UK Government has established the Genetics and Insurance Committee (GAIC), an independent review body with the specific role of evaluating the scientific and actuarial relevance of genetic tests proposed for use by the insurance industry in setting insurance premiums (see below for a discussion of the role of GAIC).

878 Insurers prefer that advisers do not give specific advice to applicants as they are not trained to underwrite. However, they can use the 'advisers guide' to brief their clients on potential or likely outcomes to certain specific conditions, occupations or vocations. The Life Insurance Code of Practice (Life Code) requires advisers to be familiar with how the life company they represent processes applications and claims, however it does not require them to know how to underwrite an application. The Life Code started on 1 September 1995 by the Insurance and Superannuation Commission (ISC) is now a circular of the Australian Securities and Investment Commission (ASIC), but does not have the force of law. The Life Code will be in place for a further two years after the commencement of the FSR (11 March 2002).

879 An inherited (autosomal recessive) disorder characterised by lifelong breakdown of red blood cells (haemolytic anaemia) and a variety of complications resulting from increased susceptibility to infection and a tendency to blockage of blood vessels: National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (2000), NHMRC, Canberra, 70.

880 Many proposal forms ask whether the intending insured has ever been refused cover and whether any insurer has ever cancelled or refused to renew a contract. Questions in proposal forms such as this may deter insureds from proceeding with an application if they lack confidence in the way that their genetic information will be used to underwrite: Australian Law Reform Commission, *Insurance Contracts*, Report 20 (1982), Australian Government Publishing Service, Canberra, 130.

Question 11–1. Is the information that agents and brokers currently receive from insurers adequate for them to advise insurance applicants effectively about the implications of genetic information? If not, what improvements could be made to the provision of such information?

The insurance proposal (application)

11.20 The insurance application sets out the terms and conditions upon which the insurer is prepared to consider and accept an application for insurance. A detailed information brochure that outlines the key features of the insurance product usually accompanies the proposal. The proposal form presents applicants with questions that allow insurers to quantify the risk relevant to the insurance sought. Some risks, while relevant for one type of insurance, may be irrelevant for others. For example, a medical history of lower back pain may be highly relevant for income protection insurance (since back pain may lead to time off work), but it may be somewhat less relevant to a life insurance policy (if the back condition does not tend to shorten lifespan). The questions asked by the insurer in the proposal, therefore, depend largely upon the type of insurance being sought. Likewise, the way that insurers are allowed to use the information gathered from insurance applications depends on the law regulating the type of insurance being sought (that is, life, health or general insurance).

Underwriting

11.21 Insurance proposals provide insurers with a key tool for determining whether they will accept insurance applicants and, if so, upon what terms. The process of obtaining and evaluating information about an applicant to determine on what terms insurance will be accepted is called 'underwriting'. Underwriting is based on actuarial data, following either of two approaches: 'mutuality' or 'community rating'.

The role of actuaries

11.22 The *Life Insurance Act 1995* (Cth) (LIA) regulates life, trauma (also known as critical illness), total or permanent disability, continuous disability policies and annuities in Australia.[881] The LIA provides for an actuarial standards body that is authorised to adopt or incorporate standards for underwriting practices as set by the Institute of Actuaries of Australia (IAAust).[882] Subject to the approval of the federal regulator, the Australian Prudential Regulation Authority (APRA),

881 See 'Life policy' as defined in LIA s 9.

882 The body is known as the Life Insurance Actuarial Standards Board (LIASB); see LIA s 100–101, and Div 4 generally.

all life insurers must have an actuary who is a Fellow of IAAust and must comply with the prescribed actuarial standards.[883]

11.23 In assessing different risk characteristics, insurers rely on medico-actuarial data, statistical data and informed judgment from actuaries and chief medical officers. The way that actuaries assimilate risk information with actuarial data is critical to the process of underwriting. The timely translation of genetic research findings about risk into actuarial standards and manuals is an issue raised by genetic information.

11.24 The key actuarial standards set by IAAust consist of graduated mortality and morbidity tables.[884] The tables are usually officially updated every four or five years, but claims experiences for individual years are published in the interim. Through other means, modifying influences can be factored in when applying the actuarial tables.[885] The time lag between official updates in published actuarial data raises a specific issue for genetic information — that is, whether the most current genetic research findings are translated into practice in a timely manner.

11.25 Consultations with the industry have revealed that reinsurers are moving towards online global manuals for their insurance company clients.[886] These manuals can be updated regularly with the most current information regarding risk.[887] In practice, this is an important development, especially with respect to the possible use of new genetic testing technologies, where information regarding the reliability and relevance of various genetic predispositions remains developmental.

Mutuality

11.26 Mutuality-based underwriting operates on the principle that insureds with similar risks should be treated in a similar way. The amount of insurance provided and the price insureds pay for that insurance is proportional to the risk involved. Under the mutual principle, insurers pool insureds 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 insureds rated at extra risk. Insureds that are declined insurance present a risk that the insurer considers is so great that they are uninsurable (at least at a realistically affordable premium).

883 LIA, s 93 and 96. See LIA, Div 3 generally, which also prescribes the powers and obligations of the appointed actuary.
884 IAAust, Australian Insured Lives Table 1995–1997; IAAust, Actuaries Disability Table 1989–1993 (IAD 89–98).
885 M Otlowski (2001) 13.
886 See below for a discussion of the role of reinsurers.
887 Swiss Re, *Consultation*, Sydney, 2 July 2001.

11.27 In mutually rated insurance, the amount of insurance sought and the particular characteristics of applicants are taken into account when rating. In personal insurance policies, the risk rating reflects the average cost of mortality or morbidity benefits provided by the policy. For example, age and sex will almost always be considered as relevant characteristics. However, according to the type of insurance, other factors such as occupation, family medical history, current health condition, lifestyle (eg a recreational preference for skydiving or race car driving), and smoking habits also may be considered.[888] Insurers then pool individuals according to similar risks, designate a risk rating for those insureds that is based on the average, and apply this average to the particular characteristics of the individual insured.

11.28 The law sometimes imposes limits on the information that insurers can use to risk rate insureds despite the perceived actuarial relevance of the information. For example, 'race' is an attribute that insurers may not use to discriminate between insureds.[889] Thus, the sad fact that life expectancy among Aboriginal Australians is markedly lower than for the population at large is not a matter that insurance companies may properly take into account in underwriting a policy for an indigenous client, despite its actuarial relevance. (A detailed discussion of the operation of discrimination law is considered in chapter 4).

Exclusions

11.29 In some cases, insurers offer exclusions to those insureds that would otherwise be considered uninsurable or underwritten with a loading. Exclusions are terms in the policy that list causes for claims that the insurer will not pay. For example, if an insured with an existing back problem would ordinarily be offered income protection insurance with a loading on the premium, the underwriter might choose to offer the insured standard terms if the back problem was excluded from coverage of the policy. Similarly, a travel insurance policy may be offered at the standard rate if conditions such as diabetes are excluded from coverage.

Deferred policies

11.30 A commonly used approach in policies where a risk factor is expected to reduce over time is to defer the policy until the risk factor has reduced. For example, if an applicant is receiving treatment for a medical condition, an insurer may offer to defer the policy until the medical condition has been treated and brought under control, and the applicant can then be re-rated. However, a disadvantage in this approach is that in the interim period no cover is provided to the insured or, if provided, it is with exclusions.

888 R Brackenridge and W Elder (1998) 181.

889 This is because the *Racial Discrimination Act 1975* (Cth) does not include exemptions in the area of insurance.

Fixed term policies

11.31 Another alternative to loading or denial of insurance for insureds who present extra risk is to offer fixed term insurance. For example, fixed term insurance for income protection might be offered where the insured demonstrates symptoms of a late–onset disease. In such cases, an insurer might offer income protection coverage for a fixed term of five or 10 years, underwritten on the basis that the condition is not likely to occur during that period.

Risk calculation in mutual insurance

11.32 The calculation of insurance risk depends upon:

- a statistical assessment of the chance that a claim will arise, based on the features of the individual insured; and
- the amount that will be paid if a claim is made.[890]

11.33 Actuaries specialise in tabulating statistics that assist underwriters in applying risk ratings to insurance policies. They rely upon a method of converting risk factors into numerical values (numerical rating system)[891] which, when applied to certain variables, provides an overall summary of the risk to be insured, referred to as the standard baseline risk or standard rating for an insurance product.[892] Unfavourable health risk factors expected to produce additional risk are usually added (loaded) to the standard baseline risk as a percentage of the standard risk.[893] Each risk factor has a rating that is expected to cover the additional risk (claims cost) that the factor causes relative to the norm.

11.34 In developing their manuals, actuaries rely upon various sources of data to determine additional risk from various risk factors, including assessment of the historical experience gained from reviewing insurance portfolios (domestic and

890 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.

891 See R Brackenridge and W Elder (1998), 61–88 for an account of the methodology applied in the numerical rating system.

892 The standard base-line risk varies between insurers, according to the each insurer's experience, strategy and objectives. Some countries (eg USA) have a 'preferred risk' class, which offers a discount on the standard rate for those insureds with favourable characteristics (eg non-smoker). Australian life and disability insurers currently operate under a single standard risk class, which does not discount based on favourable characteristics: IFSA, IAAust, *Consultation*, Sydney, 19 June 2001.

893 Percentage loadings are generally used where the risk factor is expected to produce additional risk in some fixed proportion of the standard risk (ie, if the standard risk increases, then the additional risk from the risk factor also increases). The majority of medical risk factors would fall under this type of loading. Dollar loadings are an alternative, these are used when the risk factor causes an increase in risk that is not related to the underlying standard risk (ie, if the standard risk increases the additional risk does not change). Examples of this are hazardous pursuits where the additional risk is an accident risk.

global), and surveying the literature on advances in medical research and treatment.[894]

11.35 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'.[895] Most Australian insurance companies do not reinsure the large majority of policies that fall below a certain monetary limit.[896] For example, the average sum insured on a term life policy is between $150 000 and $250 000, while reinsurers tend to be used (according to 'treaty' arrangements with primary insurers) only for policies that exceed $1 million in coverage.[897]

11.36 Nevertheless, reinsurers play a critical role in formulating basic underwriting manuals because of the large amount of data that they obtain through their dealings with many insurance companies globally, and thus their exposure to a wide range of clients and circumstances. Reinsurer manuals are generally used as a guideline across both those policies that fall within reinsurance treaties and those that do not, in order to maintain consistency in underwriting practice.[898]

11.37 Underwriters are employed by insurers to assess the risk factors that insureds disclose in the proposal 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 reinsurer 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 proposal.

11.38 A relevant issue for this inquiry is how insurers and reinsurers assimilate genetic information for underwriting purposes. Genetic information, including new techniques in analysis of DNA, 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 detail later in this chapter.

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894 Some sources of data and abstracts of various research studies relied upon by insurance underwriters include: R Brackenridge and W Elder (1998); Journal of Insurance Medicine; American Academy of Insurance Medicine; International Journal of Epidemiology.

895 Risk sharing between the insurer and reinsurer is said to be essential as it guards against large fluctuations in profits when insurers are faced with multiple claims in one area (eg, those caused by a natural disaster) and helps to maintain liquidity standards: J Outreville (1998).

896 IFSA, IAAust, *Consultation*, Sydney, 19 June 2000.

897 Ibid.

898 Ibid.

Pricing, mutuality and adverse selection

11.39 One of the key roles of the actuary is to ensure that insurers attach the right pricing standards to insurance products. Pricing insurance requires not only an evaluation of the insured's risk but also assessment of corporate strategy, profits and other transaction costs associated with distributing and servicing insurance policies.[899] Under-rating or over-rating the risk that insureds bring to the pool of insurance can have adverse impacts. Genetic information raises a significant pricing issue for mutual insurance as the current scientific and actuarial understanding of genetic test information has the potential to result in over- or under-rating risks.

11.40 Over-rating risks and thus charging excessive premiums will reduce the demand for insurance. Under-rating risks and charging a premium rate below the actual risk that insureds bring to the pool could result in a situation referred to as adverse selection. In an adverse selection environment, the value of recoverable claims exceeds the premiums charged because the calculated risk underestimates the actual risk.[900]

11.41 Adverse selection can arise when the insurer misclassifies the risk of the insured, for example, when:

- the insured does not disclose or misrepresents his or her risk and the insurer is unable to underwrite the full extent of the real risk; or
- the insurer chooses not to underwrite the full extent of the insured's risk; or
- the law does not allow insurers to use the insured's risk factors to underwrite.

11.42 Non-disclosure or misrepresentation of the risk that the insured brings to the contract of insurance can result in adverse selection. Adverse selection in this sense arises when 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 insured may obtain insurance at a rating that does not reflect the risk that he or she brings to the life insurance pool.

11.43 Insurers do not always underwrite to the full extent of the insured's risk. In the risk classification process, each company determines the classes of risk to be declined, to be issued with a specified extra premium, or to be issued at the

899 IFSA, IAAust, *Consultation*, Sydney, 19 June 2001; Genetics and Insurance Committee, *Annual Report*, 2000 (1999), Department of Health, London.

900 R Brackenridge and W Elder (1998), 30; J Outreville (1998), 152.

standard rate.[901] These risk classes differ among insurers according to their own experience, corporate strategy and objectives. For example, one insurer may take a broad view of issuing insurance at standard rates to as many persons as possible whereas another may be more selective. The former is likely to charge their 'standard' lives a higher risk premium because the pool includes some relatively poorer risks, whereas the latter is likely to charge a lower 'standard' premium to their smaller pool of 'standard lives who have, on average, a better risk profile. In general, insurers cannot be over-selective without discouraging the efforts of their agents and brokers, who are anxious to offer a reasonable premium to most of their customers.

11.44 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 into the pool is outweighed by the lower costs of underwriting and administration.[902] Insurers operate within certain medical underwriting limits, such as those published by the RGA Reinsurance Company of Australia.[903] The underwriting limits take into account a number of variables, including the amount insured, the type of insurance, age, and the health information sought, such as an examination by a general practitioner or a specialist.[904]

11.45 As a general rule, insurers will request or require more information for underwriting purposes where the amount insured is higher. Therefore, the extent of information sought may vary from a few questions about medical history on a proposal for a small amount of coverage, to very extensive information — including one or more full medical examinations, blood and urine tests, ECG[905] and chest X-ray — on policies involving large amounts, particularly for older applicants.[906]

11.46 Another reason that an insurer may choose not to underwrite to the full extent of the risk is to remain competitive with other insurers. An insurance company's approach to underwriting might be such that it is prepared to accept some applicants with significant additional risks on standard rates as part of its

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901 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).

902 A Macdonald, *Human Genetics and Insurance Issues*, Genetics and Insurance Research Centre, <http://www.ma.hw.ac.uk/~angus/papers/aberdeen.pdf>, 1 August 200110 Septmber 2001.

903 RGA Reinsurance Company of Australia, *Medical Underwriting Limits (Life/Crisis/TPD)* (2000).

904 Ibid. For example, the medical underwriting limits for requesting a general practitioner examination for a 30 year old applying for Life, Trauma and Total and Permanent Disability in 2000, ranged between $600 000 and $1 250 001.

905 An electrocardiogram (ECG) is a recording of electrical activity of the heart on a moving paper strip.

906 R Brackenridge and W Elder (1998), 214.

broad market strategy of expanding risk pools and capturing market share.[907] As has been witnessed in Australia in recent times, however, poor assessment of these risks by insurers can result in significant losses — or even insolvency.

Community rating

11.47 An alternative approach to mutuality in underwriting is community rating, with individuals paying either a flat rate or a sliding means-based premium, regardless of particular personal risk factors. Although this risk is shared collectively across the entire population pool of insureds, actuaries and underwriters still need to assess risk for community-rated insurance, to determine the premium that each insured must pay to sustain the pool.

11.48 A disadvantage in community rating is that some insureds with lower risks — such as young, healthy individuals — may pay more for an insurance product than they would under a mutuality-rated product. As a result, they may abstain from insurance or drop-out, skewing the pool towards people with a higher degree of risk, which in turn leads to higher premiums. This cycle was evident in private health insurance in Australia, which led the federal government to introduce measures in recent years to provide subsidies and tax incentives to join private health insurance.

11.49 The major advantages in community-rated insurance are access and social equity. No applicants can be denied insurance, as may happen with mutuality-rated products. Access to insurance for those with higher risks is offered at more affordable premium rates. Community-rated insurance does not limit access to those individuals who can afford to pay higher premiums for higher risks.

Health insurance and community rating

11.50 Community rating is the basis of the Australian health care system — Medicare and the private health insurance industry.

11.51 Medicare forms part of a comprehensive national public health scheme that provides all Australian citizens and permanent residents with cover for basic hospital, medical and pharmaceutical services. The Health Insurance Commission (HIC), a federal government agency, administers Medicare.[908] While a large

907 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, 62 (Memorandum submitted by Genetics Group, Faculty and Institute of Actuaries).

908 Other government programs that HIC is responsible for administering include: Pharmaceutical Benefits Scheme (PBS); Australian Childhood Immunisation Register (ACIR); General Practice Immunisation Incentives (GPII); Practice Incentives Program (PIP); 30% Private Health Insurance Rebate; Hearing Services; Compensation Recovery Program and Commonwealth Childcare Rebate: Health Insurance Commission, *Mediguide, Understanding Medicare — A Guide for Practitioners and Practice Staff*, 7th Edition (2000), Health Insurance Commission, Tuggeranong, 1.

amount of health information is collected under Medicare arrangements, individuals are not subject to mutually based underwriting. Medicare is financed through progressive income tax and an additional income-related levy for high-income earners,[909] as well as allocations through the federal budget process.

11.52 The private health insurance industry operates as a complement to Medicare. Individuals may choose to enter private health insurance agreements with one of the 44 registered health insurers who insure hospital treatment and ancillary health benefits.[910] Current federal Government policy encourages Australians to undertake private health insurance,[911] especially those on higher incomes.[912] For the quarter ending 31 March 2001, 45.1% of Australians had hospital coverage and 40.5% had ancillary coverage with a private health insurer.[913]

11.53 Significantly, for underwriting purposes, private health insurance contracts in Australia are community rated under the *National Health Act 1953* (Cth).[914] This means that insurers are prevented from using genetic information to

909 Ibid.

910 Private Health Insurance Administration Council, *Registered Health Benefits Organisations Operating in Australia*, Private Health Insurance Administration Council, <http://www.phiac.gov.au/phiac/funds/list.html>, 7 July 2001.

911 In January 1999, the federal government introduced a 30% rebate to those Australians who purchased private health insurance. Additionally, Lifetime Health Cover introduced premium loading based on age for those Australians aged over 31 years who took up private health insurance after 1 July 2000.

912 Individuals without a dependent child or children with a taxable income greater than $50 000 incur a Medicare levy surcharge. A member of a family — which may consist of a couple (married or de facto) with or without a dependent child or children — or a sole parent with a dependent child or children with a combined taxable income greater than $100 000 (plus $1,500 for each dependent child after the first) incur a Medicare levy surcharge: *Income Tax Assessment Act 1936* (Cth), Part VIIB; *Medicare Levy Act 1986* (Cth).

913 The take-up rate for private health insurance has increased sharply since the introduction of the 30% rebate. For example, an additional 14.8% of Australians took up private hospital cover between 31 March 1999 and 31 March 2000: Private Health Insurance Administration Council, *Coverage of Hospital Insurance Tables Offered by Registered Health Benefits Organisation by State*, Private Health Insurance Administration Council, <http://wwwphiac.gov.au/phiac/stats/memcov/hos_quar.htm>, 7 July 2001; Private Health Insurance Administration Council, *Coverage of Ancillary Insurance Tables Offered by Registered Health Benefits Organisation by State*, Private Health Insurance Administration Council, <http://www.phiac.gov.au/phiac/stats/memcov/anc_quar.htm>, 7 July 2001.

914 Under the *National Health Act 1953* (Cth) (NHA), s 67(1), only organisations that are registered may operate as health insurers. Section 73(2A) NHA states that the Private Health Insurance Administration Council must not grant an application to an organisation for registration or to carry on business as a registered health organisation if, under the rules of the organisation, enrolment of persons as contributors to the relevant fund may be refused by reason of their state of health. See also s 73(2B), which prevents the Council from granting registration for a restricted membership organisation unless it is satisfied that the rules of the organisation restricting membership are not designed to achieve a higher level of health than the level of health in the community generally. See also paragraph (b) of Schedule 1 setting out conditions for registration of an organisation.

rate individual risk.[915] This restriction is significant in identifying the overall impact that the use of genetic information for underwriting may have in the Australian insurance context – particularly as compared with the position in the United States, which does not have a comprehensive national health insurance system.[916]

Superannuation

11.54 Superannuation is aimed at providing employees and their dependants with a reasonable standard of living upon retirement from employment, while relieving the general revenue of the full burden of providing such support for all retirees. Some superannuation schemes also include an income maintenance insurance component.

11.55 Superannuation schemes in Australia can be split into three basic categories: award or legislation-based schemes (where contribution by employers is mandatory); personal schemes; and company schemes (contributed to by the employer and/or the employee with the aim of providing a benefit when the employee leaves the company).

11.56 In August 1999, 89% of all Australian employees were covered by a superannuation or retirement scheme and 92% of employees above the age of 20 years received superannuation as an employment benefit.[917] These statistics are mainly attributable to the compulsory nature of most employer superannuation contributions under the Superannuation Guarantee Charge.[918]

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915 There is a question as to whether a person who has tested positive for a genetic disorder, yet is still asymptomatic, is a person who shows 'signs and symptoms' for the purposes of the NHA. It is arguable that genetic information could qualify as a 'pre-existing' ailment, which is subject to a waiting period before treatment is provided under private health insurance policies. See NHA Schedule 1 (j)–(lf), which precludes payments for the duration of the specified waiting period in respect of claims arising from ailments that existed at the time the policy was entered into, irrespective of whether that ailment was actually diagnosed at the time. 'Pre-existing ailment' is defined in the Act as an ailment or illness the signs or symptoms of which, in the opinion of a medical practitioner appointed the day on which the contributor began making contributions to the organisation, existed at any time during the six months preceding the day on which the contributor began making contributions to the organisation (Schedule 1, (kc).

916 M Otlowski has noted that if genetic information was available for use in health insurance, it would add a new dimension since the question of access to health insurance is linked to the availability of health care: M Otlowski, 'Resolving the Conundrum: Should Insurers be Entitled to Access to Genetic Test Information?' (2000) 11 *Insurance Law Journal* 193, 11. Health insurance in the United States is generally made available through employer provided schemes; thus the issues in the US are compounded not just by access to insurance, but also by access to employment.

917 Australian Bureau of Statistics, *Labour: Superannuation*, Australian Bureau of Statistics, <http://www.abs.gov.au/ausstats/abs@.nsf/0/7B25013E5DF88D69CA2569DE0021ED40?Open&Highlight=0,superannuation>, 14 September 2001.

918 *Superannuation Guarantee Charge Act 1992* (Cth); See also *Superannuation Guarantee (Administration) Act 1992* (Cth).

11.57 Superannuation funds are largely excluded from mutual underwriting, with the limited exception of the insurance component of superannuation. If an employer satisfies a minimum employee threshold requirement for the super fund, known as the automatic acceptance limit (AAL), then employees are guaranteed a certain amount of life insurance based on a fixed rate. The only time that the life insurance component of group superannuation is mutually underwritten is when employees voluntarily seek a higher level of insurance coverage than the automatic cover limit (ACL) provided for that employee.

11.58 In practice, the amount of insurance provided with superannuation at a community rate depends on whether the fund is an employer–sponsored fund or industry–sponsored fund.

11.59 The ACL provided by employer funds depends upon the size of the employer's workforce and industry. From the employer's perspective, the level of cover provided can be based on the cost to the company with different levels of insurance provided to sub-groups within the organisation. Alternatively, employers sometimes apply a simpler rule, such as providing insurance on a fractional level of income earned by the employee. Likewise, within industry–sponsored superannuation funds, there are many different ways that the ACL is determined.

11.60 Generally, the level of insurance provided under the ACL is small. If employees want extra insurance cover, they can choose to extend the coverage provided by the superannuation fund above the ACL, or apply for voluntary life insurance with a life insurer. In either case, life insurance is mutually rated, based on the individual risk factors of each applicant.

11.61 Thus, the issues raised by the use of genetic information in superannuation will be limited to those employees who:

- are self-employed or employees of small business that do not satisfy the AAL; or
- require a greater amount of insurance than that provided by the ACL.

Regulating insurance contracts

11.62 As previously noted, the insurance industry in Australia is governed by a patchwork of legislation. Insurance law and practice considered in this chapter is limited to those matters governing personal insurance policies, where the collection and use of genetic information is potentially relevant.

Duty of disclosure

11.63 The insured has a legal obligation to disclose all information that is relevant to the insurance policy. The duty of disclosure is based on the principle that contracts of insurance require that 'the utmost good faith' be shown by each party. In *Carter v Boehm*, Lord Mansfield gave the classical explanation of the duty and the reason it is imposed.

> The special facts, upon which the contingent chance is to be computed, lie most commonly in the knowledge of the insured only; the under-writer trusts to his representation, and proceeds upon confidence, that he does not keep back any circumstance in his knowledge, to mislead the under-writer into a belief that the circumstance did not exist, and to induce him to estimate the [risk], as if it did not exist.[919]

11.64 The principle of utmost good faith distinguishes insurance from other contracts. It requires the insured and insurer to act in a way that encompasses concepts of fairness, reasonableness and a duty to make full disclosure of all relevant information surrounding the insurance contract.[920]

11.65 The origin of the duty of disclosure lay in the insured's superior knowledge of personal factors relevant to the risk, when underwriting expertise was in its infancy.[921] It is sometimes said that the position has, in many classes of insurance, now been reversed: insurers now have available to them sophisticated statistical data and obtain information on many aspects of the risks they assume.

11.66 However, while the insurer has superior, even exclusive, knowledge of statistical matters relevant to numerous categories and subcategories of risk, it normally does not have superior knowledge of factors peculiar to the particular risk. For example, the insurer is unlikely to know that the life to be insured has been subject to death threats, that a house proposed for insurance has been rewired by its inexpert owner rather than by a qualified electrician, or that the insured has a serious medical condition of which the symptoms have not yet become obvious to others.

11.67 Insurers and reinsurers collect a great deal of statistical data about the likelihood of loss in given areas of risk. The only practical way to measure the risk in an insurance contract is through disclosure. The applicant is in the best position to disclose relevant information about the risk that is relevant to the insurable interest.[922] If insurance companies could not rely on the vast majority of applicants

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919 *Carter v Boehm* (1766) 3 Burr 1905, 1909.

920 For a discussion of the concept of utmost good faith see Australian Law Reform Commission, *Review of the Marine Insurance Act 1909*, Report 91 (2001), Commonwealth of Australia, Sydney, ch 10.

921 Ibid.

922 Australian Law Reform Commission, *Insurance Contracts*, Report 20 (1982), Australian Government Publishing Service, Canberra, [150]–[153].

disclosing fully and accurately all material information, they would be obliged either to build in a significant uncertainty factor or to undertake extensive investigations (medical and otherwise) of all applicants. In either case, the cost of doing business and the level of premiums would rise significantly, if not prohibitively.

11.68 The duty of disclosure now exists in both statute law and common law. However, the *Insurance Contracts Act 1984* (Cth) (ICA),[923] the major piece of legislation that governs most insurance contracts, largely replaces the common law duty of disclosure. Under ICA s 22, the insurer has a duty to inform the insured clearly in writing (usually in the insurance brochure and proposal) about the general nature and effect of the duty of disclosure. Under s 21(1), the insured has a duty to disclose every matter that is known *before* the contract of insurance is entered, being a matter that:

- the insured 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 a matter so relevant.

11.69 The first test of relevance under s 21(1)(a) is said to be subjective. It imposes a duty on the insured to disclose every matter that the insured actually knows to be relevant to the insurer's decision. An applicant is said to know what might be relevant to an insurer's decision by reference to the questions contained in the proposal form. If an insured does not answer a question in the proposal, or gives an obviously incomplete or irrelevant answer, the ICA puts the onus on the insurer to prove that the non-disclosure is relevant.[924]

11.70 In the case of an obviously incomplete or irrelevant answer, the ICA deems the insurer to have waived compliance with the duty of disclosure unless s 21A is satisfied.[925] This provision requires an insurer to pose specific questions to an insured that are relevant to the risk and to request expressly that the insured disclose each 'exceptional circumstance' which is known to the insured, and which the insured knows to be, or could be reasonably expected to know to be, relevant to the insurer.

11.71 Under both tests of relevance, the essential feature of the duty of disclosure is that the insured must or ought to know *before* the insurance contract is entered that the matter is relevant. Genetic disorders present in an insured's

923 The ICA, which substantially reformed the common law position governing insurance contracts, arose from recommendations tabled in a report by the ALRC: Ibid [151], [328] and [91].
924 *Insurance Contracts Act 1984* (Cth), s 21A(8).
925 Ibid, s 21(3).

genotype will, of course, pre-date any contract of insurance entered into by the insured — indeed, the very nature of genetic information means that it pre-dates the insured's birth. However, if the insured has no knowledge of this genetic information (nor could by expected to know of it), the presence or absence of the genetic risks will have no impact on the statutory obligation of disclosure.

11.72 As a general matter, the obligation of disclosure does not extend for an indefinite period. For example, if the insured enters into an insurance contract and subsequently has a test indicating he or she has a serious medical condition, or a predisposition to a serious disorder, there would be no obligation on the insured to reveal the test result to the insurer – unless the contract itself imposes such an obligation. The new knowledge will, however, be relevant to any new contract and may be the subject of questions in relation to any proposed changes in cover.

What need not be disclosed?

11.73 Under the ICA, an insured 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.[926]

11.74 The ICA also provides that in some cases the insurer can be held to have waived its right to disclosure from the insured, where the insurer has not taken steps to investigate obviously incomplete or inaccurate answers provided by the insured in a proposal.[927]

Consequences of material non-disclosure

11.75 The insurer may raise non-disclosure as a defence when an applicant makes a claim under an insurance policy. Sections 28 and 29 of the ICA will be most relevant to contracts of personal insurance.

11.76 In a contract of life insurance, where the insurer can show that the insured failed to disclose relevant information for the purposes of the ICA, the insurer may:

926 Section 21(2) restates the common law by setting out a number of matters that an insured or intending insured is not required to disclose.

927 *Insurance Contracts Act 1984* (Cth), s 21(2).

- avoid the contract from its inception if the non-disclosure or misrepresentation was made fraudulently; or

- within three years, avoid the contract if the insurer would not have entered into the contract but for the non-disclosure; or

- within three years, vary the contract, substituting the sum insured (including any bonuses) according to a statutory formula.[928]

11.77 For all other personal insurance contracts, if an insurer can establish that the insured failed to disclose relevant information for the purposes of the ICA, 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 for the claim 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.[929] This permits the insurer to reduce its liability to zero in appropriate cases.

Duty on insurers to provide reasons for unfavourable treatment

11.78 In addition to the specific duties that it imposes upon the insured, the ICA also regulates the information, notices and reasons that insurers must provide to the insured in certain circumstances. As discussed earlier, the insurer has a duty to give the insured written notice about his or her obligations of disclosure.[930]

11.79 Upon a request from the insured, an insurer is required[931] to provide reasons where it:

- does not accept an offer to enter into a contract of life insurance;

- cancels a contract of insurance;

- indicates to the insured that it does not propose to renew the insurance cover provided under a contract of insurance; or

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928 Ibid, s 29. See ICA, s 29(4) for the statutory formula.
929 Ibid, s 28.
930 Ibid, s 22.
931 Failure to comply with a request may result in a penalty of up to 300 Penalty Units: ICA, s 75(1)(5). The legislative requirement that insurers provide reasons was a result of recommendations made in Australian Law Reform Commission, *Insurance Contracts*, Report 20 (1982), Australian Government Publishing Service, Canberra, 131. The Commission noted that an insurer should be required, upon request by the insured, to give precise details of any reasons for refusing cover or for offering cover on special terms.

- offers insurance cover to the insured on terms that are less advantageous to the insured than the terms that the insurer would otherwise offer by reason of some special risk relating to the insured or to the subject matter of the contract.[932]

11.80 An insurer can avoid penalty for failure to provide these reasons if it proves that compliance would have unreasonably put at risk the insurer's interests or the interests of some other person. Reasons must ordinarily be given in writing to the insured or the insured's nominated medical practitioner.[933]

11.81 A question for this inquiry is whether the ICA provides adequate requirements for providing reasons to insureds when less favourable terms are offered based on genetic information. It is not the current practice of insurers to disclose to applicants the specific actuarial information and calculations upon which they base their determination, due, among other things, to commercial-in-confidence concerns.[934]

11.82 With respect to accessibility, the inquiry is considering whether the steps insureds are required to take in order to obtain statistical and actuarial data — that is, the lodgement of a complaint to the Human Rights and Equal Opportunity Commission — may be too onerous. For example, a submission from Bob Williamson of the Murdoch Children's Research Institute urges that the duty of utmost good faith, which in part requires the insured to make disclosures about risk, should equally require the insurer to disclose the methods used to assess that risk if a policy is refused or subject to loading.[935]

11.83 In the United Kingdom (UK), the House of Commons Science and Technology Committee has recommended that insurers explain publicly how they use family history information in the assessment of insurance premiums, and publish the supporting data.[936] The UK Human Genetics Commission has expressed similar views in its interim recommendations on the use of genetic information in insurance, with particular regard to family history information:

> The issue of family history information presents particular difficulties. The Commission is concerned that the insurance industry's principle of open disclosure and utmost good faith by the parties seems to fall most heavily on the consumer. Few people are provided with information as to how their premiums are loaded. HGC

932 *Insurance Contracts Act 1984* (Cth), s 75.
933 Ibid.
934 See, for example, comments by L Ralph (CEO, IFSA) during a Senate inquiry into the private sector amendments: Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), The Parliament of Australia, 40.
935 B Williamson, *Submission G11*, 10 July 2001.
936 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xix.

> understands that family history information can amount to genetic information and is not always interpreted appropriately in underwriting.[937]

11.84 IFSA has stated its view that the current methods of risk assessment using genetic information are sufficiently transparent and accountable to the public:

> The Disability Discrimination Act 1992 provides consumers this protection. Consumers may lodge a complaint to the Human Rights Commission or the State equivalent that may in turn require the insurer to provide evidence in support of their underwriting decision. The Insurance Contracts Act 1984 obliges an insurer to provide to the applicant or their doctor, the grounds on which an insurance application was declined or accepted on less favourable terms. Actuarial methods are a matter of public information and the industry is happy to provide information regarding how risk is measured.[938]

11.85 The inquiry is interested in receiving views about the extent to which insurers should be required to provide applicants with evidence to support adverse underwriting decisions based on the use of genetic information.

Question 11–2. How and to what extent should insurers be required to provide applicants with information and data that supports unfavourable underwriting judgments based on genetic information?

Disclosure, relevance and genetic information

11.86 Relevance is an important issue where an insurance company seeks to underwrite on the basis of genetic information. Relevance under ICA provisions will affect disclosure obligations differently, depending on the types of genetic information considered. First, only genetic information that is useful for assessing *unfavourable* risk factors must be disclosed under s 21(2) ICA. As discussed earlier, the insured is not required to disclose information that diminishes the risk.

937 Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London.

938 Investment and Financial Services Association, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 15 February 2000, 6.

Example 11–1. Mary is applying for travel insurance as she intends to travel to Southeast Asia. In the personal questionnaire section of the insurer's proposal form, a question asks whether applicants have ever had a genetic test. Mary underwent a genetic test when she took part in a genetic carrier-screening program for sickle cell disease. The genetic test revealed that Mary was a carrier for sickle cell disease. Does Mary have a legal duty to reveal the genetic test result?

Mary is not obliged to reveal the genetic test result in this case as carrier status for sickle cell gene actually reduces the risk of developing malaria.[939] Section 21(2) ICA states that an insured is not required to disclose a matter that diminishes the risk.

11.87 Second, genetic information that does not diminish the risk, but is relevant to the risk, must be disclosed. However, the consequences of non-disclosure will depend upon the loss suffered by the insurer.[940] Therefore, where genetic information is proven to be relevant but the non-disclosure by the insured would not have had a material effect on the insurer's decision to accept the proposal, the resulting consequences may be minor. The impact will depend entirely on the relevance of the genetic information to the risk underwritten, which raises questions about the scientific reliability and actuarial relevance of genetic test information.[941]

Privacy considerations

11.88 The privacy framework and how it affects genetic information generally, is considered in chapter 3. This section considers the application of privacy principles to the handling of genetic information in the insurance context.

11.89 Historically, the insurance industry in Australia has a strong record of meeting and exceeding privacy requirements. As the Privacy Commissioner stated in an information paper on privacy, insurance and genetic information:

939 The carrier state affords protection against malaria because those who are carrier have abnormal red blood cells, which die soon after being infected with the malaria parasite, compared with a normal red blood cell, which continues to work and so provides an environment for the malaria parasite to grow.

940 ICA, Div 3 provides the remedies for non-disclosure and misrepresentation. ICA s 33 provides that no other remedies exist, other than those provided by the ICA. For example, there are no other general rights of avoidance at common law.

941 However, ICA, s 60 provides that a failure of utmost good faith by the insured in a contract of general insurance can allow the insurer to cancel the contract.

> [L]ife 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 practices.[942]

11.90 Considering the vast amount of sensitive information (including health information) held by the insurance industry in Australia, complaints about misuse or improper disclosure have been rare.[943]

11.91 The *Privacy Act 1998* (Cth) (*Privacy Act*) is the major piece of legislation that provides safeguards against breaches of privacy, including in the area of insurance.[944] The Privacy Act's safeguards are set out in a number of Information Privacy Principles (IPPs) and National Privacy Principles (NPPs).[945] In general terms, the privacy protection afforded by the IPPs extends only to the personal information handling practices of government agencies.

11.92 However, from 21 December 2001, private sector organisations will be covered by new provisions of the *Privacy Act*, which will require them to adhere to the NPPs. Insurers, actuaries, advisers and other significant actors in Australian insurance will be subject to this extension of federal privacy law. While many advisers would come within the small business exemption provided under the new amendments (because they have an annual turn-over of less than $3 million), they would nevertheless be caught by the new arrangements to the extent that they hold any health information, such as that contained in proposal forms and medical reports.[946]

11.93 In a submission by the Insurance Council of Australia, the peak organisation representing 90% of income written by private sector general insurers, the Council expressed the view that the new amendments to the *Privacy Act* adequately dealt with the protection of genetic information.[947] The Investment and Financial Services Association (IFSA) shared this view during the public inquiry into the Privacy Amendment (Private Sector) Bill 2000, by the Senate Legal and Constitutional Legislation Committee.[948] IFSA has also produced an industry policy on genetic testing (see below for a discussion of IFSA's Policy on Genetic

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942 Federal Privacy Commissioner, *The Privacy Implications of Genetic Testing* (1996), Office of the Federal Privacy Commissioner, Sydney, 40.

943 See Life Insurance Complaints Board, *Annual Report* (1995), Life Insurance Complaints Board, Melbourne, which reports very few complaints about the handling by life insurance companies of health information.

944 While privacy legislation exists at the state level, the federal nature of 'insurance' is enshrined in the *Constitution*, thus the Commonwealth *Privacy Act 1988* (Cth) may be the most effective statutory privacy protection.

945 Ibid, s 14 (IPPs), Schedule 3 (NPPs).

946 Ibid, s 6D(4)(b). See ch 5 for a detailed discussion of the exemption.

947 R Drummond, *Submission G10*, 27 June 2001.

948 Commonwealth of Australia, *Parliamentary Debates*, Senate Legal and Constitutional Legislation Committee, 8 September 2000, 32.

Testing), which it claims provides consumers with an effective and robust regime for ensuring the privacy of their personal information:

> The whole aim of our policy is to discourage unnecessary and inappropriate testing, while ensuring that insurance remains accessible and affordable. Key quick points of our policy are that we will not initiate genetic tests but, if tests have been done, customers must disclose the results of those tests when they apply for insurance. Existing tests will only be obtained with the written consent of the applicant. We will, of course, maintain strict confidentiality of all test results, as we do with all other health information. The results of any genetic tests will be used to assess only the applicant, never their families or their relatives.[949]

Collection of genetic information

11.94 When collecting health information from applicants in the proposal, insurers must ensure that only 'personal information' that is necessary for underwriting is collected.[950] Moreover, 'sensitive information' (including genetic and other health information) must only be collected with the consent of the applicant or insured.[951]

11.95 Proposals for personal insurance usually include a standard medical authority, which gives the insurer written consent to obtain full particulars of the insured person's medical history, including details of any clinical notes that have been made.[952] A key issue raised by the collection of highly sensitive information, such as genetic information, is whether medical authorities provided in the proposal are effective consent. An alternative might be to provide a separate authority for highly sensitive information so that only health information required for underwriting purposes is collected.

11.96 On one view, an individual's consent may not be truly voluntary if the individual will be denied some benefit or be disadvantaged in some way if he or she refuses consent.[953] In the insurance context, refusal to provide insurers with consent to collect genetic information may result in adverse terms or denial of insurance. From the insurer's perspective, the collection of health information to quantify the risk that an insured brings to the contract is essential to the viability of the industry. Indeed, the disclosure of risk information for insurance purposes is entrenched in legislation.[954]

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949 Ibid *Parliamentary Debates*, 33.
950 NPP 1.
951 NPP 10.
952 Under IFSA's Policy on Genetic Testing, life insurers have agreed that 'Insurers will ensure that results of existing genetic tests are only obtained with the written consent of the tested individual': Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999), cl 6
953 See ch 4.
954 ICA s 21. See above, for a detailed discussion of the duty of disclosure and how it may apply to genetic information.

11.97 The inquiry is interested in receiving views about whether, under current insurance practice, there is an appropriate balance between the interests of applicants to provide informed consent free from any undue pressure, and the legitimate needs of the insurance industry to collect relevant information for classifying and managing risk, and ensuring the sustainability of the industry.

Question 11–3. Should the standard medical authority provided for all types of health information continue to be used in relation to highly sensitive information, including genetic information? Alternatively, should an enhanced level of consent be required from the applicant in relation to genetic information to ensure that it is only collected when necessary?

Use, re-use and disclosure

11.98 In most circumstances, insurance industry participants must not use or disclose personal information about an insured for a purpose (the secondary purpose) other than the primary purpose of collection, unless such uses and/or disclosures are related (directly related in the case of sensitive information) to the primary purpose of collection and within the insured's reasonable expectations.[955]

11.99 During the Senate hearings into the Privacy Amendment (Private Sector) Bill 2000, Senator Natasha Stott Despoja asked whether there was a temptation for insurers to re-use the genetic information obtained in respect of one applicant to underwrite other applicants, such as members of the same family. The CEO of IFSA, Lynn Ralph, responded by distinguishing between *indirect* uses of genetic information about third parties, which is voluntarily disclosed by applicants, and *secondary* uses of genetic information obtained without consent:

> Right now we do ask about family history. We will ask what your parents passed away from or whether they had cancer or a heart disease. So right now we are actually getting some informal genetic information, and we have been doing that for many years. We do that by asking you for that information. We do not get that information from the file from your father's insurance. Right now we do not use information that you have provided to us about your health in relation to any of your other family members. The fact that our policy on genetic testing says that we will not use it for your family members is basically just a continuation of the sorts of practices that we are currently using.[956]

11.100 In most circumstances, the NPPs only allow organisations to collect personal health information from the individual concerned. However, an important issue arises from the current legal use of third-party health information when it

955 NPP 2.

956 Senate Legal and Constitutional Legislation Committee, *Inquiry into the Provisions of the Privacy Amendment (Private Sector) Bill 2000* (2000), The Parliament of Australia 47.

relates to genetic test information, as opposed to family history. When an applicant discloses information about relatives who have been diagnosed with a disease, the information is relatively static and certain, and so can be easily and clearly described by the applicant. For example, an applicant's account of an immediate family member who has cystic fibrosis may provide insurers with sufficiently reliable information for underwriting purposes.

11.101 However, an applicant's second-hand account of an immediate family member's genetic test results, which revealed a predisposition for cystic fibrosis, may not provide the same level of sufficiently reliable information for underwriting purposes. Applicants are likely to struggle with the complexity of the detailed information contained in such test results (such as the specific genetic mutation, when there may be hundreds of possibilities),[957] as well as subtleties of interpreting what the results mean, especially in terms of predictive value.[958]

11.102 Nevertheless, this concern is largely theoretical at present, as it is not apparent that in practice applicants are asked about genetic tests that family members have taken.

Actuaries

11.103 Actuaries who conduct research using genetic information for actuarial and statistical analysis will also need to consider the effect of the new private sector privacy regime. The privacy implications for actuaries will depend on whether the information is identified or de-identified.[959] Actuaries may use de-identified genetic information for research and statistical analysis without consent.

11.104 In a recent submission to the Federal Privacy Commissioner, the Institute of Actuaries of Australia (IAAust) noted that 'actuarial work in many cases will not require the use of data from which the person who provided the data can be identified'. The IAAust further expressed its support for the principle that de-identified data sets be excluded from the NPPs.

> We strongly support this principle, and the ability to use an identifying number on unit record data sets, or some other identifier apart from the name or personal contact details of the person who provided the data. Such identifying numbers would be included for reference purposes only, as a linkage between the core data record which

957 Eg, there are more than 600 genetic mutations for cystic fibrosis. See R Trent (1997), 43–46.

958 Ibid. See also J Beckwith and J Alper, 'Reconsidering Genetic Anti-discrimination Legislation' (1998) 26 *The Journal of Law, Medicine and Ethics* 205.

959 The *Privacy Act* does not apply to information unless it is personal information 'about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion': *Privacy Act 1988* (Cth), s 6(1).

includes personal information and is protected by the privacy legislation, and the de-identified record which is used for data analysis.[960]

Question 11–4. In the specific context of insurance, do the new private sector privacy laws and arrangements provide an adequate framework for the protection of genetic information?

Question 11–5. To what extent would it be appropriate for insurers to request for underwriting purposes:

- information about family medical history?
- the results of any existing genetic tests or analysis in relation to the applicant?
- that the applicant undergo genetic testing?
- the results of any existing genetic tests or analysis from members of the applicant's family?

Anti-discrimination law

11.105 The anti-discrimination regime in Australia is covered in detail in chapter 4. However, it is appropriate to highlight significant legislative provisions that apply in the area of insurance. Of particular importance to this inquiry is disability discrimination law, under the *Disability Discrimination Act 1992* (Cth) (DDA), to the extent that genetic predisposition of illness may be used to differentiate applicants.

Insurance exemptions

11.106 Section 24 DDA makes it an offence to discriminate against any person in the provision of goods, services or facilities on the basis of that person's disability.

11.107 The insurance industry operates by making distinctions between risks and by offering the same insurance products on different terms to different individuals. The DDA s 46 recognises the inherent nature of mutual insurance business by providing a broad exemption to insurers, where the:

960 Institute of Actuaries of Australia, *Submission in Response to "Draft Health Privacy Guidelines — A Consultation Document Issued by the Office of the Federal Privacy Commissioner"*, 14 May 2001. In this context, the IAAust also noted NPP 7, which disallows the use of identifiers that have been issued by federal government agencies, such as Medicare numbers.

- discrimination is based upon actuarial or statistical data on which it is reasonable for the insurer to rely, and the discrimination is itself reasonable given the data and other factors; or

- discrimination is reasonable having regard to any other reasonable factors, in the event that no such actuarial or statistical data is available and cannot be reasonably obtained.

11.108 According to Guidelines provided by the Human Rights and Equal Opportunity Commission (HREOC),[961] 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.[962]

11.109 If there are no relevant statistics or actuarial data available, 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 upon, which include:

- medical opinion;

- opinions from other professional groups;

- actuarial advice or opinion;

- relevant information about the individual seeking insurance; and

- commercial judgment.[963]

11.110 The Genetic Privacy and Non-discrimination Bill 1998, introduced into federal Parliament by Senator Stott Despoja, is one attempt to outlaw discrimination on the basis of genetic information in insurance and employment (The Bill is discussed in detail below).[964]

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961 Pursuant to s 67(1)(k) of the DDA, the Human Rights and Equal Opportunity Commission has the power to issue guidelines to assist better understanding of rights and obligations under the Act. See: Human Rights and Equal Opportunity Commission, *Guidelines for Providers of Insurance and Superannuation*, Human and Equal Opportunity Commission, <http://www.hreoc.gov.au/disability_rights/standards/Insurance/insurance_adv.html>, 27 August 2001.

962 Ibid.

963 Ibid.

964 Genetic Privacy and Non-discrimination Bill 1998 (Cth), cl 17.

Question 11–6. In the specific context of insurance, do existing anti-discrimination laws provide an adequate framework for protection against discrimination based on genetic information?

The use of genetic information in insurance

11.111 Numerous issues are raised by the inclusion of genetic testing and information in insurance, these include:

- the predictive significance and actuarial relevance of genetic information;
- the impact on health and genetic research;
- the necessity of genetic information for underwriting;
- the need to distinguish genetic from non-genetic risk information; and
- equity of access to insurance.

Predictive significance and actuarial relevance of genetic information

11.112 A number of inquiries, committees,[965] community organisations and insurers[966] have recognised the importance of establishing the relevance of genetic information prior to use in underwriting. Relevance in the context of genetic information and insurance needs to be considered from two perspectives:

- the scientific reliability and relevance of predictive genetic test information; and
- the actuarial relevance of predictive genetic test information when applied to risk rating for insurance purposes.

11.113 One concern is that where the scientific reliability or actuarial relevance of genetic information remains unproven, its use may result in unlawful or otherwise unjustifiable discrimination.

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965 Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance* (1997), Human Genetics Advisory Commission, London; Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London; House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xvi–xix; Genetics and Insurance Committee, *Annual Report, April 1999–June 2000* (2000), Department of Health, London.

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

11.114 Issues of relevance and reasonableness are not strictly limited to new forms of genetic information derived from the direct analysis of DNA. The use of family medical history (a form of genetic information) has been flagged by both the Human Genetics Commission (HGC) and the House of Commons Science and Technology Committee as presenting significant concerns that need to be addressed. In an interim recommendation on insurance and genetics, the HGC stated:

> The issue of family history information presents particular difficulties. The commission is concerned that the insurance industry's principle of open disclosure and utmost good faith by the parties seems to fall most heavily on the consumer. Few people are provided with information as to how their premiums are loaded. HGC understands that family history information can amount to genetic information and is not always interpreted appropriately in underwriting. During the moratorium period HGC will address the issue as to how family history information is used by insurers.[967]

Scientific relevance

11.115 As discussed in chapter 2, genotype does not equal phenotype.[968] In other words, except for a number of rare monogenic disorders, the genetic expression of a disease does not lead to the certain development of that disease. However, the fact that a genetic test now may be performed and results obtained creates a danger 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.[969]

11.116 Genetic information is at least three-dimensional. First, genetic test information may indicate a predisposition to a disorder that is dominant or recessive. Second, it may indicate a predisposition ranging anywhere from single-gene to multifactorial. Third, even among the more predictive single-gene disorders, the degree of symptom expression and time of onset will vary between individuals. These factors will influence the scientific relevance of predictive genetic test information.

11.117 Scientific relevance will affect the utility of genetic test information used for insurance underwriting. For example, a genetic test that indicated a recessive predisposition to a multifactorial disorder will not be as scientifically (or medically) relevant as a dominant single-gene disorder. Scientific relevance is an important issue that requires consideration by third parties intending to rely upon distinctions between different types of genetic information. As Martin Bobrow has noted:

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967 Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London.

968 For a detailed discussion about genotype-to-phenotype correlation see ch 2.

969 M Otlowski (2001), 37.

> [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.[970]

Actuarial relevance

11.118 In one sense, all information pertaining to the risk is actuarially relevant. As discussed earlier, risk factors such as age, gender, family history, occupation, place of residence, and lifestyle are all actuarially relevant information. Insurers view genetic test information as a natural extension of the risk information that could assist in the underwriting process — and they already use family history, which is a basic form of predictive genetic information, to underwrite.

11.119 Clause 3 of the IFSA Policy on Genetic Testing[971] (IFSA Policy) provides that 'insurers may request that all existing genetic test results be made available to the insurer for the purposes of classifying the risk'. The IFSA Policy does not purport, however, to provide an enforceable framework for the use of only actuarially relevant genetic information.

11.120 How insurers convert genetic test information into actuarially useful information is an important consideration. The inquiry is interested in examining the scientific and actuarial relevance of genetic information in insurance underwriting and the mechanisms for ensuring that scientific and actuarial relevance is established before genetic information is used for underwriting.

11.121 Angus Macdonald suggests that the insurance industry needs to take a broad view of the research base that underpins underwriting practice and how that affects social and business policy when using genetic information.[972] He notes that for actuarial purposes the industry needs to develop models that delineate clearly the effects of various policy options and pinpoint where research is needed.[973] As Macdonald maintains:

> Although much market research is carried out, little of it is published, and perhaps even less of it would be relevant. I suggest the insurance industry might consider what research could be done, in the public interest as well as its own. A useful first step would be to carry out panel surveys of industry practitioners, medical professionals, and the public, to find out what effect genetic information would have on their desire for insurance, given their respective levels of knowledge.[974]

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970 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xvi.

971 Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999). See below for a discussion of the IFSA Policy.

972 A Macdonald, 'Modeling the Impact of Genetics on Insurance' (1999) 3 *North American Actuarial Journal* 83, 98. A Macdonald is the Director of the Genetics and Insurance Research Centre, which has written widely on issues of actuarial relevance of genetic information, see: http://www.ma.hw.ac.uk/ams/res/girc.html.

973 Ibid, 99.

974 Ibid, 99.

11.122 The President of the Institute of Actuaries of Australia (IAAust), Dr David Knox, has suggested that the Institute is interested in developing a similar approach adopted by insurers and government in the United Kingdom:

> We are very interested in developing something similar to what they have in the UK, where there is a forum of genetics in insurance, where experts from the consumer movement ethicists, geneticists and actuaries can come together, talk around the issues, and advise the government accordingly.[975]

11.123 The UK government has introduced a Genetics and Insurance Committee (GAIC), whose task it is to determine applications for approval of specific genetic tests in insurance, considering the tests' scientific and actuarial relevance. The UK approach to genetic information in insurance is discussed further below.

11.124 The IAAust has taken steps to engage public debate on wider issues of genetics and also particular issues relating to insurance in a recent text, *Genetics in Society 2001*.[976] Reflecting on the current state of play, the authors state that:

> British actuaries, and to a lesser extent their USA counterparts, have been leading the way in this new area, incorporating genetic knowledge into actuarial models. Their work has been particularly strong in its multi-disciplinary approach, incorporating the expertise of geneticists, public health economists, demographers and epidemiologists. However, research is still at an early stage of development and much work remains to be done.[977]

Question 11–7. How should insurers and government address the need to ensure the scientific reliability and actuarial relevance of genetic information used for underwriting purposes?

Impact on health and research

11.125 Clinicians are becoming concerned that the health care of patients could be adversely affected if they were not reassured that diagnostic genetic tests were not used in insurance.[978] The expanding use of clinical genetics for early detection and treatment has the potential to improve significantly the quality of life for people with certain genetic conditions. For example, individuals shown to have the gene associated with familial polyposis (FAP) are at high risk of developing

975 Commonwealth of Australia, *Parliamentary Debates*, Senate, 1 September 2000, 698.
976 A Doble and others (2001).
977 Ibid, 74.
978 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347 364; 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 42–44. See also House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xvii–xviii.

colorectal cancer. Once the gene is detected the individual can be kept under regular surveillance and preventative measures implemented.[979] However, the Esso Familial Polyposis Register has expressed concern that permitting insurers to use genetic test information will impose significant barriers to such testing in these at-risk families.[980]

11.126 Medical and scientific researchers expressed concerns that the fear of running foul of insurance disclosure rules will inhibit widespread community participation in research programs, stunting the development of genetic research and promising new therapies.

11.127 In an early submission received by the inquiry, Bob Williamson stated that 'there is a critical tension between fear of adverse selection (by the insurance companies) and fear that people will refuse to undergo legitimate testing which will improve health (by clinicians and the community)'.[981] However, as Ron Trent has indicated in consultations with the inquiry, genetic test results are usually not given to volunteers who take part in genetics research because of the experimental and often unreliable nature of the results.[982] Therefore, genetic testing for research purposes can be quite clearly distinguished from that done in a clinical context, where tests are carried out for a specific purpose with clear potential benefits for the patient.[983]

11.128 In one respect, where genetic test results performed in a research setting are not disclosed to potential insurance applicants, there will be no impact for insurance underwriting. However, a concern has been expressed that the public, including insurers, often misunderstands the distinction between diagnostic and research test results. As the House of Commons — Science and Technology Committee noted, this confusion may create difficulties as volunteers are not sure whether they will have to disclose the results of any tests in which they take part.[984]

11.129 In at least one area of research, IFSA has sought to address these concerns. The Genetic Health Service Victoria, in collaboration with the Murdoch Children's Research Institute, recently announced a pilot genetic screening program (HaemScreen) for the preventable genetic disease haemochromatosis.[985]

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979 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xix.

980 M Otlowski (2001) 43.

981 R Trent, *Consultation*, Sydney, 4 April 2001.

982 Ibid. See also House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xxi.

983 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xxi.

984 Investment and Financial Services Association, *Gene Testing for Haemochromatosis — Will it Impact on Your Insurance?* (2001), Sydney, xxi.

985 Investment and Financial Services Association, *World First on Genetic Testing and Life Insurance*, (2001).

Haemochromatosis is a disorder that can result in damage and functional impairment of many organs, including the liver, pancreas, and endocrine glands. Early identification of those susceptible to haemochromatosis through genetic testing and appropriate treatment often means that the symptoms of the disease may be prevented. HaemScreen is a voluntary screening program for haemochroatosis, which offers genetic testing for people between the ages of 18 and 35 in the workplace.[986]

11.130 After consultation with HaemScreen, IFSA has issued a practice advice, which summarises the possible impacts that gene-positive status for haemochromatosis may have for insurance purposes.[987] HaemScreen is unusual because it is an example where research genetic testing provides clinically accurate diagnostic results, which are disclosed to participants. In this case, the life insurance industry has taken active steps to clarify its position and explain how genetic test results may affect insurance. However, the issue could be clarified further with more specific explanation of the effects that gene-positive haemochromatosis test results will have upon insurance underwriting practice.[988]

Question 11–8. Is there any evidence that the potential use of genetic information by insurance companies is deterring individuals from taking genetic tests for clinical diagnosis or volunteering for genetic research? If so, how should these issues be addressed?

Is genetic information necessary for underwriting?

11.131 In consultations with the inquiry, IFSA has stated that adverse selection may result if genetic information were excluded from insurance underwriting.[989] The concern is that if insurance applicants are able to hide genetic test information, insurers will be faced with a disproportionate number of people at higher risk applying for extended coverage. Accordingly, if higher risk insurance applicants know they can hide genetic risk factors, they have an incentive to obtain insurance. Consequently, if insurers are unable to rate risk accurately, the value of recoverable claims will exceed the premiums charged, eventually resulting in higher insurance premiums for the entire pool of insurance, providing a disincentive for those with

986 See www.haemscreen.com for more details.

987 Investment and Financial Services Association, *Gene Testing for Haemochromatosis — Will it Impact on Your Insurance?* (2001), Sydney.

988 For example, in the United Kingdom, the Association of British Insurers (ABI) has issued a statement, which provides that ABI members will only use genetic tests where the results have been communicated to the individual as part of a clinical diagnostic process and they have been approved or lodged with GAIC: K Clifford and R Luculano, 'AIDS and Insurance: The Rationale for AIDS-related Testing' (1987) 100 *Harvard Law Review* 1806, 79, 80 (Supplementary memorandum from the Association of British Insurers).

989 IFSA, *Consultation*, Sydney, 19 June 2001.

low risk to obtain insurance. As a consequence, a spiral of price increases is said to result, where low risk individuals drop out and the proportion of high-risk insureds systematically increases the price of insurance, eventually challenging the sustainability of the industry. However, the incidence of adverse selection at this stage is largely a theoretical and speculative concern as no statistical evidence has been produced to indicate that the exclusion of genetic information creates such a result.

11.132 The comparison between genetic test results and HIV is a particularly interesting example. When HIV-AIDS was first discovered in early 1980s, it was considered to be much like a diagnosis of actual or at least imminent and unavoidable disease, which resulted in swift and certain death. The insurance industry was one of the strongest proponents for the use of HIV antibody testing at a time when it was feared that HIV-AIDS would result in widespread adverse selection.[990] Yet, many years since the discovery of the virus 'many people who are infected with HIV now survive for more than 10 years'.[991] As Trudo Lemmens suggests, 'it is still unclear how long life can be prolonged for those who are currently infected and have access to experimental drugs. Research further suggests that some HIV-infected people might not even develop the disease'.[992] Likewise, early reactions to new genetic test information have been granted far greater probative value than they justify.[993]

11.133 Proponents of the widespread inclusion of genetic test information in insurance claim that the special nature of insurance contracts involving utmost good faith, requires that insurers be aware of all relevant risks, including genetic risks in personal insurance contracts.[994] The IFSA Policy provides that all *existing* genetic test results must be disclosed for the purpose of classifying risk, to reduce the possibility of adverse selection in the insurance market.[995] However, as IFSA has identified, the use of genetic test information is not currently widespread in the

990 See for example B Schatz, 'The AIDS Insurance Crisis: Underwriting or Overreaching?' (1987) 100 *Harvard Law Review* 1782; T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347.

991 C Salsberg, 'Resurrecting the Woolly Mammoth: Science, Law, Ethics, Politics, and Religion' (2000) *Stanford Technology Law Review* 1 370; R Brackenridge and W Elder (1998). See also T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 885–895, which suggests that the average survival period after HIV infection is 11 years in industrialised nations.

992 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 370.

993 See House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London for a highly critical view of the adoption of specific genetic tests in the UK. The Committee concluded that 'insurers appear to have been far more interested in establishing their future right to use genetic test results in assessing premium, than in whether or not they are reliable or relevant'.

994 See Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999); Investment and Financial Services Association, *The Facts on Life Insurance and Genetic Testing in Australia*, (2001) Investment and Financial Services Association.

995 Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999), cl 3.

Australian insurance industry.[996] Consequently, the immediate short-term impact of excluding genetic test information from insurance underwriting appears to be minor. As the UK House of Commons Science and Technology Committee noted in its recent inquiry:

> [A]t present the very small number of cases involving genetic tests results could allow insurers to ignore all genetic test results with relative impunity, allowing time to establish firmly their scientific and actuarial relevance.[997]

11.134 Additionally, the collection and use of any advanced health information can be a costly process. As noted above, insurers usually accept a pragmatic trade-off between the cost of accepting a few higher risks and the much higher costs associated with ordering extensive examination and testing of most applicants, except where a particularly high level of cover is sought.[998]

11.135 The performance and interpretation of genetic testing is complex and expensive proposition.[999] Commentators also have questioned the scientific and actuarial relevance of genetic testing at this early stage of its development, suggesting that the current cost of obtaining and interpreting genetic test information generally outweighs its probative value as a tool in underwriting insurance policies.[1000]

11.136 However, over time, advances in the information base and in genetic testing technology (such as the gene chip)[1001] may lead to the routine use of genetic testing in much the same way that other diagnostic tests, such as X-rays and blood tests, are now commonplace. This possibility lends weight to the argument that adverse selection may result at some point in the future.

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996 See comments by L Ralph, CEO, IFSA, 'Right now our understanding is that very few applicants for life insurance have actually got a genetic test in their hand. We are talking about very few instances at this point in time.': Senate Legal and Constitutional Legislation Committee, *Provisions of the Privacy Amendment (Private Sector) Bill* (2000), The Parliament of Australia, Canberra, 45.

997 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xviii.

998 For example, according to the RGA Reinsurance Company table of medical underwriting limits, insurers generally only request a physician specialist examination for a person aged between 45–50 years, for life, TPD or trauma insurance if the amount insured is over $1million: RGA Reinsurance Company of Australia, *Medical Underwriting Limits (Life/Crisis/TPD)* (2000).

999 But see O Schöffski, J Schmidtke and M Stuhrmann, 'Cost-Effectiveness of Population-Based Genetic Hemochromatosis Screening' (2000) 3 *Community Genetics* 2 where the authors conclude that the costs of population-based genetic screening for haemochromatosis are acceptable compared to the costs of other health care measures.

1000 See for example Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London; Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance* (1997), Human Genetics Advisory Commission, London; House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London; T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347; M Otlowski (2001).

1001 S Moore, 'Making Chips to Probe Genes', *IEEE Spectrum*, 1 March 2001, 5454-60.

11.137 Conversely, others have questioned the increase in adverse selection based on genetic testing since genetic information already collected by insurers discloses the risk and has a similar underwriting result.[1002]

Question 11–9. Does existing family medical history information requested from applicants in the majority of personal insurance proposals provide a sufficient level of information for risk rating, such that genetic test information might be excluded altogether from insurance underwriting?

Question 11–10. If genetic information were to be excluded from underwriting, to what extent would this threaten the viability of the market for personal insurance?

Distinguishing genetic from non-genetic risk information

11.138 IFSA has suggested that genetic information, just as with any other health information, should be available for underwriting.[1003] However, the IFSA Policy on Genetic Testing distinguishes between different types of health information, by defining and treating genetic test information exclusively.[1004] Likewise, regulation that has been proposed in Australia and abroad, distinguishes between genetic and non-genetic information.

11.139 Lemmens and others have argued strongly against distinguishing genetic test information from other genetic information, or even other health information, when regulating the collection and use of risk factors in insurance. He argues that statutes dealing with genetic information suffer from problems of definition; they are often seriously narrow or overly general and unworkable.[1005]

11.140 Commentators have argued that calls for regulation that focus on genetic test information are based on a false belief that genes are qualitatively different from other predictive health information — genetic essentialism.[1006] As Lawrence Gostin states, by 'articulating these differences, governments afford genetic data an "exceptional" status' (that is, genetic exceptionalism).[1007] In short, genetic

1002 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 28.
1003 Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999).
1004 Ibid cl 1.
1005 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347.
1006 Ibid. See also L Gostin and J Hodge, Jr, 'Genetic Privacy and the Law: An End to Genetic Exceptionalism' (1999) 40 *Jurimetrics* 21; G Spiteri, 'Genetic Testing and its Implications for Australian Insurance Law' (2000) 7 *James Cook University Law Review* 96.
1007 L Gostin and J Hodge, Jr, 'Genetic Privacy and the Law: An End to Genetic Exceptionalism' (1999) 40 *Jurimetrics* 21, 23. See ch 2 for a discussion of genetic exceptionalism.

essentialism can lead to regulation that is genetically exceptionalist. Indeed, the Senate Legal and Constitutional Legislation Committee report on the Stott Despoja Bill describes at length the special character of genetic information that distinguishes it from other personal information.[1008]

11.141 Genetic information is more often than not about possibilities and probabilities, rather than certainties as is commonly misconceived. Genetic information, as with other sources of health information used by insurers, indicates a factor of risk. In some cases, predictive genetic information gives an estimate of risk that may be relevant for insurance, but it is not the only source of predictive health risk information. Other potential sources of probabilistic information include information gathered from medical tests indicating high cholesterol levels, asymptomatic hepatitis B infection or early HIV infection.[1009] All of these risk factors *may* have insurance implications, and may even sometimes provide similar or more cogent information for insurance underwriting than genetic information.

11.142 Overstating the prophetic character of genetic information as an underwriting tool in insurance may raise significant issues for insurers and regulators:

> On the one hand, reliance by an insurer on the notion of genetic essentialism, can lead to unfair discrimination where insurers misinterpret a genetic test result as determinative that disease will manifest. On the other hand, unwitting reliance on genetic essentialism by legislators, can lead to laws that are genetically exceptionalist in nature.[1010]

11.143 Genetic information can reveal similar risk factors between family members and ethnic groups.[1011] However, it is not the only type of health information that can be used to indicate a shared risk between family members, ethnic groups or other groups, in insurance underwriting. The fact that a partner of an insurance applicant is suffering from HIV-AIDS indicates something about that

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1008 Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-discrimination Bill 1998* (1999), The Parliament of Australia, Canberra, 156. But see M Rothstein (1997), 60–73 for a critique of genetic exceptionalism. See also T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347; L Gostin and J Hodge, Jr, 'Genetic Privacy and the Law: An End to Genetic Exceptionalism' (1999) 40 *Jurimetrics* 21; G Spiteri, 'Genetic Testing and its Implications for Australian Insurance Law' (2000) 7 *James Cook University Law Review* 96.

1009 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 370.

1010 G Spiteri, 'Genetic Testing and its Implications for Australian Insurance Law' (2000) 7 *James Cook University Law Review* 96, 112.

1011 Genetic information has been said to traverse the bounds of personal autonomy where genetic tests reveal information about the family of those who undergo testing: T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347 371. Aspects of autonomy of genetic test information have important ethical ramifications with respect to issues of confidentiality, the ethical duty to collaborate in family studies, the duty to inform or disclose to family members information of genetic risks, and informed consent, which are discussed in chapter 3.

person's risk of infection. For insurance underwriting purposes, insurers ask applicants questions that allude to sexual preference and sexual activity to determine whether further testing for HIV is required. Information regarding sexual preference, sexual activity and HIV status may not only have shared consequences between partners, but is also highly sensitive.

11.144 Moreover, it is already accepted practice for insurers to use shared genetic information (that is, family medical history) to underwrite.[1012] While new genetic test information raises important reliability and relevance issues, it may be difficult to argue that it raises entirely new concerns between family members and partners.[1013]

11.145 Another characteristic that is often invoked by advocates of genetically exceptionalist regulation is that genetic information is relevant for populations: ethnic, racial or local groups.[1014] As discussed in chapter 5, the potential for discrimination and stigmatisation to result from inferences drawn from genetic associations among African-American communities (sickle-cell trait) in employment is well documented.[1015] However, genetic information is not unique in this context either. Death rates are statistically higher for indigenous Australians than for the total Australian population in every age group.[1016] HIV/AIDS is known to be more prevalent among gays and intravenous drug users, and within specific ethnic groups.[1017] For example, postal codes have been used in at least one epidemiological study to determine the prevalence of HIV/AIDS in Canadian communities.[1018]

11.146 An individual's inability to control his or her genetic make-up is another argument used to bolster genetic exceptionalism. As the argument runs, because genetics is beyond individual control, people should not be adversely affected by

1012 However, privacy law restricts insurers from collecting genetic information in one insurance proposal and using that information to directly underwrite another: see the discussion below regarding privacy law that applies if insurers between family members misuse genetic information. See also Investment and Financial Services Association, *IFSA's Policy on Genetic Testing* (1999), cl 7, which provides that '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'.

1013 However, see above, which discusses the difficulties in using genetic test information in the same way that family history information is currently used for underwriting purposes.

1014 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 372.

1015 See also J Seltzer, 'The Cassandra Complex: An Employer's Dilemma in the Genetic Workplace' (1998) 27 *Hofstra Law Review* 411 for an account of the issues that genetic information raises in employment.

1016 See Australian Bureau of Statistics, *Mortality of Aboriginal and Torres Strait Islander Australians*, 3315.0 (1997), Australian Bureau of Statistics, Canberra, which indicates that the largest differences are among people aged 35–54 years old, where mortality rates in this age group are 6–7 times higher for indigenous people.

1017 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 374.

1018 For example, B Dickens of the University of Toronto has indicated that a HIV-AIDS epidemiology study had been conducted in Canada by post code: B Dickens, *Consultation*, Sydney, 28 March 2000.

conditions for which they are not responsible.[1019] The assertion that responsibility ought to attach to certain risk factors for insurance and not others raises three important issues.

11.147 First, the relationship between genotype and disease is not simple. The complex interactions between genotype, environment and lifestyle all have an impact upon disease; thus the assignment of responsibility over one's health is a difficult matter to demarcate. As Lemmens maintains, to hold people accountable for 'lifestyle-related' increased health risks in insurance, like the claim that HIV-AIDS is somehow a 'self-inflicted' condition, further discriminates against those already vulnerable to the negative effects of discrimination.[1020]

11.148 Second, behavioural genetics offers an ironic comparison for those who consider that genetic risks should not be the basis of discrimination in insurance, while lifestyle-related risks should be because they are within an individual's control. Alcohol consumption and smoking have always been considered to be lifestyle choices, which sometimes merit adverse underwriting in personal insurance. However, preliminary research into behavioural genetics suggests that genetic factors contribute to alcoholism and nicotine addiction.[1021] Therefore, by this rationale, if genetic factors somehow contribute to alcoholism and nicotine addiction, do people that can show a genetic causal nexus relinquish 'responsibility'? How does one decide between a genetic and non-genetic cause?

11.149 Finally, according to Murray genetic exceptionalism depends on a 'two-bucket theory' of disease. According to this model, there are two buckets — one labelled 'genetic', the other labelled 'non-genetic' — and we should be able to toss every disease and risk factor into one of the two.[1022] The inequitable effects of regulation that seeks to distinguish between genetic and non-genetic health risks for insurance underwriting have been highlighted in the following examples:

> Under some of the selective genetics laws, a woman who carries the BRCA 1 gene and who is thereby at higher risk for developing breast cancer, cannot be charged a higher premium. However, another woman who has undergone a mastectomy because of breast cancer, who does not have one of the identified mutations and who has been successfully treated, could be excluded or forced to pay higher premiums. If a predicative genetic test for schizophrenia were developed (which is unlikely at this time) a person identified as being at high risk for the disease could not be excluded from life insurance. Other people who have been treated for depression may

1019 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 375.

1020 Ibid.

1021 Ibid; M Rothstein, 'New Discoveries in Genetics, Including Behavioural Genetics, Will Raise a Host of Legal Questions Requiring Careful Scrutiny by the Courts' (1999) 83 *Judicature* 117.

1022 T Murray (1997), 67.

> encounter difficulty in obtaining a similar contract if their condition were to not be linked to specific genetic mutations.[1023]

11.150 Selective justice, which focuses on the exclusive protection of particular types of genetic information from insurance underwriting has the practical effect of distinguishing between people who can find a genetic causal nexus and those that can not, offering protection only to those individuals who fit within an arbitrary definition of what is genetic.[1024]

Question 11–11. Would the equitable treatment of all applicants for insurance 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?

Equity of access to insurance

11.151 The main reasons that insurers argue for the inclusion of genetic risk information in insurance are economic concerns that adverse selection may result and, secondly, moral concerns that insurance contracts are rooted in equity of information between the insurer and insured.[1025] In the same way, those who argue against the inclusion of genetic information in insurance claim that the inclusion of genetic information raises economic and equitable concerns where individuals are precluded from access to insurance and, secondly, moral concerns that discrimination, privacy and ethical issues require the exclusion of genetic information from insurance.

11.152 Concerns about equity for those who seek the inclusion of genetic information are expressed in terms of the fundamental goal of insurance, which is said to be equity among the pool of insureds, so that individuals with the same or similar risk are charged the same premium.[1026] According to Robert Pokorski, 'an

1023 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 381.

1024 G Spiteri, 'Genetic Testing and its Implications for Australian Insurance Law' (2000) 7 *James Cook University Law Review* 96, 113.

1025 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 384.

1026 For example see 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.

insurer may — and must — discriminate to achieve equity, *insofar as the discrimination remains fair* [emphasis added]'.[1027]

11.153 Concerns about equity, by those who seek the exclusion of genetic information from insurance underwriting are expressed in terms of societal goals and distributive justice, which can be said to be a debate about the social equity of access to insurance. Fairness, in this sense, goes beyond the accurate determination of actuarial risk based on genetic information to a debate about the role of insurance in Australian society.

11.154 For reasons of public policy, the law may prohibit insurers from using certain risk factors, or certain information, to underwrite. In many cases, such public policy interventions in the market will inhibit full underwriting only at the margins without significantly affecting the nature or viability of the entire risk pool. For example, Australian insurers may not take race or ethnicity into account in life insurance underwriting because of anti-discrimination principles, even where actuarial data may indicate differential mortality rates. Nevertheless, insurers have not suggested that this has had any particularly negative impact on operations.

11.155 However, where such public policy considerations cut across the entire economic structure of a form of insurance, such that mutuality-based underwriting will no longer work, it may be necessary for government to mandate the use of community rating and perhaps to assume some financial responsibility through the provision of direct grants or tax relief.

11.156 An argument raised by those who would restrict the use of genetic information in insurance is that access to such information by insurers will effectively limit the availability of insurance based on genetic status, creating a 'genetic underclass'. From an insurer's perspective, the removal of particular risks from insurance underwriting moves mutuality-based insurance closer to community rating.

11.157 The UK Human Genetics Commission (HGC), which is reviewing the wider social and ethical implications of the use of genetic information in insurance (among other areas), has issued interim recommendations to the government for the immediate implementation of a moratorium on the use of genetic tests by insurers. The HGC noted that 'the [UK insurance] industry has accepted that genetic tests of any real predictive value are only relevant to a very few rare

1027 See 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.

diseases and agree that to exclude their use would have no serious economic impact on the insurance industry'.[1028]

11.158 However, IFSA has suggested that where life insurance is a voluntary product, it should not be a vehicle of public sector social welfare.

Equity in mutuality-rated personal insurance in Australia

11.159 A comparison of health insurance (both private and public) as a good between Australia and other countries offers a useful starting point when considering how mutually rated personal insurance is perceived in Australian society, and whether it is a good which requires some form of protection. Importantly, other countries with similar universal health care systems to Australia (for example, United Kingdom and Netherlands) have already approached the use of genetic information through the introduction of moratoriums. While similarities in the protection offered in health insurance in Australia and internationally may not be reflective of the way that mutually rated personal insurance contracts are perceived by Australians, the comparison is useful nonetheless.

11.160 As discussed earlier, the use of genetic information in insurance presents many challenges, some which may not be unique, and if treated in an exceptional way may create inequity. However, according to Lemmens, the most significant impact of genetics in insurance is that it will enable insurers to establish more detailed risk assessments once genetic testing becomes cheaper and more accurate, resulting in more individualised risk assessments that reduce insurance pools.[1029] Lemmens claims that it may be impossible to deal with the social problems resulting from the application of genetic technology with patchwork legislation. He suggests that a general approach that takes into account the financial and social pressure on individuals affected by disease or risk of disease is necessary.

11.161 The inquiry is interested in considering how Australians perceive the distribution of mutually rated personal insurance and whether some types of personal insurance are social goods requiring protection from the use of genetic and other health risk information to exclude access (for example, similar to private health insurance).

1028 Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London. See below for a discussion of the HGC interim recommendation on the use of genetic information in insurance.

1029 T Lemmens (1999), 32.

Question 11–12. Are there practical and cost effective mechanisms that could be introduced in the mutually rated personal insurance market to enhance access and equity for persons who might otherwise be disadvantaged because of genetic status? For example:

- providing a basic level of cover through community rating, with mutuality used for policies seeking coverage above this level?
- 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?

Current approaches to genetics and insurance

11.162 In Europe, the call for regulation has resulted in two approaches: either stringent legislation[1030] or voluntary imposition of moratoriums by the insurance industry.[1031] In the United States, genetic-specific anti-discrimination legislation has been enacted in over 44 states, whose focus is upon the exclusion of specific types of genetic test information.[1032]

Europe

United Kingdom

11.163 In the United Kingdom, the insurance industry and the government have approached these issues through the adoption of a comprehensive Genetic Testing Code of Practice (ABI Code)[1033] and the establishment of the Genetics and Insurance Committee (GAIC), whose specific remit is to evaluate the scientific and actuarial relevance of genetic tests proposed for use by the insurance industry.

1030 At least three European countries have already implemented explicit legislation prohibiting the use of genetic testing for insurance purposes: Austria, Belgium and Norway: T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 360.

1031 The United Kingdom has operated under a voluntary moratorium implemented by the Association of British Insurers (ABI) since 1997. The effectiveness of the self-imposed and industry–regulated moratorium was highly criticised in a recent report by the House of Commons and the Human Genetics Commission: See House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London; Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London.

1032 See L Gostin and J Hodge, Jr, 'Genetic Privacy and the Law: An End to Genetic Exceptionalism' (1999) 40 *Jurimetrics* 21 for an overview of genetic information legislation in the United States of America. See also T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347, 362.

1033 The Association of British Insurers (ABI) represents 96% of UK insurance business (400 companies).

11.164 The ABI Code provides a set of principles that deal comprehensively with the collection, use and storage of genetic information, covering insurance practice, security and confidentiality, education and training, underwriting, applicants' obligations, and appeals processes. The key elements of the ABI Code can be summarised as requiring that:

(a) Applicants for insurance must not be asked to undergo a genetic test in order to obtain insurance.[1034]

(b) Insurers may, however, ask to see the results of certain genetic tests that applicants have already taken.[1035]

(c) Genetic test results need not be disclosed in applications for insurance (any insurance) with a value of up to £300 000.[1036]

(d) If an insurer is considering declining an application on the basis of a genetic test result, it must consider how it can offer some insurance to the applicant, for example, by changing the length of the policy or offering different cover.[1037]

(e) Insurers will only take account of the results of those genetic tests that the ABI's genetics adviser has concluded are reliable and relevant for insurance purposes. To date, the ABI's Genetic Adviser has given approval for the use of the following genetic tests, in each case for critical illness insurance, income protection and long term care:[1038]

- Huntington's disease (also approved for use by GAIC);
- Early onset Alzheimer's Disease (applications lodged by the ABI with GAIC for approval for genetic testing for Amyloid precursor protein gene (APP) and Presenilin 1 gene (PS1)); and

1034 Association of British Insurers, *Genetic Testing: ABI Code of Practice* (1999), Association of British Insurers, London, Principle 2.

1035 Ibid, Principle 33, 4.

1036 See Association of British Insurers, *Life Insurance and Genetics — A Policy Statement*, Association of British Insurers, <www.insurance.org.uk/INDUSTRY/abikey/pol1.asp>, 6 March 2001, which altered the previous position in the UK, increasing the moratorium from £100 000 to £300 000 (approximately $820 000) and widening its application to all forms of insurance. But see Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London, which recommends an exception be made for policies greater than £500 000.

1037 Association of British Insurers, *Genetic Testing: ABI Code of Practice* (1999), Association of British Insurers, London, Principle 36.

1038 See Genetics and Insurance Committee, *Decision of the Genetics and Insurance Committee (GAIC) Concerning the Application for Approval to Use Genetic Test Results for Life Insurance Risk Assessment in Huntington's Disease*, GAIC/01.1 (2000), Department of Health, London and House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, 43–45 (Memorandum submitted by the Genetics and Insurance Committee).

- Hereditary breast and ovarian cancer (applications lodged by the ABI with GAIC for approval for genetic testing for BRCA1 and BRCA2).

  Insurers may continue to take account of these tests until they have been considered by GAIC. Only if GAIC agrees that they are valid for insurance purposes may insurers continue to use them.[1039]

(f) If GAIC does not approve the use by insurers of a test result, insurers will stop using it. The industry will also re-underwrite, back to 1 November 1998, applications for people who were declined insurance or offered higher premiums, as a result of a 'non-approved' test result being taken into account. Where higher premiums have been paid, the difference will be refunded.[1040]

(g) Insurers must have a procedure in place to deal with complaints relating to the Code of Practice. When the insurer responds to a complaint, it must inform the customers of their right to invoke the adjudication system set up under the Code.[1041]

11.165 GAIC is the principal means by which the UK government influences the use of genetic information in insurance. GAIC is served by an advisory committee that includes nominated representatives from the insurance industry, the actuarial association, the scientific community, and a community interest group.[1042] Under its terms of reference, GAIC is required to:

- develop and publish criteria for the evaluation of specific genetic tests, their application to particular conditions and their reliability and relevance to particular types of insurance;

- evaluate particular tests against those criteria and promulgate its findings; and

- report to Health, Treasury and Department of Trade and Industry Ministers, on proposals received by GAIC from insurance providers and the subsequent level of compliance by the industry with the recommendations.

11.166 GAIC has recognised that three conditions need to be met before a test can be suitable for use when underwriting insurance proposals:

1039 Association of British Insurers, *Genetic Testing: ABI Code of Practice* (1999), Association of British Insurers, London, Principle 33.

1040 Ibid, Principle 5.

1041 Ibid, Principles 21, 22.

1042 Association of British Insurers (ABI), the Chief Medical Officer, the Faculty and Institute of Actuaries and the Genetic Interest Group (GIG): Genetics and Insurance Committee, *Annual Report*, 2000 (1999), Department of Health, London.

> Is the test technically reliable? Does it accurately detect the specific changes sought for the named condition? This is the technical relevance of the test.
>
> Does a positive result in the test have any implications for the health of the individual? This is the clinical relevance of the test.
>
> Does the health implications [*sic*] make any difference to the likelihood of a claim under the proposed insurance product? This is the actuarial relevance of the test.[1043]

11.167 The House of Commons Science and Technology Committee considered the effectiveness of GAIC and the ABI Code in some depth in its report on insurance and genetics. A key recommendation made by the Committee was that compliance with the ABI Code be enforced with meaningful sanctions. The Committee recommended that:

> Insurers must prove that they are capable of regulating themselves effectively and thoroughly, with sanctions in place to ensure compliance. The ABI's Code of Practice is a welcome step in the right direction by insurers but it is inadequate in its present form. The reformed GAIC should make recommendations to the ABI for its Code of Practice. The GAIC should also closely monitor insurers' compliance with the Code.

11.168 The Human Genetics Commission (HGC) in its interim recommendations criticised the insurance industry's enforcement of self-regulation of genetic information in the UK. The HGC recommended the implementation of a Government moratorium which should embrace the following:

> No insurance company should require disclosure of adverse results of any genetic tests, or use such results in determining the availability or terms of all classes of insurance.
>
> The moratorium should last for a period of not less than three years. This will allow time for a full review of regulatory options and afford the opportunity to collect data which is not currently available. The moratorium should continue if issues have not been resolved satisfactorily within this period.
>
> The moratorium will not affect the current ability of insurance companies to take into account favourable results of any genetic test results which the applicant has chosen to disclose.
>
> The issue of family history information presents particular difficulties. The Commission is concerned that the insurance industry's principle of open disclosure and utmost good faith by the parties seems to fall most heavily on the consumer. Few people are provided with information as to how their premiums are loaded. HGC understands that family history information can amount to genetic information and is not always interpreted appropriately in underwriting. During the moratorium period HGC will address the issue as to how family history information is used by insurers.

1043 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, 45 (Memorandum submitted by the Genetics and Insurance Committee).

> An exception should be made for policies greater than £500,000. This will address concerns about adverse selection, the process by which persons having a known risk set out to acquire substantial insurance cover. (The HGC, however, has yet to see evidence of the extent to which adverse selection takes place in this context.) We recommend this upper financial limit on the basis of the industry's own tables and information as a protection from significant financial loss.
>
> Only genetic tests approved by the Genetics and Insurance Committee (GAIC) should be taken into account for these high-value policies. The HGC believes that there remains a need for an expert body of this kind, but that the criticisms of the GAIC voiced by the House of Commons Science and Technology Select Committee must be addressed.
>
> In view of the failing of the current system of self-regulation of the insurance industry a method of independent enforcement of this moratorium will be needed. The HGC believes that legislation will be necessary to achieve this.
>
> During the moratorium period, the HGC will continue with its consideration of the wider issues and should work with other bodies to identify a system which enjoys public confidence and the confidence of the insurance industry. An appropriate recommendation could then be made to the Government which could replace the moratorium with new arrangements.[1044]

Sweden

11.169 Following an investigation into the likely effect of implementing a moratorium on the use of genetic information in insurance, the Swedish State and the Swedish Insurance Federation Concerning Genetic Testing signed an agreement in May 1999 governing the use of such information by life and health insurer members of the federation. The agreement states that members will not require predictive genetic testing of current or prospective policy holders.[1045] Nor are members permitted to inquire as to existing genetic information held by such persons. However these restrictions do not apply above certain thresholds of policy size. The agreement has the same general effect as the Swedish Insurance Federation's *Voluntary Code* of 1998, which is an agreement between members of the Insurance Federation to limit the use of genetic information in risk assessment.

Netherlands

11.170 In the Netherlands, the *Medical Checks Act 1997* covers persons undergoing medical examinations for life insurance and civil disability insurance, including health checks and screening before the insurance contract is concluded. Any testing must not unreasonably infringe on the person's privacy.[1046] In

1044 Human Genetics Commission, *The Use of Genetic Information in Insurance: Interim Recommendations of the Human Genetics Commission* (2001), Human Genetics Commission, London.

1045 The Agreement entered into force on 1 July 1999 and applies up to and including 31 December 2002. See Swedish Insurance Federation, *Annual Report* (1999), Swedish Insurance Federation.

1046 *Medical Checks Act 1997*, Art 3.

particular, a medical check must not include a test that entails a disproportionate risk for the person tested when compared to the usefulness of the test for the requesting party.[1047] The Act thus embraces a proportionality test for the determination of the acceptance of genetic tests. The Act also imposes an 'enquiry limit' relating to the questioning of relatives of a person in order to determine family history of a given trait. Questioning of this kind is permissible only where the value of the policy exceeds a given monetary threshold.

United States of America

11.171 Regulatory developments in the United States are limited in relevance because the focus of the issues in the US relates to the use of genetic information in health insurance, which is mutuality-rated. During consultations, the American Council of Life Insurers (ACLI) indicated that because genetics issues have largely been focussed in the area of health insurance, and because health insurance is governed by the States, much of the legislation regarding genetic information and insurance is at the state level.[1048] In the United States, at least 44 States have enacted specific legislation regulating the use of genetic data by insurers, either through genetic anti-discrimination legislation, privacy legislation or a mixture of both.[1049] Legislation between States varies, however, most generally prohibit insurers from excluding cover or raising premiums due to information about genetic abnormalities.

11.172 In 1996, the federal government introduced the *Health Insurance Portability and Accountability Act of 1996* (HIPAA), following recommendations by a National Institutes of Health working group on genetic information and health insurance. Amongst other matters, the working group recommended that information about past, present, or future health status, including genetic information, should not be used to deny health care coverage or service to anyone.[1050] For group health insurance, the HIPAA provides the following protections.

- Prohibition against excluding an individual from group insurance because of past or present medical problems, including genetic information.

- Prohibition against charging a higher premium to an individual than to others in group insurance.

1047 Ibid, Art 3(2)(a).
1048 ACLI, *Consultation*, 4 September 2001.
1049 T Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?' (2000) 45 *McGill Law Journal* 347 362.
1050 National Center for Human Genome Research, *Task Force Report: Genetic Information and Insurance* (1993), National Institutes of Health, Bethesda.

- Prohibition against exclusions in group health plans for a pre-existing condition to 12 months, and prohibits such exclusions if the individual has been previously covered for that condition for 12 months or more.

- Explicit provisions that provide that genetic information in the absence of a current diagnosis of illness shall not be considered a pre-existing condition.

11.173 In December 2000, the Secretary of Health and Human Services issued privacy regulations to accompany the HIPAA relating to protected health information used in health insurance. The regulations require that only the minimum necessary health information should be disclosed, except where medical records are transferred for the purposes of treatment.[1051]

Australia

Genetic Privacy and Non-discrimination Bill 1998 (Cth)

11.174 Under the Genetic Privacy and Non-discrimination Bill 1998 (Cth) (Stott Despoja Bill), genetic discrimination is defined as the different treatment of individuals (and their family members) based on genetic differences (presumed or actual), and is distinguished from discrimination based on the actual presence of the symptoms of a genetic disorder.

11.175 Genetic discrimination is described as occurring when an act, involving a distinction, exclusion, restriction or preference, is based on genetic information and has the purpose or effect of nullifying or impairing the recognition, enjoyment or exercise, on an equal footing, of any human right or fundamental freedom in the political, economic, social, cultural or any other field of public life.[1052]

11.176 In addition to the general prohibition against discrimination, the Stott Despoja Bill provides a specific reference to the area of insurance, which provides that:

> An insurer may request or require or use the genetic information of an individual if the genetic information from a genetic analysis has already been undertaken and a genetic record exists, but an insurer must not:
>
> (a) terminate, restrict, limit, refuse to renew, or otherwise apply conditions to the coverage of an individual or family member under the policy or plan involved, or restrict the sale of the policy or plan to an individual or family member on the basis of any genetic information about a healthy individual or a healthy family member, or on the basis of a request for or receipt of genetic services by an individual or family member; or

1051 N Jones, *Genetic Information: Legal Issues Relating to Discrimination and Privacy*, National Council for Science and the Environment, <www.cnie.org/nle/st-55.html>, 23 August 2001.

1052 Genetic Privacy and Non-discrimination Bill 1998 (Cth), cl 17.

> (b) discriminate against an individual's family in the provision of insurance coverage; or
>
> © require an applicant for insurance coverage, or an individual or family member who is enrolled under an insurance coverage policy or plan, to be subjected to genetic analysis or to be questioned about genetic information.[1053]

11.177 The Stott Despoja Bill focuses on the exclusion of certain types of genetic information from insurance, which it defines as:

> (a) information from a DNA sample about genotype; or
>
> (b) information from mutation analysis; or
>
> © information about nucleotide and polypeptide sequence(s); or
>
> (d) information about gene(s) or gene products.[1054]

11.178 The Stott Despoja Bill, as with many other proposals for regulation of genetic information in the area of insurance, distinguishes between genetic and non-genetic health risks and also between genetic information generally and genetic analysis. See below for discussion of the efficacy of legislation that distinguishes between genetic and non-genetic information.

IFSA's Policy on Genetic Testing

11.179 Both positive and negative genetic test results may be actuarially relevant. If a positive genetic test is relevant to assessing risk, should negative tests also be actuarially relevant to discounting risk?

11.180 For example, the House of Commons – Science Technology Committee considered a case where an insurance applicant had a family history of Huntington's chorea, but had a favourable genetic test for the disorder.[1055] The Committee strongly supported the use of negative genetic tests to offer standard rates in this situation since insureds with a family medical history for Huntington's are often declined for insurance or offered premiums with a high loading. In its recommendations, the Committee concluded that:

1053 Ibid, see cl 17 generally and cl 19 in the area of insurance.

1054 Ibid, cl 7.

1055 The predictive genetic test for Huntington's chorea is one of the very few examples where genetic information derived from family history information is less predictive than that derived from the genetic test.

> the evidence presented to us seems to indicate that the only tests that are currently of any real relevance and reliability in an insurance context are those which show a negative result, i.e. an absence of the defective gene.[1056]

11.181 Australian personal insurers use one standard-base line rate, not several — but there have been suggestions that genetic test information could be used not merely to adjust an individual's risk rating to the standard rate, but affirmatively to create new sub-categories of *preferred* risk ratings, as is sometimes done overseas.

11.182 In Australia, IFSA has produced a policy on the use of genetic testing and information in life insurance, applicable to its membership as an aspect of the partly self-regulating nature of the industry. The IFSA Policy on Genetic Testing (the IFSA Policy) provides that:

> 1. For the purposes of this policy, genetic tests are defined as "the direct analysis of DNA, RNA, genes or chromosomes for the purpose of determining predisposition to a particular disease or group of diseases, but excluding DNA, RNA, gene or chromosome tests for acquired disease".
>
> 2. Insurers will not initiate any genetic tests on applicants for insurance.
>
> 3. Insurers may request that all existing genetic test results be made available to the insurer for the purposes of classifying the risk.
>
> 4. In order to prevent indirect coercion to undergo genetic tests, insurers will not use genetic tests as the basis of preferred risk underwriting, (i.e. offering individuals insurance at a lower than standard rate).
>
> 5. When assessing the overall risk associated with a particular genotype (genetic make-up), insurers will take into account the benefits of special medical surveillance, early medical intervention, and likelihood of successful treatment.
>
> 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 results of genetic tests.
>
> 9. Access to the results of genetic tests will be restricted to the insurer's underwriters and reinsurers. The results will be made available to other third parties only with the written authorization of the life insured or in the normal course of discovery during legal proceedings.

1056 House of Commons — Select Committee on Science and Technology, *Genetics and Insurance* (2000–1), The Stationery Office Limited, London, xix.

11.183 IFSA initially applied to the Australian Consumer and Competition Commission (ACCC) for authorisation of its entire policy but subsequently applied only in respect of clauses 2 and 4,[1057] which could be construed as anti-competitive on the basis that an insurer would be prohibited from offering a competitively priced or discounted policy to a person who had undergone genetic testing which did *not* reveal any significant disorders.[1058] The *Trade Practices Act 1974* (Cth) provides that the ACCC can give 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.[1059]

11.184 In support of its applications, IFSA submitted that the primary purpose of the IFSA Policy was to provide a framework in which insurers do not initiate genetic tests. According to IFSA, the key issue of the application was whether there was public benefit in insurers not initiating genetic tests. Submissions received by the ACCC raised a number of concerns, including:

- concerns regarding the predictive significance of genetic test information and the possibility of discrimination resulting from misinterpretation of risk;
- concerns about transparency in actuarial methods used to assess risk based on genetic test information;
- concerns regarding community willingness to participate in genetic research; and
- privacy and confidentiality issues.

11.185 In a highly critical submission from the NSW Privacy Commissioner, several concerns were raised in relation to the predictive significance of genetic test information and the possibility of resulting unlawful discrimination through misinterpretation of risk. The Commissioner submitted:

> Paragraph 5, while marking an improvement on earlier versions of the draft policy does not adequately address the risk of genetic based discrimination. It only requires insurers to take known limiters of a specific genetic risk into account to balance a putative risk based on genetic test results. It makes no specific commitment as to the weight to be given to these factors. It provides no obligation to consider the established statistical probability of morbidity from a particular genetic indicator nor the variability in terms of the time involved in the possible onset or manifestation of

1057 Applications for ACCC Authorisation A30200 and A30201, respectively.

1058 IFSA applied for authorisation pursuant to s 88(1) of the *Trade Practices Act 1974* (Cth) (TPA), concerning arrangements that may have the effect of substantially lessening competition, within the meaning of section 45 of the TPA.

1059 TPA s 90(7), 90(8). While there is some variation in the language between sub-sections 90(7) and (8), the ACCC has adopted the view taken by the Trade Practices Tribunal that in practical application the tests are essentially the same: *Re Media Council of Australia (No. 2)* (1987) ATPR 40-774 48,418.

> the condition. The prospect that people will be arbitrarily discriminated against because of genetic indicators where the actual risks can not be identified or estimated is the real issue of concern in relation to risks of genetic discrimination.[1060]

11.186 A submission from the Human Genetics Society of Australasia (HGSA) raised concerns in relation to the ability of current actuarial models used to integrate genetic test information into underwriting:

> The HGSA urges the insurance industry to review its actuarial modelling of the impact of predictable genetic disease. The HGSA wishes to promote trust and confidence between geneticists and the insurance industry and encourages the industry to seek statistical and epidemiological information from geneticists expert in these areas.[1061]

11.187 Similarly, the Australian Medical Association submitted that:

> insurers make the actuarial and statistical methods of risk assessment for genetic tests transparent and accountable to the public. These methods must be reviewed and revised on a recurrent basis to account for advances and innovations in genetic testing and associated treatment.[1062]

11.188 As to privacy and confidentiality issues, the NSW Privacy Commissioner also raised several concerns.

> Allowing insurers under paragraph 3 of the draft policy to require an applicant for insurance to produce all existing genetic test results is overly intrusive and would result in an excessive collection of personal information. As more conditions for which routine testing is indicated are discovered, this paragraph would become increasingly excessive. Even now, it would technically require almost any applicant born in New South Wales since 1974 to produce the results of routine newborn screening tests.[1063]

11.189 In a draft determination on the IFSA applications, the ACCC proposed to deny authorisation of the draft Policy, concluding that the Policy was not likely to result in a public benefit and that significant anti-competitive detriment would arise from a collective agreement to prevent the offer of lower–than–standard premiums based on genetic test results.

1060 Office of the NSW Privacy Commissioner, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 8 August 2000.

1061 Human Genetics Society of Australasia, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 22 December 1999.

1062 See Australian Medical Association, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 10 December 1999.

1063 Office of the NSW Privacy Commissioner, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 8 August 2000.

11.190 However, in its November 2000 determination, the ACCC noted that following the pre-decision conference at the request of the AMA, it received numerous submissions in support of authorisation of clauses 2 and 4 of the policy, despite its anti-competitive effects.[1064] For example the HGSA noted that:

> We submit that any benefit of increased competition between insurance companies that might arise from the ability to request (demand) predictive genetic tests prior to underwriting insurance and/or the offering of inducements to take genetic tests with an option to refuse (or load) insurance on the basis of the outcome, are greatly outweighed by the destruction of the social fabric of society that will be caused by what IFSA, itself, has called a genetic 'free for all'.[1065]

11.191 Although the ACCC initially was disinclined to authorise the policy, in November 2000 it granted IFSA a two-year authorisation of clauses 2 and 4, noting the establishment of this joint 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.[1066]

11.192 In what appears to be an attempt to address some of the complex privacy and actuarial concerns raised by the use of genetic test information, IFSA and its members have recently agreed to amend its Policy:

> Representatives of all life insurance companies selling retail risk insurance products attended a meeting in June 2001 to consider IFSA's current Genetic Testing Policy. At that meeting it was unanimously agreed that the policy should be mandatory. It was also agreed that the policy should be extended to include a statement on privacy as well as a requirement for insurers to explain, in a more transparent manner, the reasons for rejecting applications for insurance cover or offering modifications.[1067]

1064 See Australian Medical Association, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 8 August 2000, M Otlowski, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 7 August 2000, Human Genetics Society of Australasia, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 22 December 1999.

1065 Human Genetics Society of Australasia, *Submission to the ACCC Regarding Applications for Authorisation by IFSA*, 22 December 1999.

1066 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.

1067 Investment and Financial Services Association, 'Genetic Testing', *The IFSA Voice*, September 2001, 4.

12. Other services and contexts

Contents

Introduction

12.1 Chapters 10 and 11 have examined the discrimination and privacy issues in connection with the use of genetic information in insurance and employment. There are a variety of other contexts in which genetic information is currently being used, or may be used in the future. This Chapter discusses the other contexts in which individuals, organisations or government may seek to collect, store, use or disclose an individual's genetic information, and considers the existing regulatory framework in relation to these contexts.

Anti-discrimination legislation

12.2 As discussed in Chapter 5, the *Disability Discrimination Act 1992* (Cth) (DDA) is the federal anti-discrimination legislation with most application to genetic information. The provisions discussed in this chapter are generally 'limited application provisions' (see Chapter 5 for more detail).

12.3 The DDA prohibits a person or organisation that provides goods or services, or makes facilities available, from discriminating against an individual on the ground of his or her disability:

- by refusing to provide the goods or services, or to make the facilities available;

- in the manner in which the goods and services are provided, or the facilities are made available; or

- in the terms and conditions on which it provides the individual with the goods or services, or makes the facilities available.[1068]

12.4 A 'service' includes services relating to banking, insurance, entertainment, transport or travel, telecommunications, a service of the kind provided by members of a profession or trade, or by a government, government authority or a local government body.[1069]

Privacy legislation

12.5 The framework for the privacy protection of personal information is detailed in Chapter 4. Briefly, at the federal level, the collection, use, storage and disclosure of personal information by Commonwealth agencies is regulated by the Information Privacy Principles (IPPs), and the private sector by the National Privacy Principles (NPPs). State and territory privacy legislation may also be applicable.

Trade practices legislation

12.6 Finally, it may be that the *Trade Practices Act 1974* (Cth) (TPA) will provide some protection against corporations engaging in unconscionable behaviour in the supply of goods or services of a kind ordinarily acquired for personal, domestic or household use or consumption.[1070] However, a court may consider the 'legitimate interests' of the corporation when determining whether its conduct has been unconscionable.

Genetic information in other contexts

Government services

12.7 Section 29 of the DDA provides that it is unlawful for a person who performs a function or exercises a power under a Commonwealth law or program [1071] to discriminate against an individual on the basis of his or her disability.

1068 *Disability Discrimination Act 1992* (Cth) s 24(1).
1069 Ibid, s 4(1).
1070 See *Trade Practices Act 1974* (Cth) s 51AB.
1071 Or who has any responsibility for the administration of a Commonwealth law or the conduct of a Commonwealth program: *Disability Discrimination Act 1992* (Cth) s 29.

12.8 In future, federal, state and territory government agencies may seek access to an individual's genetic information for purposes of identification, as well as in determining eligibility for certain programs.

12.9 For example, the federal Attorney-General's portfolio has predicted that by 2005, the 100 Points System of identification currently used by Commonwealth agencies could be replaced by new systems to verify identity, such as photographic images and DNA.[1072] The use of such identification systems raises privacy concerns similar to those raised in the 'Australia Card' debate of the mid-1980s — however, it is important to remember that the collection, use and storage of such genetic information by Commonwealth agencies would be subject to the *Privacy Act.*

12.10 In future, government departments may seek access to an individual's genetic information to determine his or her eligibility for certain social security and training programs. Departments might seek to limit access to training programs for individuals with a predisposition to a possibly debilitating genetic disease on the basis that such training would be a waste of resources in the long term. However, in relation to Commonwealth programs, any unlawful discriminatory use of such information by a Commonwealth agency may be prohibited under s 29 of the DDA.

Immigration

12.11 Genetic information might be used in Australia's immigration program in a number of ways, including:

- as proof of a family relationship — between an applicant and an Australian citizen or permanent resident, or between an applicant and each family member listed on the application;[1073]

- as a measure against so-called 'people smuggling'— the federal government has announced its intention to introduce the DNA testing of asylum seekers to determine whether they previously have been denied a protection visa, or whether they already have protection in another country;[1074] or

1072 Submission to Joint Parliamentary Committee on the NCA Inquiry into Law Enforcement Implications of New Technology, 25 September 2001.

1073 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.

1074 Department of Immigration and Multicultural Affairs, *Fact Sheet 83 — People Smuggling*, Commonwealth of Australia, <http://www.dima.gov.au/facts/83people.htm>, 2 August 2001.

- as a component of the 'health requirement' that is applied to all immigration applicants.[1075] However, there is no present evidence of this usage.

12.12 The use of genetic information in the immigration context raises concerns for the privacy of individual genetic information as well as possible discrimination on the basis of that information. In relation to the collection, storage and possible later disclosure of the information the Department of Immigration and Multicultural Affairs will be subject to the IPPs.

12.13 The DDA contains a specific exemption in relation to immigration. Section 52 provides that any discriminatory provisions in the *Migration Act 1958* (Cth) (*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. Therefore, it is currently not unlawful to discriminate against an individual on the basis of his or her genetic information, provided the discrimination complies with the *Migration Act* or regulations.

Education

12.14 Section 22 of the DDA prohibits educational authorities [1076] from discriminating against individuals on the basis of their disabilities.

12.15 Currently, a number of secondary schools in Sydney and Melbourne allow voluntary genetic screening programs to identify carriers of certain genetic conditions. These programs are outlined in detail in Chapter 9.

12.16 Laura Rothstein has suggested that schools may seek to acquire, have or use genetic information for the following reasons.

- If a school has genetic information about a learning disability such as dyslexia, it may be able to provide remedial training for the child.

- Where a condition relates to potential behavioural and disciplinary problems, the school may observe the child more closely, and provide behaviour management before problems occur.

- In relation to conditions involving health impairments, the school may be able to provide appropriate services for the child.[1077]

1075 Department of Immigration and Multicultural Affairs, *Fact Sheet 22 — The Health Requirement*, Commonwealth of Australia, <http://www.dima.gov.au/facts/22health.htm>, 2 August 2001.

1076 That is, bodies administering a school, college, university or other institution providing education or training.

1077 L Rothstein, 'Chapter 17: Genetic Information in Schools' in M Rothstein (1997), 317–318.

12.17 However, there is a concern that schools and other educational institutions may also seek to use genetic information to discriminate against individuals. For example, an institution may seek to collect genetic information to determine eligibility for scholarship grants in the belief that funding students who are susceptible to serious (and possibly life threatening) genetic illnesses might be a waste of limited resources.[1078] Discrimination on these grounds would appear to be unlawful under the DDA, unless the educational authority is able to obtain a temporary exemption from the operation of the legislation.

12.18 Alternatively, Rothstein has suggested that schools may be able to provide genetic information to social service agencies for public health services and planning.[1079] This information could be collected through genetic screening programs similar to the 'carrier testing' programs that are already conducted. This raises a number of ethical and privacy concerns — in particular, concerns that in future, poorly funded schools might facilitate the genetic testing and screening of their students by others for monetary reasons.[1080]

Health services

12.19 The regulatory framework for the protection against discrimination and breaches of privacy in the provision of health services is outlined in Chapters 8 and 9.

12.20 In future, health providers may seek access to individuals' genetic information in order to determine eligibility for a number of health services such as IVF treatment, organ transplants or even aged care facilities.[1081] The reason for seeking this information may be to limit the access of individuals with a predisposition to serious genetic illnesses, in the belief that limited resources should be reserved for more healthy individuals.[1082]

12.21 Additionally, in an effort to ensure the smooth running of an aged care facility, a provider may seek to exclude applicants or residents with a genetic predisposition to certain 'high maintenance' disorders. For example, in light of the resources needed to properly care for residents suffering from Alzheimer's disease, a facility may seek to exclude any applicants with a predisposition to that disorder.

1078 R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 334.

1079 L Rothstein, 'Chapter 17: Genetic Information in Schools' in M Rothstein (1997), 318.

1080 Ibid, 319.

1081 Discrimination in the provision of access to aged care facilities is prohibited under s 25 of the DDA, with a similar exemption for unjustifiable hardship.

1082 For example, similar principles are already used in relation to heart transplants, in which suitability is determined by whether a patient has given up smoking and, if necessary, alcohol: see A Keogh, *Information Sheet, National Clinical Cardiovascular Advisory Committee*, Heart Foundation, <http://www.heartfoundation.com.au/docs/hhc3.htm>, 2 August 2001.

12.22 As noted above, discrimination against individuals in the provision of health services on the basis of their genetic disabilities would appear to be unlawful under the DDA, unless the organisation is able to obtain a temporary exemption from the DDA, or is able to show that it would be an unjustifiable hardship to provide the special services and facilities to the person suffering the disability.

Other services

12.23 In future, providers of goods and services may seek to collect individual genetic information for a variety of reasons. For example, the airline industry may seek to screen individuals who are susceptible to deep vein thrombosis (also known as 'economy class syndrome') from employment, or from flying with the airline, through fear of potential liability for any injury suffered.

12.24 While this form of discrimination would appear to be prohibited under the DDA, it may be rendered lawful if the organisation were able to obtain a temporary exemption from the DDA, or else could show that it would be an unjustifiable hardship to provide the special services and facilities to the person suffering the disability.

Aboriginality

12.25 One of the interesting outcomes of the Human Genome Project to date is that there is no clear genetic basis for the concept of 'race'. However, some scientists predict that it may be possible in future to identify some physical characteristics, such as eye, hair and skin colour, from genetic information (ie, a DNA sample). As discussed in Chapter 2, genetic information also can have links beyond the individual to the broader descent group or community.

12.26 Thus, the inquiry has heard suggestions that, in future, there may be arguments that genetic information could or should be used as a means of establishing or proving Aboriginal or Torres Strait Islander identity, for the purposes of determining eligibility for membership or voting rights in Indigenous organisations such as the Aboriginal and Torres Strait Islander Commission (ATSIC); for the purposes of determining eligibility for the provision of entitlements and services reserved for Indigenous people (such as Abstudy); or, perhaps, even in the context of native title determination applications.[1083] The push to use genetic information could come from either direction: that is, a person asserting Aboriginal identity which has not been accepted by the community, or a government authority might seek to offer genetic evidence in support of this claim;

1083 For example, where a native title claim group is defined as the biological descendants of certain known ancestors, DNA evidence could, if necessary, be used by individuals to show their biological connection with those ancestors.

conversely, a party might use (or call for) genetic information to dispute someone else's entitlements, voting rights, etc.

12.27 This raises the question of whether — even assuming that there is the technical capacity — genetic testing is an appropriate means of determining 'Aboriginality'. To date, the concept has relied upon a social construct of identity: that a person is a member of an Aboriginal community if he or she identifies as a member of the community, and is accepted by that community as one of its members. There is a real question whether there would be any value in insisting upon evidence of a *genetic* link to that community. This certainly would affect the status of persons adopted into that community, and perhaps persons with mixed Aboriginal and European or Asian (or other) ancestry, among others. As a matter of policy, should genetic science have any role to play in determining personal identity, or in determining racial or ethnic identity and membership?

Sport

12.28 Finally, genetic testing might be used in sport, to establish whether an individual has a genetic predisposition to certain sports-related illnesses and injuries. For example, research suggests a possible genetic predisposition to brain injury, known as 'punch drunk syndrome', which would be of particular relevance to boxers. It has been suggested that a milder form of this condition can occur in rugby, soccer and any sport associated with repetitive blows to the head.[1084]

12.29 Such genetic testing may lead to discrimination against certain athletes. For example, an athlete with a susceptibility to a particular injury may never in fact develop the injury, but may be dropped from the team by management in an effort to avoid potential liability if the injury manifests. Alternatively, a sports co-ordination body may seek to impose certain conditions on players to minimise its own liability for any injuries they may suffer. For example, the Professional Boxing and Martial Arts Board (Vic) has proposed the genetic testing of all professional boxers in Victoria as a condition of their licence to fight (see Chapter 10 for more detail).

12.30 Generally, the DDA prohibits discrimination in the provision of access to sporting services as a result of a disability, however there are certain exemptions to this prohibition. For example, an athlete may be lawfully excluded from a sporting activity if he or she is unable to perform the actions reasonably required in relation to the sporting activity.[1085]

1084 B Jordan, 'Genetic Susceptibility to Brain Injury in Sports: A Role for Genetic Testing in Athletes' (1998) 26(2) *The Physician and Sportsmedicine*.

1085 *Disability Discrimination Act 1992* (Cth), s 28(3).

12.31 In any case, in practice it may be difficult to prove that certain genetic test results formed the basis of a particular decision. The team or professional association may argue that the athlete was simply dropped on the basis of his or her 'form'.

12.32 Finally, it has been suggested that in the future, athletes may indulge in gene therapy as a means to increase their performance.[1086] This would raise a number of ethical issues in relation to 'fair play' in sport.

Question 12–1. Do existing anti-discrimination laws provide adequate protection against unfair or improper use of genetic information in the context of:

- the provision of government services, including access to education and health services?
- immigration processes?
- determining Aboriginal or other communal identity?
- participation in sport?
- or any other activities, services or entitlements?

To the extent any deficiencies may be identified, how should these be remedied?

Question 12–2. Are there any other contexts in which the current or potential use of genetic information may raise ethical concerns, or have implications for unfair discrimination or personal privacy?

1086 J Longman, 'Getting the Athletic Edge May Mean Altering the Gene — Pushing the Limits', *The New York Times*, 22 June 2001.

13. Law enforcement issues

Contents

Introduction

13.1 Forensic DNA testing is used in law enforcement primarily for the purpose of identification — to identify victims, deceased persons and suspects.[1087] It is also used to exclude suspects from criminal investigations, to obtain acquittals from criminal conviction, and to press for reversals of convictions on appeal.

13.2 Where an offender has left any DNA samples at a crime scene (for example in the form of blood, hair, sweat, semen or saliva), a forensic analyst will compare these samples with a DNA sample taken from a suspect — or a DNA database — to find a match. If there is a match between the samples, the analyst will consider the statistical likelihood that the sample found at the crime scene could have come from someone other than the suspect or victim. This analysis may then be used as evidence at trial (see Chapter 14 for more detail).

13.3 Already, DNA analysis has led to the identification of suspects in relation to a number of outstanding criminal investigations in Australia. For example, in Queensland in 2001, a man was convicted of a 1983 murder after his DNA was matched with the DNA obtained from semen stains found on a towel that had covered the victim's body.[1088]

13.4 In Scotland in 2001, a man was convicted of the 1978 rape and murder of a 17-year-old girl. The police had interviewed hundreds of men at the time of the murder but did not find the suspect until a hair taken from the body (and held in a police station for more than 20 years) was examined for DNA evidence. The hair had a trace of semen on it, which by DNA analysis led the police to the offender.[1089]

13.5 In the United States by April 2000, DNA evidence had been used to obtain the quashing of 64 criminal convictions.[1090] One of these cases involved a

1087 Most forensic DNA testing involves analysis of the nuclear DNA (see Chapter 2 for more detail). Alternatively, forensic DNA testing may involve analysis of the mitochondrial DNA found within human cells, but outside of the nucleus. This form of DNA is inherited from the maternal line only, and is not unique to an individual. Forensic testing of the mtDNA usually involves analysis of hair and bone samples, for example in the identification of deceased persons: S Robinson (2001). This form of DNA analysis was used to identify the remains of the former Russian Tsar, Nicholas II, and members of his family.

1088 S Harris, 'How DNA Creates Bodies of Evidence', *The Sunday Telegraph* (Sydney), 25 February 2001. The jury was told that the probability that another person could have had the same DNA profile was one in 43 trillion: J Nolan, 'DNA Slams Door on Killer's Freedom', *Courier Mail* (Brisbane), 17 February 2001.

1089 G Seenan, 'Man Jailed for 1978 Murder', *The Guardian* (London), 14 June 2001.

1090 B Saul, 'Genetic Policing: Forensic DNA Testing in New South Wales' (2001) 13(1) *Current Issues in Criminal Justice* 74, 91.

man who had come within nine days of execution for an offence that he did not commit.[1091]

13.6 More recently, a new forensic use of DNA has developed with the introduction of DNA databases. Forensic analysts are able to generate profiles from DNA samples sourced from, for example, crime scenes, suspects, and convicted offenders. The profile is created by analysing the length variation of alleles at a number of locations (or loci) on a section of the DNA known as 'junk' or non-coding DNA. Currently, Australian forensic laboratories examine nine loci along the DNA molecule as well as a sex gene.[1092] The DNA profile takes the form of a series of numbers that reflect the length variation at each of these loci.

13.7 Comparison of profiles on the database can be used to link a crime scene to a crime scene, or an offender or suspect to a crime scene. Police are able to use this information as a source of intelligence. For example, a link between an offender or suspect and a crime scene is known as a 'cold hit' because it allows the police to 'identify' a suspect by his or her DNA profile alone where there are no other leads available in the case. Therefore, the database could potentially allow police to solve a number of unsolved crimes.

Regulation of the use of forensic material

Australian jurisdictions

13.8 The framework for DNA forensic testing at the federal level is provided in the *Crimes Act 1914* (Cth) (*Crimes Act*). Part 1D of the *Crimes Act* sets out the regime for the collection, use, storage and destruction of 'forensic material'[1093] taken from 'suspects',[1094] volunteers and 'serious offenders'.[1095]

13.9 The *Crimes Act* was amended by the *Crimes Amendment (Forensic Procedures) Act 2001* (Cth) (*Forensic Procedures Act*), which came into force on 20 June 2001. The *Forensic Procedures Act* inserted more detailed provisions into the *Crimes Act* in relation to the carrying out of forensic procedures, and expanded the scope of the coverage regarding volunteers and serious offenders. It also provided a legislative framework for the operation of a national DNA database

1091 'DNA Gets the Verdict', *The Daily Telegraph* (Sydney), 21 February 2001.

1092 An Introduction to DNA Profiling' (Paper presented at DNA Evidence — Prosecuting Under the Microscope International Conference, Adelaide, 10 September 2001).

1093 'Forensic material' means samples, hand prints, finger prints, foot prints, toe prints, photographs, video recordings, casts or impressions taken from or of a person's body by a forensic procedure: *Crimes Act 1914* (Cth) s 23WA(1).

1094 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 summonsed to appear before a court in relation to an indictable offence: Ibid s 23WA(1).

1095 A 'serious offender' is a person who has been convicted of an offence punishable by at least five years imprisonment: Ibid.

system known as the National Criminal Investigation DNA Database (NCIDD). The database is operated by CrimTrac, an executive agency established under the *Public Service Act 1999* (Cth).

13.10 Once it is fully operational, the database will contain DNA profiles from each of the participating States and Territories, and will administer the sharing of profiles for law enforcement purposes between the participating jurisdictions. By June 2002, it is expected to hold about 25,000 DNA profiles.[1096] Profiles held on the national database will not be shared between jurisdictions until information-sharing agreements have been finalised.

13.11 The *Forensic Procedures Act* was based on the Model Forensic Procedures Bill 2000 (Cth) (Model Bill), drafted by the Model Criminal Code Officers Committee (MCCOC) of the Standing Committee of Attorneys-General. The States and Territories have implemented their own legislation in relation to DNA forensic procedures. A number of jurisdictions have also based their legislation on the Model Bill[1097] but several jurisdictions have chosen to introduce different schemes.[1098]

Other jurisdictions

13.12 Forensic DNA databases have also been established in the United Kingdom, the United States, Canada and New Zealand.

13.13 The United Kingdom currently has the largest forensic DNA database in the world. Currently, a non-intimate sample (eg a mouth swab or hair) may be taken, without consent, from any person suspected of being involved in, charged with, about to be reported for, or convicted of a 'recordable offence'.[1099] The profiles created from these DNA samples are stored on the national database. As at September 2000, the database contained more than 940,000 profiles; it is expected soon to contain profiles of one third of all males in the United Kingdom between the ages of 16 and 30 years.[1100] By June 2000, the database had linked evidence

1096 Senator the Hon Christopher Ellison (Minister for Justice and Customs), 'CrimTrac's New Crime Fighting Systems Switched On' (2001) *Media Release*.

1097 For example, *Crimes (Forensic Procedures) Act 2000* (NSW); *Criminal Law (Forensic Procedures) Act 1998* (SA); Part 4 of the *Crimes Act 1958* (Vic); *Crimes (Forensic Procedures) Act 2000* (ACT).

1098 For example, the Queensland legislation is broader in scope, allowing police to take DNA samples without consent from all persons arrested or charged in relation to an indictable offence: see *Police Powers and Responsibilities Act 2000* (Qld) s 311. This has been interpreted to include those prisoners summarily convicted of indictable offences*: Brogden v Commissioner of the Police Service* (Unreported, Queensland Court of Appeal, de Jersey CJ, Williams JA and Mackenzie J, 17 May 2001).

1099 *Police and Criminal Evidence Act 1984* (UK). A 'recordable offence' includes the majority of offences investigated by the police: see Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London, 42.

1100 A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921, 944.

found at crime scenes to 75,000 offenders and had excluded more than 51,000 suspects from criminal investigations.[1101]

13.14 The United States also has a national DNA database system known as the Combined DNA Index System (CODIS).[1102] This is a three-tiered computer system operated by the Federal Bureau of Investigation (FBI), which facilitates the exchange of DNA profile information between participating local, state and federal jurisdictions. Each state jurisdiction also has its own DNA database and these jurisdictions have the option to participate in the national CODIS system.[1103] The offences for which a DNA sample may be taken from an individual vary among jurisdictions. The CODIS system has only three indexes of profiles: convicted offenders (this is mostly restricted to individuals convicted of sex offences and violent felonies), unknown suspects (ie samples taken from crime scenes), and an anonymous population file used for statistical analysis.[1104]

13.15 Canada also has a national DNA database, operated by the Royal Canadian Mounted Police.[1105] Under Canadian legislation, a court may issue a warrant to obtain a DNA sample from a suspect; however, these samples generally may be used only for the purpose for which they were obtained and may not be stored on the database. A DNA sample may be collected from offenders convicted of designated offences upon the issue of a court order; the profiles created from these samples are then stored on the DNA database.[1106] The database contains only two indexes: convicted offenders, which contains the DNA profiles of offenders convicted of serious crimes, and the crime scenes index.[1107]

13.16 In summary, the forensic DNA databases operating in the United States and Canada are more limited in scope than the Australian NCIDD. They do not contain the profiles of suspects or volunteers.

1101 Ibid.

1102 *DNA Identification Act 1994* (US). The US Department of Defence also operates a non-forensic DNA databank of DNA samples of all its service members on active duty or in the reserve armed forces. These samples are taken compulsorily from soldiers for the purpose of identifying their remains if they are killed in combat. In February 1997, the registry consisted of 1.65 million samples; it is expected to hold 18 million samples at maximum capacity: 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, 976, 984; see also A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921**,** 924.

1103 A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921, 941.

1104 D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London, 23.

1105 See *DNA Identification Act 1998* (Canada).

1106 See generally, D Crosby, *Protection of Genetic Information: An International Comparison* (2000), Human Genetics Commission, London, 15–22.

1107 M Windover, 'Canada's Databank Need Addressed: The RCMP Bank on Crime-Fighting Success' (2001) 4(1) *Biotechnology Focus* 1, 1.

The Commonwealth framework

Forensic procedures

13.17 A DNA sample may be taken from an individual through an 'intimate forensic procedure' or a 'non-intimate forensic procedure'.

13.18 An 'intimate forensic procedure' is carried out on intimate parts of the body, such as the genital or anal area, or the buttocks or breasts. This includes an external examination, the taking of a sample of blood, saliva or pubic hair, or the taking of a sample by buccal swab, swab or washing from an intimate area, or by vacuum suction, scraping or by 'tape lifting' from an intimate area, or the taking of a dental impression, or a photograph, video recording, or an impression or cast from an intimate area of the body.[1108]

13.19 A 'non-intimate forensic procedure' is carried out on other parts of the body. This includes an external examination that requires touching the body or removing clothing, the taking of a sample of hair (other than pubic hair), the taking of a sample from a nail or under a nail, the taking of a sample by swab or by washing a non-intimate part of the body, or by vacuum suction, by scraping or by 'tape lifting' from a non-intimate area, or the taking of a hand, finger, foot or toe print, or a photograph, video recording, or an impression or cast.[1109]

Informed consent

13.20 A forensic procedure may be carried out on a suspect, volunteer or serious offender, with his or her 'informed consent'.[1110] This consent must be requested and obtained prior to the procedure, and the process of informing (including providing the required information about the procedure) and obtaining consent must generally be recorded.[1111] The individual must be informed that he or she may refuse consent and the consequences of not consenting.[1112] He or she must also be given an opportunity to communicate with a lawyer before providing (or refusing) consent.[1113] The individual must also be informed of the right to ask that a medical practitioner or dentist (of choice) be present during certain forensic procedures.[1114]

13.21 If a suspect or a serious offender refuses to consent to a forensic procedure it may nevertheless proceed if it is authorised by a senior constable (for a non-intimate procedure), or a magistrate (for an intimate procedure) — provided

1108 *Crimes Act 1914* (Cth) s 23WA(1).
1109 Ibid.
1110 Ibid ss 23WD(1), 23XWC(1), 23WQ(2).
1111 Ibid s 23XWM.
1112 Ibid ss 23XWJ(1)(g), 23XWJ(1)(h).
1113 Ibid s 23WF(2)(d).
1114 Ibid s 23WJ(2).

that it is considered justified under the broad range of matters set out in the legislation.[1115]

13.22 However, if the individual is a child, an 'incapable person' or an Aboriginal or Torres Strait Islander person, special safeguards apply. For example, a child or an incapable person cannot consent to a forensic procedure.[1116] If a suspect is an Aboriginal or Torres Strait Islander person, the police must not request his or her consent before first ensuring that an 'interview friend' is present and informing a member of an Aboriginal legal aid organisation that the individual will be asked to consent to a procedure. The police need not do so, however, if the right is waived or if they have reasonable grounds to believe that, considering the individual's level of education and understanding, he or she is not at a disadvantage in relation to the request for consent by comparison with other members of the Australian community.[1117]

Carrying out forensic procedures

13.23 A forensic procedure must be carried out in circumstances that provide reasonable privacy to the individual.[1118] The person conducting the procedure may use 'reasonable force' to enable the procedure to be carried out or to prevent the loss, destruction or contamination of the sample,[1119] but he or she must not conduct the procedure in a cruel, inhuman or degrading manner.[1120] The forensic procedure must be video-recorded unless the individual objects or it is not practicable to do so.[1121] If the procedure is not recorded an independent person must be present while it is being carried out.[1122]

13.24 Interestingly, a forensic procedure may be conducted on a suspect in relation to an 'indictable offence', being a Commonwealth offence punishable by at least 12 months' imprisonment.[1123] However, a forensic procedure may only be conducted on a convicted offender in relation to a 'serious offence', punishable by at least five years' imprisonment. This leads to a curious position in which individuals who are suspected of indictable offences punishable by less than five years imprisonment may be subjected to compulsory forensic procedures even though they could not be subjected to these procedures if convicted of these

1115 In relation to suspects, see ibid ss 23WM(1), 23WS; in relation to serious offenders, see ss 23XWK, 23XWP(6).
1116 Ibid s 23WE(1), (2).
1117 Ibid ss 23WG, 23WX(4). This safeguard also applies if an application is made to a magistrate for an order that a forensic procedure be carried out and during the carrying out of the forensic procedure.
1118 Ibid ss 23XI, 23XWE(1) and 23XWQ(5) provide that Division 6 also applies to the carrying out of a forensic procedure on serious offenders and volunteers.
1119 Ibid s 23XJ(1).
1120 Ibid s 23XK.
1121 Ibid ss 23XT, 23XWM.
1122 See ibid s 23XT.
1123 Ibid s 4G.

offences. Once convicted, their DNA profiles will be stored on the 'serious offenders' index in NCIDD[1124] even though they are not, by definition, serious offenders.

Storage of profiles on NCIDD

13.25 Profiles stored in the various indexes on NCIDD may be matched with other permitted indexes for law enforcement purposes, including the generation of 'cold hits'. The legislation in the jurisdiction in which the DNA sample was obtained will regulate which indexes may be matched against each other.

13.26 NCIDD contains a number of indexes including an index of serious offenders, crime scenes,[1125] unknown deceased persons awaiting identification, missing persons,[1126] suspects, volunteers (including a limited purpose and an unlimited purpose index), and a statistical index. Further indexes may be added by regulations.[1127] The DNA profiles obtained from volunteers are stored either on the volunteers (limited purposes) index or the volunteers (unlimited purposes) index in the database. A profile in the limited purposes database may only be used for the specific investigation to which it relates.[1128] Volunteers must be advised that they have a choice between these two indexes.

13.27 The information held by CrimTrac consists of the DNA profile, a sample number, a case identifier, and the jurisdiction from which the profile originated. The legislation-matching category must also be noted — indicating which indexes it may be matched against — and the destruction date. The actual DNA sample and the identity of the person to whom it relates, are held at the forensic laboratory where the sample was analysed.

13.28 As each State and Territory joins the national system, they may also store their DNA profiles on the database. The number and type of indexes in which these profiles may be stored will depend on the relevant state and territory forensics legislation.

1124 Ibid s 23YDAC.

1125 This includes DNA profiles derived from forensic material found at any place where an offence was committed; on or within the body of the victim; on anything worn or carried by the victim at the time the offence was committed; or on or within the body of any person, on any thing or at any place associated with the commission of a prescribed offence: Ibid s 23YDAC.

1126 This includes DNA profiles derived from forensic material of missing persons and volunteers who are blood relatives of missing persons: Ibid.

1127 Ibid.

1128 When considering these provisions, the Senate Legal and Constitutional Legislation Committee expressed concerns about the volunteers (unlimited purposes) index. It noted privacy concerns about the unlimited use of volunteers' information, particularly the NSW Privacy Commissioner's submission that samples from volunteers should only be used to eliminate them from a specific inquiry and should be destroyed after completion of the particular investigation: Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, para 3.12.

13.29 Variations between the federal, state and territory legislation will also impact on the types of indexes that may be matched on the NCIDD system. For example, if one State does not allow matching between the volunteers index and the crime scene index, NCIDD will not be permitted to match a profile from that State (stored on the volunteers index) with a profile from another State (stored on the crime scene index). In fact, due to the many variations in the respective matching rules, a complex net of matching protocols will be necessary to ensure federal, state and territory legislation is not inadvertently breached in the operation of NCIDD.

Destruction of forensic material

13.30 'Destruction' of forensic material is defined as the destruction of any means of identifying that material. The *Crimes Act* does not require the physical destruction of the DNA sample or the DNA profile but merely its de-identification.[1129]

13.31 The *Crimes Ac*t provides that volunteers may agree with the Commissioner of the Australian Federal Police (AFP) (or one of his or her constables or staff members)[1130] a date for de-identification of their forensic material, but it does not provide a clear framework for making or recording these agreements. A suspect's forensic material must be de-identified as soon as practicable after 12 months have elapsed since the material was taken, provided that charges have not been instituted or have been withdrawn.[1131] If the suspect is acquitted, the forensic material must be de-identified as soon as practicable after that occurs.[1132]

13.32 A convicted offender's forensic material will be retained indefinitely unless his or her conviction is quashed, in which case the forensic material must be de-identified as soon as practicable after that date.[1133] There is no requirement for the destruction of forensic material taken from crime scenes or stored on the missing persons or unknown deceased persons indexes.

Oversight and review

13.33 By June 2002, the Minister must cause an independent review of the operation of Part 1D of the *Crimes Act*, including the effectiveness of independent oversight and accountability mechanisms for the DNA database system. The report

1129 *Crimes Act 1914* (Cth) s 23WA(5).
1130 Ibid s 23YQ(1).
1131 Ibid s 23YD(2); however, a magistrate may extend this period upon application by a constable or the DPP if satisfied that there are special reasons for doing so: s 23YD(5).
1132 Provided no appeal is lodged, or an appeal is lodged and the acquittal is confirmed or the appeal is withdrawn: Ibid s 23YD(3)(b).
1133 Ibid s 23YDAA.

must then be tabled before both Houses of Parliament.[1134] Additionally, as with most other Commonwealth agencies, the activities of CrimTrac and the AFP are subject to the *Privacy Act* as well as oversight by the Privacy Commissioner and the Commonwealth Ombudsman.[1135]

Concerns with the use of DNA forensic material

13.34 There are a number of concerns about the use of DNA forensic testing and profiling in the law enforcement context. Generally, these concerns relate to:

- consent and collection;
- chain of custody and contamination;
- storage and destruction of DNA profiles and samples;
- effectiveness of safeguards;
- privacy; and
- future expansion.

Consent and collection

The scope of the testing

13.35 The *Crimes Act* provisions for requesting consent and authorising compulsory forensic procedures on suspects and serious offenders raise a number of concerns.

13.36 First, an AFP constable may ask a suspect to consent to a forensic procedure if he or she is satisfied on the balance of probabilities that the individual is a suspect, there are reasonable grounds to believe the forensic procedure is likely to produce evidence tending to confirm or deny that the suspect committed an indictable offence, and the request is justified in all the circumstances, as set out in the legislation.[1136] This provision is very broad. In light of the fact that DNA analysis may effectively exclude a person as a suspect to a crime, forensic procedures will often be 'likely to confirm or deny' an individual's involvement.

1134 Ibid s 23YV.
1135 See the *Ombudsman Act 1976* (Cth) and the *Complaints (Australian Federal Police) Act 1981* (Cth).
1136 *Crimes Act 1914* (Cth) s 23WI.

13.37 Second, in relation to suspects who do not consent to a procedure, the decision-maker[1137] must consider a number of matters, including whether there are reasonable grounds to believe that the suspect committed a relevant offence, the forensic procedure is likely to produce evidence tending to confirm or disprove that the suspect committed a relevant offence, and the carrying out of the forensic procedure without consent is justified in all the circumstances.[1138]

13.38 In determining the last matter, the decision-maker must balance the public interest in obtaining evidence and investigating crime against the public interest in upholding the physical integrity of a suspect.[1139] As with most aspects of operational policing, it leaves a very broad discretion in the hands of the decision-maker. In practice, it may be unlikely that a senior constable would strike the balance in the suspect's favour if he or she actually has a reasonable suspicion that the suspect committed the offence in question.

13.39 Third, until the *Forensic Procedures Act* came into force, DNA samples could be taken from convicted offenders only in the form of blood samples, and only by order of a magistrate where there were reasonable grounds to believe the offender may have committed another serious offence or would do so in the future.[1140]

13.40 The scope of testing has now been expanded to include a large number of offenders, classified as 'serious offenders'. Before ordering a compulsory procedure, a decision-maker must consider the seriousness of the circumstances surrounding the offence committed by the individual, whether the procedure 'could' assist law enforcement, and whether carrying out the procedure without consent is justified in all the circumstances.[1141] Again, this test is very broad. Due to the fact that DNA analysis may exclude an individual from suspicion in an offence, the collection and analysis of DNA samples generally 'could' assist law enforcement. Further, there is no provision for a serious offender to challenge an order whether made by a senior constable or a magistrate.

13.41 Finally, the *Crimes Act* provides that an individual must be given an opportunity to communicate with a lawyer before providing or refusing consent to

1137 That is, either the senior constable or the magistrate, depending whether the forensic procedure is a non-intimate or an intimate forensic procedure, respectively.

1138 Ibid ss 23WO(1), 23WT(2).

1139 *Crimes Act 1914* (Cth) ss 23WO(2), 23WT(2).

1140 Ibid s 23YQ(3).

1141 Ibid ss 23XWL, 23XWO(7). By contrast, in New South Wales a police officer may authorise a non-intimate forensic procedure where the offender has been requested to consent to the carrying out of the forensic procedure, the offender has not consented, and the police officer has taken into account whether the Act would authorise the forensic procedure to be carried out in the absence of the order: *Crimes (Forensic Procedures) Act 2000* (NSW) ss 70(1), 71. See s 74 regarding court authorisation of intimate forensic procedures.

a forensic procedure.[1142] In practice, this right may be more apparent than real. For example, where an individual is arrested in the middle of the night or in a remote region, it may be difficult to find a lawyer willing to attend the police station to give advice. In practice, access to legal representation for these purposes may also be restricted as a result of limited legal aid resources.

Question 13–1. To what extent do the tests set out in Part 1D of the *Crimes Act 1914* (Cth), under which a decision-maker may authorise a forensic procedure in the absence of the consent of a suspect or a serious offender, adequately balance the public interest in law enforcement with protecting the privacy rights of those individuals?

Vulnerable persons

13.42 The *Crimes Act* provides important safeguards for vulnerable persons. A volunteer who is a child or an incapable person cannot consent to a forensic procedure[1143] but informed consent may be requested of his or her parent or guardian.[1144] A 'child' is defined as a person between the age of 10 and 18 years.[1145] An 'incapable person' is an adult who is incapable of understanding the general nature, purpose and effect of the procedure, or is incapable of indicating whether or not he or she consents to a forensic procedure.[1146] The police must follow the procedural requirements regarding informed consent in relation to the parent or guardian when requesting consent to conduct a forensic procedure on a child or incapable person.[1147]

13.43 These safeguards raise a number of concerns. First, they presume that the parent or guardian will always act (or even intend to act) in the best interests of the child or incapable person, but this may not always be the case. Also, the legislation does not provide the child or incapable person with any right to information about the nature or consequence of the procedure — it is only the parent or guardian who

1142 *Crimes Act 1914* (Cth), s 23WF(2)(d).
1143 Ibid s 23WE.
1144 Ibid s 23XWQ(2). Note that if the parent or guardian gives, but subsequently withdraws, consent, a magistrate may order that the forensic procedure be carried out regardless: s 23XWU(1)(c).
1145 Ibid s 23WA(1).
1146 Ibid.
1147 Non-English speakers are given a procedural protection under s 23YDA, which provides that where a constable believes on reasonable grounds that the suspect is unable, because of inadequate knowledge of the English language or a physical disability, to communicate orally with reasonable fluency in the English language, he or she must arrange for the presence of an interpreter before asking a suspect to consent, or authorising or conducting a forensic procedure on the individual.

must be informed.[1148] Therefore, the child or incapable person is effectively left out of the informing process despite being the subject of the procedure.

13.44 Although the child or incapable person is given an ultimate right to object to the procedure,[1149] it has been suggested that this safeguard may be somewhat illusory in light of the socialisation process by which children are generally taught to accept directions from adult authority figures.[1150]

13.45 Additionally, the definition of 'incapable person' may be too narrow to ensure the protection of many individuals who are mentally ill or incapacitated, or who lack the ability to understand fully the implications of the procedure. In practice, it is left to police to determine whether a suspect is able to understand the nature and effect of the forensic procedure, and is able to indicate his or her consent to the procedure. If the police misjudge an individual's capacity to understand the process, the suspect may be denied the procedural safeguard intended by the provision.[1151]

13.46 For example, New South Wales police recently asked a suspect suffering from schizophrenia to consent to a forensic procedure. The suspect later applied to have the forensic material destroyed, arguing that the police had failed to identify that his psychiatric illness rendered him an 'incapable person', unable to consent to a procedure.[1152] Justice Studdert considered the application and observed that the definition of an 'incapable person' was narrowly drafted.[1153] Indeed, it may be that courts will interpret the provision as applying only to individuals who are so severely mentally ill or handicapped that they cannot understand or speak to the police officers, to the exclusion of individuals suffering from less obvious psychiatric or intellectual disabilities.

13.47 Generally, Aboriginal and Torres Strait Islander suspects may only be asked to consent to a forensic procedure if an 'interview friend' is present and a representative of an Aboriginal legal aid organisation has been notified.[1154] An interview friend or a legal representative must also be present during the carrying

1148 R Ludbrook (2001).
1149 *Crimes Act 1914* (Cth) s 23XWQ(4).
1150 R Ludbrook (2001).
1151 The potential for police to misunderstand the nature of an individual's intellectual disabilities was highlighted in the New South Wales Law Reform Commission, *People With an Intellectual Disability and the Criminal Justice System*, Report 80 (1996), New South Wales, Sydney.
1152 *Kerr v Commissioner of Police and Ors* (Unreported, NSW Supreme Court, Studdert J, 27 July 2001). The applicant provided a number of other grounds for the order, including stating that the police had misled him in relation to the procedure. The police had obtained an interim order to conduct a procedure but the permitted time frame had lapsed. The police then told the suspect that if he refused to consent to the procedure, the interim order allowed it to be carried out regardless. The suspect then consented to the procedure.
1153 Ibid, 12.
1154 See *Crimes Act 1914* (Cth) s 23WG.

out of a forensic procedure on an Aboriginal or Torres Strait Islander suspect, serious offender or volunteer.[1155]

13.48 This provision raises a number of concerns. First, the safeguard applies only to someone whom a constable reasonably believes to be Aboriginal or Torres Strait Islander.[1156] It is understood that police must enquire whether a person is Aboriginal or Torres Strait Islander upon arrest, but the legislation does not provide for self-identification. Thus, in practice, there may be occasions in which a suspect's aboriginality is not identified or taken into account.

13.49 Second, the legislation requires a representative of an Aboriginal legal aid organisation to be 'notified' but it does not require a representative to be 'present' when an individual is asked to consent to a forensic procedure. If a lawyer is notified but is unable to attend the police station or otherwise provide advice to the individual, this protection may be more apparent than real.

13.50 Third, in order to be an effective safeguard, it is important that the interview friend is able to assist the suspect in understanding the police request for a forensic procedure as well as ensuring the suspect's customary beliefs are taken into account.[1157] An interview friend who has no particular knowledge of these matters, or of the suspect's legal rights, may be of little help to the suspect.[1158]

13.51 Fourth, the police need not provide access to an interview friend where the suspect waives his or her right to one, or where a senior constable reasonably believes that, due to the individual's level of education and understanding, he or she is not at a disadvantage in comparison with members of the general Australian community.[1159] Again, in practice, there may be occasions in which this safeguard is bypassed through misjudgement by an individual officer or otherwise.

13.52 Finally, the police also have the power to exclude an interview friend if he or she unreasonably interferes with or obstructs the process of requesting consent, or carrying out the procedure. This leaves a broad discretion in the hands of police investigators.

Question 13–2. Do the existing legal safeguards adequately protect the rights of vulnerable persons in relation to informed consent, and from unfair

1155 Ibid s 23XR(2).
1156 For example, see Ibid ss 23WG(3), 23XR(1).
1157 See Senate Legal and Constitutional Legislation Committee Inquiry into the Crimes Amendment (Forensic Procedures) Bill 1997, *Transcript* (1997), Commonwealth of Australia, Canberra, 628 (Robert Goodrick).
1158 *R v Phung and Huynh* (Unreported, NSW Supreme Court, Wood J, 26 February 2001).
1159 *Crimes Act 1914* (Cth) s 23WG(3).

discrimination based on their vulnerable status? If not, how might these safeguards be improved?

Prisoners and 'reasonable force'

13.53 Despite the legislative safeguards in relation to consent and the carrying out of forensic procedures, a number of concerns have been raised in relation to the testing of serious offenders. These concerns focus on possible unfair discrimination against prisoners in the way in which they are tested, as well as concerns about bodily privacy.

13.54 An estimated 1,000 federal prisoners may be regarded as 'serious offenders' under the *Crimes Act*. However, the program of testing these prisoners has not yet substantially commenced.[1160] By comparison, as at 14 August 2001, 5,627 NSW prisoners had undergone forensic procedures under the NSW legislation. Of these, 5,327 prisoners were tested by buccal swab, 290 by taking hair samples, and two by taking blood samples. A number of prisoners stated that they did not wish to consent to a forensic procedure but complied with the order of a senior police officer; only two prisoners were tested as a result of a court order.[1161]

13.55 These statistics suggest that the vast majority of serious offenders have consented to undergo forensic procedures. However, there have been numerous allegations that prisoners in NSW prisons have felt intimidated into consenting by the threat of loss of privileges, reclassification of security status, the use of physical restraints, and other forms of harassment.[1162] Indeed, these practices may not be confined to NSW. In April 2001, it was reported that Tasmanian officials were considering the threat of withdrawal of privileges, such as visiting rights, as a means of persuading prisoners to comply with forensic procedures.[1163]

13.56 Another concern is that those conducting the forensic procedures may be using more than 'reasonable force'. In a case involving the testing of Victorian prisoners, the court heard that when a prisoner refused to consent to a forensic procedure gas was allegedly sprayed into his cell. He stated that he was then shackled around the wrists, dragged to the showers and washed down, dragged to the visitors' area and informed that a procedure would take place. He confirmed

1160 Dr James Robertson, Director of Forensic Services, AFP, *Consultation*, Canberra, 23 August 2001.

1161 Standing Committee on Law and Justice Inquiry into the Operation of the Crimes (Forensic Procedures) Act 2000, *Transcripts*, Parliament of New South Wales, Sydney, <http://www.parliament.nsw.gov.au/prod/web/PHweb.nsf/Committee?OpenFrameSet>, 15 August 2001, 27 (Dr Tony Raymond).

1162 M Strutt, *Consent by Coercion: the Administration of Part 7 of the Crimes (Forensic Procedures) Act in NSW Prisons*, (2001) unpublished; see also D Cronin, 'Goulburn Inmate 'Bullied' Over DNA', *The Canberra Times*, 23 February 2001.

1163 E Whinnett, 'Charges Tipped After DNA Tests', *The Mercury* (Hobart), 27 April 2001.

that he did not consent but stated that if the forensic procedure were to proceed, he wanted it performed by his own doctor. He stated that he was then held down while a blood sample was taken from his thumb.[1164]

13.57 In May 2001, the SBS program *Insight* reported concerns regarding allegations of unreasonable force during the forensic testing of Victorian prisoners, including the allegations noted above. The program showed an official videotape demonstrating the standard procedure for prisoners who resist a forensic procedure. The videotape showed a prisoner being held to a chair by police in full riot gear while they extracted a body sample from him. Police dogs were also present to keep the prisoner in the chair.[1165] This raises a question as to what amount of force is 'reasonable' where a prisoner resists a validly authorised forensic procedure, and what degree of resistance is necessary before reasonable force may be applied.

13.58 Additionally, there is evidence that at least one jurisdiction has conducted illegal forensic procedures on prisoners. In 2001, about 130 ACT prisoners serving sentences in NSW prisons were subjected to forensic procedures until the NSW government admitted that it had no power to take these samples from them. It is understood that the DNA samples obtained from these prisoners were subsequently destroyed.[1166] This raises concerns that the legislative safeguards have been taken less seriously in relation to prisoners than other groups in the community.

13.59 Finally, the *Crimes Act* provides that it is an offence to obstruct, hinder or resist a forensic procedure and this offence is punishable by two years' imprisonment.[1167] While this offence may be considered necessary to ensure that individuals comply with court orders to undergo forensic procedures, it may be open to abuse by police and prison authorities. The threat of such a charge may be a persuasive means of eliciting consent; it may also be effective in silencing an 'interview friend' (if present) who objects to the conduct of a forensic procedure.

Volunteers and mass population screening programs

13.60 A DNA mass population screening occurs when an entire class of individuals in an area is subjected to voluntary DNA sampling to identify the

1164 *Lednar & Others v Magistrates' Court* (Unreported, Supreme Court of Victoria, Gillard J, 22 December 2000).

1165 A Jackson, 'Undue Force Claim on DNA', *The Age* (Melbourne), 1 June 2001, reporting on the SBS program *Insight*, 31 May 2001.

1166 D Cronin, 'Goulburn Inmate 'Bullied' Over DNA', *Canberra Times*, 23 February 2001.

1167 *Crimes Act 1914* (Cth) s 23XWA. See also s 23XWP(4), which provides that an offender ordered to submit to a forensic procedure is guilty of an offence if he or she, without reasonable excuse, refuses or fails to permit the forensic procedure to be carried out.

offender in a criminal investigation.[1168] The use of such programs has been reported in the United Kingdom, Canada, France, Germany and Australia.[1169]

13.61 In April 2000, a mass population screening program was used in an attempt to identify the perpetrator of a sexual assault in the NSW rural town of Wee Waa. In response to the sexual assault of an elderly woman, the entire male population of the town between the ages of 18 and 45 years was asked to volunteer DNA samples in order to identify the offender. Most of the 600 men in the town volunteered their samples. As it turned out, the offender confessed prior to the analysis of his DNA sample.[1170]

13.62 Police investigators also appear to be using population screening programs on a smaller scale. Police may ask a number of suspects to 'volunteer' their DNA samples to be tested in order to exclude them as suspects in a criminal investigation. For example, in a case involving the murder of an elderly woman in her home,[1171] police investigators found that 17 men had visited her house for various reasons before the murder. They asked each man to give a blood sample for DNA analysis, and the results excluded 16 of those men from suspicion. In a recent NSW rape case in which there was only one offender, the police asked two men to volunteer their DNA samples in order to be excluded from the investigation.[1172] Finally, in Western Australia, police took voluntary DNA samples from a number of motorists to identify the person who had been throwing rocks into passing traffic.[1173]

13.63 While this can be an effective way of excluding the innocent from suspicion at an early stage of a criminal investigation, it raises concerns of the possible undermining of the right to silence and the privilege against self-incrimination, as well as a reversal of the onus of proof. In practice, individuals may come under strong suspicion unless they can prove by DNA analysis that they were not involved in an offence.[1174] For example, during the Wee Waa procedure,

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1168 A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921, 956.

1169 Human Genetics Commission, *Whose Hands on Your Genes?* (2000), Human Genetics Commission, London, 45.

1170 B Saul, 'Genetic Policing: Forensic DNA Testing in New South Wales' (2001) 13(1) *Current Issues in Criminal Justice* 74, 75–76.

1171 *R v Jarrett* (1994) 73 A Crim R 160.

1172 R Watson, 'DNA Tests Under Way — Two Men Volunteer Swabs to Clear Air', *The Manly Daily* (Sydney), 10 May 2001.

1173 S Heinzman, 'DNA Test for Rock Thrower', *West Australian* (Perth), 23 March 2001.

1174 In 1997, the majority of the male population between the ages of 18–35 years in a French farming village 'voluntarily' submitted their DNA samples in a murder investigation in relation to a 13-year-old British girl who was raped and strangled in her bed while staying in the village. Investigators admitted that there was no evidence that a local man had committed the offence, or that he belonged to the age group tested: C Scowby, 'Private Costs of 'Safer Communities': DNA Evidence and Data Banking in Canada' (1999) 5 *Appeal* 86, 92. Indeed, DNA testing carried out independently of this program has recently matched a Spanish man, who was visiting the village at the time of murder, to the crime scene: A Gillan, 'US Judge Orders Extradition of Suspect in Brittany Hostel Murder', *The Guardian* (London), 20 June 2001.

the local Police Commander implied that every Wee Waa man was a suspect, saying that it was important 'to eliminate those people who are innocent so they don't have a cloud hanging over their head'.[1175]

13.64 Indeed, it has been suggested that the use of 'voluntary' forensic procedures has led to a new tool of criminal investigation known as 'DNA request surveillance', by which police investigators observe the response of individuals required to consent to a forensic procedure. If their behaviour reveals any signs of fear of incrimination, they may become suspects in the investigation.[1176]

13.65 The use of mass population screening programs in criminal investigations raises a number of concerns. For example, is it appropriate that police with no other leads in an investigation should 'fish' for such leads by requiring members of the community affirmatively to exclude themselves from consideration by submitting to a DNA test? The use of mass population screening programs also raises concerns about the role of community pressure in acquiring consent. It is possible that political and community pressure to undergo testing will undermine or nullify a volunteer's formal right to refuse a forensic test. If so, will this undermine the safeguard of requiring 'informed consent'? Alternatively, if the results of these procedures are released through the media, this may seriously prejudice an individual's chance of a fair trial.

13.66 These procedures may also be used in a way that discriminates against certain ethnic groups within the community. For example, in the US, a serial rapist was described by one of his victims as a six-foot tall 'light skinned, black man'. The police then asked many black men who were not linked to the crimes by any other evidence to provide blood samples for DNA analysis. If they refused, police obtained warrants to take a sample without their consent.[1177] Similar concerns could arise in the Australian community if police were perceived to be targeting a number of members of a particular ethnic group.

Question 13–3. In relation to volunteers, do the provisions of Part 1D of the *Crimes Act 1914* (Cth) adequately protect the principles of 'informed consent', individual privacy and protection from racial and other unfair discrimination? If not, how might these safeguards be improved?

1175 Cited by B Saul, 'Genetic Policing: Forensic DNA Testing in New South Wales' (2001) 13(1) *Current Issues in Criminal Justice* 74, 77.

1176 J Gans (2001), 1–2.

1177 R Sasser Peterson, 'DNA Databases: When Fear Goes Too Far' (2000) 37 *American Criminal Law Review* 1219, 1227.

Chain of custody and contamination issues

13.67 It is essential that a chain of custody is maintained for forensic samples. From the time a sample is first collected until it is presented in court as evidence, a complete record of who has handled it, were it has been stored, and what analyses have been performed must be generated and maintained.

13.68 There are opportunities for contamination during the collection, analysis and storage of DNA samples. Examples of this include contact between items from the victim and the suspect, and contamination of a sample with the perspiration or saliva (eg through sneezing) of the crime scene examiner.[1178] There is also a possibility of mislabelling of samples at the collection stage or in the analysis stage in the laboratory. Furthermore, the integrity of the sample may be compromised through degradation caused by incorrect handling and storage procedures.

13.69 In Australia, non-compliance with chain of custody procedures, and the chance of contamination or degradation through improper handling and storage, are at least minimised by the adoption of internationally recognised standards and guidelines.[1179]

13.70 There is also a danger that blood, a hair sample or other DNA evidence may be planted at a crime scene in order to implicate innocent persons in the crime. Police, the actual offender, or other persons might plant the false evidence.[1180] This is a potentially more serious problem than other false evidence as DNA evidence is endowed with an aura of 'science' and independence, unlike, for example, eyewitness evidence or alleged confessions. However, there has not been any reported instance of such activities in Australia.

Storage and destruction of DNA profiles and samples

13.71 As noted above, the *Crimes Act* does not provide for the destruction of DNA profiles — or the DNA samples from which they are created — stored in the crime scene, unknown deceased persons, or missing persons indexes of NCIDD. It is presumed that these profiles will be removed from the database when the cases are resolved. However, subject to other regulation, the absence of a legislative destruction requirement means that the profiles may be stored indefinitely. While

1178 National Commission on the Future of DNA Evidence, *What Every Law Enforcement Officer Should Know About DNA Evidence*, National Institute of Justice, <www.ojp.usdoj.gov/>, 23 May 2001.

1179 For example, see the 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.

1180 See *R v Lisoff* (Unreported, NSW Court of Criminal Appeal, Spigelman CJ, Newman and Sully JJ, 22 November 1999). It has been suggested that 'DNA evidence has proven to be so persuasive that some cunning criminals are going to elaborate lengths to avoid being identified by their DNA. They have donned condoms and gloves, forced rape victims to shower or bathe, and even planted DNA evidence from somebody else at the scene of their own crimes': M Hansen, 'The Great Detective' (2001) *American Bar Association Journal*.

on the database, they may be matched with other permitted indexes, including the crime scene index.

13.72 The long-term retention of these profiles, and forensic material may have serious privacy implications. At present, the DNA profiles of certain crime victims might be stored on the crime scene index,[1181] and the profiles of the relatives of missing persons will be stored on the missing persons index (rather than the volunteers (limited persons) index).[1182] These individuals may have personal reasons for objecting to the long–term storage of their profiles, and to the potential matching of their profiles against other permitted indexes in the database. One reason may be a philosophical belief in the privacy of one's genetic information. Another reason may be that the individual has committed outstanding offences and does not wish to be discovered.[1183] Either of these reasons may deter an individual (such as a victim of a sexual offence or the relative of a missing person) from consenting to a forensic procedure in these circumstances.

13.73 The provisions for 'destruction' of forensic material also raise concerns. First, 'destruction' of forensic material is defined merely as de-identification of that material. This allows the indefinite retention of both the DNA sample (presumably by the forensic laboratory) and the DNA profile, provided that they are retained in a de-identified form. This may raise concerns as to the future re-identification of that material.[1184]

13.74 It might also raise concerns as to the use of DNA samples, such as a few strands of hair, for planting evidence at crime scenes. However, in light of the fact that most forensic procedures are conducted by way of a buccal swab or a finger prick (which produces a small amount of blood which is stored on a card, rather than any volume of liquid), it may be unlikely that there will be sufficient sample

1181 The crime scene index includes DNA profiles derived from forensic material found on or within the body of the victim of a prescribed offence: *Crimes Act 1914* (Cth) s 23YDAC. However, where the victim and offender's DNA samples are mixed (eg in the case of a sexual assault), the forensic analyst will usually separate the victim's sample from the offender's before creating the DNA profile to be stored in the crime scene index.

1182 The missing persons index includes DNA profiles derived from forensic material of volunteers who are relatives by blood of missing persons: Ibid s 23YDAC. It is unclear whether these volunteers will have the right to agree upon the destruction date for their profiles.

1183 Standing Committee on Law and Justice Inquiry into the Operation of the Crimes (Forensic Procedures) Act 2000, *Transcripts*, Parliament of New South Wales, Sydney, <http://www.parliament.nsw.gov.au/prod/web/PHweb.nsf/Committee?OpenFrameSet>, 31 July 2001, 20 (Dr Jeremy Gans).

1184 A number of the submissions made to the Senate Legal and Constitutional Legislation Committee in relation to the *Forensic Procedures Act* expressed concerns about the potential for re-identification of the material. For example, the prisoners' rights group, Justice Action, submitted: 'We are being asked to accept that laboratories no longer have our tissue sample if they simply erase the name on the slide. Apparently the lab or agency will then be free to do as they please with our genetic material or the millions of duplicates made using PCR [Polymerase Chain Reaction] technology': Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, 12, quoting Justice Action, *Submission to the Senate Legal and Constitutional Committee Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000*, 31 October 2000.

for such use. Indeed, to date there has been very little evidence of widespread mishandling of DNA samples in criminal investigations.

13.75 Second, the term 'forensic material' includes a DNA sample taken from an individual's body by a forensic procedure, but it does not include the DNA profile created from the sample.[1185] While the *Crimes Act* specifies the various de-identification dates for DNA samples, no provision specifically requires the de-identification of DNA profiles. Instead, the Act contains a criminal offence for any person who recklessly causes identifying information to be recorded or retained in NCIDD once the forensic material from which it was obtained is required to be destroyed.[1186] Therefore it is clear that the DNA profile should be de-identified at the same time as the DNA sample, but the failure to specify this duty in the legislation may lead to ambiguity. Additionally, unlike the forensic material provisions, it does not permit an individual to bring legal action to ensure that the de-identification has been carried out.

13.76 Third, except in relation to forensic material taken from serious offenders,[1187] the *Crimes Act* does not specify who is responsible for informing a forensic laboratory of the deadline for de-identification of forensic material. This may lead to the retention of identifying information long after the required de-identification date. Additionally, as there is no formal process for an individual to verify that his or her forensic material has in fact been de-identified, this may lead to serious concerns among volunteers and other individuals as to their genetic privacy and the possible future uses of their genetic material.

13.77 A fourth concern relates to possible secondary use of DNA samples once they have been de-identified. The *Crimes Act* and *Privacy Act* do not regulate the use of de-identified information. Subject to other regulation, it is possible that the forensic laboratory or other organisations may use de-identified DNA samples for other purposes. While existing legislation, criminal penalties, National Association of Testing Authorities, Australia (NATA) accreditation requirements and ethical principles minimise concerns, the inquiry would be interested to hear community attitudes to the availability of such de-identified samples for research and other purposes.

13.78 A final concern relates to the lack of uniformity in the destruction of forensic material on NCIDD. Section 23YUD(2) of the *Crimes Act* provides that such forensic material must not be recorded or maintained in a database that may be used to discover an individual's identity, after the forensic material is required to be destroyed in its originating jurisdiction. This appears to safeguard the privacy of forensic material once it has been passed on from the federal jurisdiction to a

1185 *Crimes Act 1914* (Cth) s 23WA(5).
1186 Ibid s 23YDAG(1)–(3).
1187 Ibid s 23YDAA.

State or Territory, but it may be difficult for the originating jurisdiction to ensure that this information has in fact been destroyed.[1188]

> **Question 13–4.** Do the storage and destruction provisions of Part 1D of the *Crimes Act 1914* (Cth), in relation to forensic material and profiles, adequately protect individual privacy? If not, how might these safeguards provisions be improved?

Effectiveness of safeguards

Legislative offences

13.79 The confidentiality of information held by laboratories may be protected by administrative means, such as holding the information in secure areas within the laboratory, limiting access to these areas, and protecting the confidentiality of computerised files by the use of security clearance, passwords, and audit trails. Apart from these measures, the main safeguards against improper use of the database are the criminal offences set out in the *Crimes Act*. These are intended to deter individuals from abusing the system by providing a maximum penalty of two years' imprisonment for each offence.

13.80 The *Crimes Act* prohibits access to any identifiable information stored on the DNA database system other than as stipulated in the legislation.[1189] It is an offence to recklessly supply forensic material for the purpose of deriving a DNA profile after it is required to be destroyed,[1190] improperly disclose information stored on the database system or revealed by a forensic procedure,[1191] or recklessly match two DNA profiles on the database system, unless permitted by the legislation.[1192] A person will be 'reckless' if he or she is aware of a substantial risk that the matching (or supply) will occur and, having regard to these circumstances, it is unjustifiable to take that risk.[1193]

13.81 There are also a number of offences relating to the recording, retention and removal of identifying information on the DNA database system. For example it is an offence to recklessly record or retain identifying information in a DNA

1188 For example, the legislative provisions for use and storage of DNA samples in the Northern Territory are quite different to the federal legislation. The police may maintain a database of 'any information obtained'; the Commissioner may retain a sample for the period 'he or she thinks fit'; and a DNA sample may be subjected to any analysis the Commissioner thinks fit: *Police Administration Act 1978* (NT) s 147.

1189 *Crimes Act 1914* (Cth) s 23YDAE(1), (2).

1190 Ibid s 23YDAD(1).

1191 Ibid s 23YO(1).

1192 Ibid s 23YDAF(2).

1193 *Criminal Code Act 1995* (Cth) s 5.4.

database system after the required destruction date for the forensic material.[1194] Additionally, the responsible person is guilty of an offence if he or she does not ensure that any identifying information in relation to volunteers or offenders is removed as soon as practicable after the required destruction date.[1195] Interestingly, there is no such offence in relation to destruction of a suspect's identifying information.

13.82 The intention of Parliament in providing these criminal offences was to ensure community confidence in the integrity of the DNA profiles stored in the database.[1196] However, a number of concerns remain. First, provisions focus on the inappropriate use of information stored in a DNA database system. For example, as noted above, it is an offence to recklessly record or retain identifying information obtained from forensic material 'in a DNA database system' after the forensic material is required to be destroyed. However, it is unclear whether information stored 'in a DNA database system' includes the forensic material from which the profiles stored on the system are derived. If it does not, this may leave a regulatory gap in relation to these DNA samples.

13.83 Second, the DNA profile of a suspect or serious offender will be stored on NCIDD and may be matched against other indexes until it is destroyed. If the individual is ultimately found not guilty of the relevant offence (eg if he or she is acquitted or the conviction is quashed), or the charges are withdrawn, the DNA profile of an innocent person will have been available for matching or sharing with other jurisdictions for a 12-month period. This may be considered an unacceptable invasion of an innocent person's privacy.

Sharing of forensic information among jurisdictions

13.84 Division 11 of Part 1D of the *Crimes Act* provides for the sharing of information held on DNA database systems between the federal and other participating state and territory jurisdictions. The federal Minister may enter into agreements with each of the participating jurisdictions to share information held on the DNA databases for the purposes of law enforcement.[1197] It is understood that no such agreements have been finalised to date. This information sharing may be useful where a criminal offence has been committed in one jurisdiction but the suspect is now living in another jurisdiction.

1194 *Crimes Act 1914* (Cth) s 23YDAG(1).
1195 Ibid ss 23YDAG(2), (3).
1196 Parliament of Australia, *Parliamentary Debates*, Legislative Assembly, 26 March 2001, 25635 (The Hon Daryl Williams). He further stated: 'Normal police disciplinary procedures are not adequate to regulate the matching of DNA profiles in the national DNA law enforcement database. Specific offences prohibiting impermissible matching is [sic] considered necessary to ensure the community can have confidence in the integrity of the DNA profiles stored on the system.'
1197 *Crimes Act 1914* (Cth) s 23YP.

13.85 Furthermore, ss 23YP(2)-(3) of the *Crimes Act* provide that so long as the forensic material was lawfully obtained in the jurisdiction in which it was taken, it may be used for investigative, evidentiary or statistical purposes of the Commonwealth, even if its retention or use would otherwise constitute a breach of the federal legislation.

13.86 The proposed sharing of forensic information among the various jurisdictions raises a number of concerns, particularly in relation to the lack of uniformity in provisions for the collection, storage and destruction of forensic material, and the protection of the privacy of that information in the jurisdictions with which it is shared.

13.87 Due to the variations in forensics legislation between the federal, state and territory jurisdictions a complex net of matching protocols will be required to ensure that unauthorised matching of profiles between indexes does not occur. For example, while it is permissible to match a missing persons profile against a crime scene profile in the federal jurisdiction, this may not be permissible in a particular state jurisdiction — matching protocols would be necessary to ensure the latter, unlawful matching does not occur.

Example 13–1. In the Northern Territory, a DNA sample may lawfully be taken without consent from an individual convicted of any criminal offence for which he or she may be imprisoned. By comparison, in the federal jurisdiction, a DNA sample may be taken without consent from an individual convicted of a serious offence, punishable by at least five years' imprisonment.

Jon is convicted of a fairly minor offence in the Northern Territory. The Northern Territory police subject him to a forensic procedure and his DNA profile is stored on NCIDD. Jon is later suspected of a minor offence under the federal *Crimes Act*. He refuses to 'volunteer' for a forensic procedure and, due to the nature of the offence, the AFP cannot conduct a forensic procedure without his consent.

The AFP may, however, match the crime scene DNA profile against other permitted indexes on NCIDD. If a match is found with Jon's profile, which was added by the Northern Territory police, the AFP may use this information in its investigations, or as evidence in prosecuting Jon, even though it had no legal right to obtain the genetic information directly from Jon.

13.88 The Senate Legal and Constitutional Legislation Committee noted that this was 'the most contentious aspect' of the *Forensic Procedures Act*. It quoted the NSW Privacy Commissioner's submission as follows:

> The effect of this section appears to be to allow the Commonwealth or any State or Territory agency to avoid the restrictions on access or use if this is authorised by legislation in the jurisdiction placing the data on the National Database. It would also allow agencies of a State or Territory to access or use any information on the National Database as authorised by its own legislation. This might not be a problem if all State and Territories passed laws that were consistent with the model code provisions. In fact there has been something of a bidding war between some State and Territories, encouraged by their Police Commissioners and by a desire to appear 'tough on crime', to minimise and downgrade the recommended protective provisions.[1198]

13.89 The Committee concluded that 'uniform adoption of the highest standards in the collection, use and disposal of information is fundamental to the effectiveness of legislation'.[1199] Indeed, while the provision is based on the Model Bill, the MCCOC noted that inconsistent legislation for the taking, retention and use of forensic material would be undesirable. It stated that it

> only favours recommending the … provision if there is consistency and does so on the basis that in preparing the model it must assume there will be consistency.[1200]

13.90 It may be that each of the participating jurisdictions will amend its forensic procedures legislation to provide this uniformity. In the absence of this, the ministerial agreements between the participating jurisdictions will form the basis of the information sharing. Therefore, it is important to consider what protections will be provided in these agreements. Specifically, will they provide uniform arrangements for the use, disclosure and destruction of forensic material and DNA profiles shared between the jurisdictions?

13.91 Even if such uniformity is achieved it is uncertain how persons other than the parties to the agreements may ensure compliance. For example, should an individual whose forensic material has been 'shared' between jurisdictions have a legislative or other right to ensure that the privacy protection applicable in the jurisdiction in which the forensic procedure was conducted has in fact been enforced?

1198 Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, para 3.57, quoting Privacy New South Wales, *Submission to the Senate Legal and Constitutional Committee Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000*, 7 November 2000, 4.

1199 Senate Legal and Constitutional Legislation Committee, *Inquiry into Provisions of the Crimes Amendment (Forensic Procedures) Bill 2000* (2000), Canberra, para 3.63.

1200 Model Criminal Code Officers Committee, *Model Forensic Procedures Bill: DNA Database Provisions (Discussion Paper)* (1999), Standing Committee of Attorneys-General, Canberra, 89.

Question 13–5. Should the sharing of forensic material and DNA profiles across jurisdictions be regulated by legislation, or by ministerial agreements? Is a national, uniform approach required in this area to protect the privacy of an individual's genetic information?

Privacy

13.92 As noted above, the *Crimes Act* provides for a framework for the privacy protection of forensic material and DNA profiles held pursuant to the legislation. This framework is based on provisions regulating the use, supply and storage of the forensic information, and specific criminal offences for breaching these provisions.

13.93 At the federal level, the collection, use, disclosure and destruction of forensic material is also regulated by the *Privacy Act*. The legislative framework for privacy protection is set out in detail in Chapter 4. Briefly, the Information Privacy Principles (IPPs) apply to the collection, use, storage and destruction of all identifiable forensic information by the AFP and CrimTrac.[1201] Health providers and forensic laboratories that hold identifiable personal information are regulated under applicable federal, state or territory privacy legislation. The *Privacy Act* and state information privacy legislation generally enable personal information to be collected, used and disclosed for law enforcement purposes.[1202]

Information held on forensic databases

13.94 As noted above, CrimTrac and the AFP (with the exception of the forensic laboratory attached to the AFP) do not have access to any identifying information in relation to a DNA profile held on NCIDD. This information is held by the forensic laboratory that created the profile, and the confidentiality of information held by forensic laboratories may therefore be of concern.

13.95 Under the *Crimes Act* framework, the laboratory retains the original DNA sample, a record of the DNA profile it created from the sample, and the name of the person to whom the forensic material relates (if that is known). The laboratories have duties to protect the confidentiality of that information under the criminal offence provisions in the *Crimes Act*, the *Privacy Act* (or other applicable state or territory privacy legislation) and the NATA accreditation criteria applying to accredited forensic laboratories.

13.96 However, the confidentiality of this information could be undermined in several ways. First, police investigators may choose to retain a part of a DNA sample taken from a crime scene or an individual rather than send the entire sample

1201 *Privacy Act 1988* (Cth) s 6(1).
1202 See eg Ibid NPP 2.1(h); *Privacy and Personal Information Protection Act 1998* (NSW) s 23(5).

to the forensic laboratory. This sample may then be analysed informally (eg by a private laboratory) or it may be used to plant DNA evidence at a crime scene to implicate a particular individual.

13.97 In practice, such misuse may be unlikely. Formal operating procedures in NATA-accredited laboratories will minimise the opportunity for informal or irregular analyses. Additionally, if the DNA sample is extremely small — and samples may be so small that they are not visible to the naked eye — it may be almost impossible to separate a part of the sample prior to sending it to the laboratory.

13.98 Second, in particularly high profile criminal investigations, pressure might be applied to forensic laboratories to informally disclose the identifying information held by them, or to conduct informal analyses of DNA samples to determine a match. This might occur where a match between certain indexes on NCIDD would not be permissible under the *Crimes Act*. Generally, the *Crimes Act* and applicable privacy legislation would proscribe the disclosure of such information.

13.99 Third, a number of state and territory jurisdictions have already established their own DNA databases[1203] which are regulated separately in each jurisdiction. In practice, this may allow a parallel system in which state and territory databases operate with fewer safeguards than under the national CrimTrac system.

Question 13–6. Do existing laws and accreditation requirements adequately protect the confidentiality of genetic information held in forensic laboratories under Part 1D of the *Crimes Act 1914* (Cth)? If not, how might these safeguards be improved?

Access to Guthrie cards

13.100 Another privacy concern relates to police access to individual Guthrie cards (see Chapter 7 for more detail) for law enforcement purposes. For example, the NSW Police Service has requested access to these cards to identify human remains,[1204] to investigate cases in which there is no body but a crime appears to

1203 For example, Victoria, Tasmania, the Northern Territory and NSW each have their own DNA databases: Standing Committee on Law and Justice Inquiry into the Operation of the Crimes (Forensic Procedures) Act 2000, *Transcripts*, Parliament of New South Wales, Sydney, <http://www.parliament.nsw.gov.au/prod/web/PHweb.nsf/Committee?OpenFrameSet>, 15 August, 2001, 24 (Dr Tony Raymond).

1204 For example, in *R v McIntyre* (Unreported, NSW Supreme Court, Bell J, 11 April 2001). Requests for access to Guthrie cards have also been made in Victoria, by families of deceased persons and by the Victorian Institute of Forensic Medicine, to assist in identifying human remains: L Skene, 'Access to and

have been committed (eg if blood stains are found at the location at which a missing person was last seen), and where a suspect is unavailable for testing (because he or she is in prison in another jurisdiction or otherwise out of the country).[1205]

13.101 Generally, the *Privacy Act* provides that personal information may be disclosed to police where the disclosure is reasonably necessary for the enforcement of criminal law.[1206] However, in such cases, the hospitals holding the cards might deny access to them in accordance with their own professional codes of conduct and ethics.[1207] In New South Wales, the Police Service is currently negotiating a Memorandum of Understanding (MOU) with the NSW Department of Health to establish a framework for limited access to Guthrie cards for law enforcement purposes.[1208] In the absence of such an MOU, it is unclear what process for police access to this information would apply.

Question 13–7. Is there a need for a national policy regarding access to 'Guthrie cards' for law enforcement purposes? If so, what should be the major elements of the policy, and should such a policy be cast in the form of legislation?

The testing of relations

13.102 A potential privacy concern relates to the genetic similarities within family groups. In light of the similar genetic makeup of close relatives, it is possible that police may in future seek to conduct a forensic procedure on a close relative of a suspect where the suspect is not available for testing. For example, if a suspect has left Australia, the police may request that his or her sibling provide a DNA sample to determine whether the suspect should be excluded from suspicion, or whether there is a probability that the suspect may have left the DNA sample found at a crime scene.

13.103 The familial nature of the genetic information may thereby allow an expansion in police investigation methods. However, if police investigators ask an individual to consent to a forensic procedure for the purpose of investigating his or

Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5(2) *Journal of Law and Medicine* 137, 139.

1205 Dr Tony Raymond, Director of Forensic Services, NSW Police Service, *Communication*, 14 June 2001.

1206 *Privacy Act 1988 (Cth)*, IPP 11.1(e); see also NPP 2.1(f), (g) and (h), NPP 2.2.

1207 Office of the Federal Privacy Commissioner, *Draft Health Privacy Guidelines* (2001), Office of the Federal Privacy Commissioner, Sydney, 64.

1208 Dr Bridget Wilcken, Clinical Director of the Newborn Screening Programme and Biochemical Genetics, NSW Westmead Children's Hospital, *Communication*, 6 June 2001; Dr Tony Raymond, Director of Forensic Services, NSW Police Service, *Communication*, 14 June 2001.

her relative, the individual should be informed that this is the purpose of the procedure; otherwise any consent given would not be 'informed consent'.

Future expansion

13.104 Serious offenders and criminal suspects are two groups within the community who currently may be subjected to compulsory forensic DNA testing. The question is whether the scope of such testing should or could be expanded in future to other groups within the community and, if so, what limitations should be placed on such expansion.[1209]

13.105 The recent expansion in the compulsory testing of serious offenders under the *Crimes Act* was justified by the notion that prisoners, as a group within the community, have reduced expectations of, and rights to, privacy, as well as by arguments that some will be repeat offenders. The MCCOC stated:

> The approach proposed in this discussion paper is based on the view that if a person is convicted of a serious offence, then it is reasonable for society to expect that person to not only surrender their freedom to mix with society for some time, or to live in accordance with conditional freedom … but to also be required to give samples to assist with the detection of a repeat offence. Indeed providing the sample may even deter the offender from committing further crime. This rationale has more to do with the fact the person belongs to a class of people who are likely to re-offend rather than the specific circumstances of the person.[1210]

13.106 More recently, in response to the use of DNA evidence to quash the conviction of a man wrongly convicted of rape — in circumstances in which earlier testing would have excluded the man as a suspect in the offence — the Queensland government announced its intention to expand the scope of its compulsory forensic testing from individuals *convicted* of indictable offences to individuals *charged* with indictable offences.[1211]

13.107 These powers have since been applied to a 19-year-old university student who was subjected to a compulsory forensic procedure following her arrest for putting up anti-CHOGM posters at her university; the woman had been charged with wilful damage. Her lawyer, Terry O'Gorman, warned, 'When DNA powers were brought in a couple of years ago, we said they would be misused. Unfortunately, our predictions are now true.'[1212]

1209 R Sasser Peterson, 'DNA Databases: When Fear Goes Too Far' (2000) 37 *American Criminal Law Review* 1219, 1220.

1210 Model Criminal Code Officers Committee, *Model Forensic Procedures Bill: DNA Database Provisions (Discussion Paper)* (1999), Standing Committee of Attorneys-General, Canberra, 51.

1211 *Queensland's DNA Testing Program to Expand*, ABC News Online, <http://www.abc.gov.au/news/>, 15 April 2001; P Morley, 'Prisoners to Face DNA Blitz', *Sunday Mail*, 15 April 2001; see also *R v Button* (Unreported, Queensland Court of Appeal, Williams JA, White and Holmes JJ, 10 April 2001).

1212 A Wilson, 'Student in DNA Arrest', *The Australian*, 5 September 2001.

13.108 As DNA technology advances, new methods of DNA analysis may allow forensic analysts to access increasing amounts of personal information about an individual from his or her DNA sample. In future, there may be pressure to expand the scope of NCIDD, or to create a new DNA database to include particular community groups, all arrestees, all individuals applying to enter Australia as tourists, immigrants, or asylum seekers, or even all Australians.[1213]

Future use of forensic samples

13.109 As noted above, the *Crimes Act* does not regulate the collection or destruction of DNA samples found at crime scenes. While the NATA guidelines provide certain accreditation criteria for forensic laboratories dealing with crime scene samples, these do not have legislative force and may be subject to change.

13.110 In light of suggestions that it may in future be possible to determine physical characteristics from a DNA sample,[1214] certain privacy and ethical concerns arise. For example, if an individual's racial or ethnic background may be determined from a DNA sample, this may lead to unfair discrimination against persons within his or her community, based on race or ethnicity. As the technology advances, the Australian community may wish to see greater monitoring of this area of criminal investigation.

13.111 Forensic laboratories store forensic DNA samples after analysis for a number of reasons. It may be necessary to access the DNA sample at a later date for re-analysis when technology improves, for use by defence counsel in criminal proceedings, or for facilitating routine quality control tests.[1215] However, the laboratories' continued possession of these samples opens the possibility of future testing for reasons related to law enforcement or otherwise. This testing may be permitted by future legislation, or in certain circumstances it may be conducted in the absence of authorisation. As technology improves, concerns regarding the future use of these samples will increase. The ethical question is, what limits should be placed on the future use and testing of that material?

Question 13–8. In relation to forensic material found at crime scenes, should Part 1D of the *Crimes Act 1914* (Cth) be amended to regulate its collection and destruction?

1213 For example, the suggestion by a federal MP, Mr Peter Lindsay, in April 2001 that mandatory DNA sampling of all Australians be introduced in order to create a comprehensive national DNA database was met by strong opposition from civil liberties groups: *MP Calls for DNA Sampling of All Australians*, ABC Online News, <http://www.abc.gov.au/news/>, 26 April 2001.

1214 For example, see R van Oorschot and others (2001).

1215 A Stevens, 'Arresting Crime: Expanding the Scope of DNA Databases in America' (2001) 79 *Texas Law Review* 921, 935.

Dilution of safeguards

13.112 Another concern is the possible future dilution of the safeguards currently embedded in the legislation. Indeed, a number of the safeguards that were inserted into the *Crimes Act* when forensic DNA testing was first introduced have since been removed. For example, a suspect was originally entitled to request the presence of a medical practitioner or dentist of his or her choice to be present during a forensic procedure. There are now limitations as to the types of procedures for which an individual may request the presence of this third party.[1216]

13.113 Safeguards relating to the storage or destruction of forensic material may be diluted in the future. Recent developments in the United Kingdom may be instructive. Previously, the *Police and Evidence Act 1984* (UK) provided that police must destroy the DNA samples — and cease to use any information derived from them, such as DNA profiles — of all persons who were acquitted, or whose convictions had been quashed. This safeguard has subsequently been removed by an amendment allowing the retention of the samples, and information derived from them, once an individual has been acquitted or if proceedings are not instituted — provided that they are used only for purposes related to the prevention and detection of crime. Volunteers' samples (and profiles) may also be retained permanently with their consent; however, once given, this consent cannot be withdrawn.[1217] Currently, there are about 1 million DNA samples held in relation to the United Kingdom national DNA database; as a result of this amendments, it is expected that 3.5 million samples will be held within three years.[1218]

13.114 It is possible that in future in Australia, individuals or groups may suggest a similar expansion in the scope of the framework for forensic procedures, and/or the removal of existing safeguards in certain circumstances.

1216 The Explanatory Memorandum for the *Forensic Procedures Act* commented, 'For simple forensic procedures it was considered overly protective and inefficient to allow a suspect to request the presence of his or her medical practitioner at the carrying out of the relevant procedure': *Crimes (Forensic Procedures) Amendment Bill, Explanatory Memorandum 2000* (Cth), para 65.

1217 *Criminal Justice and Police Act 2001* (UK) s 82; see also J Meek, 'DNA Inventor Slams Plans for Database', *The Guardian* (London), 3 May 2001

1218 R Campion, 'Crime Reporter' (2001) *Solicitors Journal* 111, 111.

14. Evidence issues

Contents

Introduction

14.1 Genetic information has been used as evidence in court proceedings since the mid–1980s. DNA evidence is increasingly used in criminal proceedings, as a means of excluding or identifying a possible offender. The evidence may take the form of written records of matches between DNA samples, and/or oral evidence provided by an expert scientific witness of such a match, and the statistical analysis of that match. DNA evidence is also used in family law proceedings to establish paternity, as well as other civil proceedings — for example, in negligence suits in relation to causation or the amount of damages that will be awarded to a plaintiff.

14.2 There are a number of issues relating to the use of DNA evidence in both criminal and civil proceedings. For example, as with other forms of evidence, DNA evidence should be accurate and reliable, properly obtained, and capable of being understood by the jury and other participants in the proceedings. The inter-jurisdictional admissibility of DNA evidence under the *Crimes Act 1914* (Cth) *(Crimes Act)* raises privacy concerns. The equality of access to DNA evidence for pre- and post-conviction hearings may be seen as an ethical concern. Finally, the regulation of access to paternity testing raises concerns relating to both privacy and ethics.

Use of DNA evidence in criminal proceedings

14.3 DNA evidence may be offered in criminal proceedings by either the prosecution or the defence. The prosecution may seek to introduce DNA evidence of a match between a DNA sample found at a crime scene or on the victim, and a sample taken from the defendant, in order to provide proof that the defendant committed the offence. The prosecution may seek to give weight to this evidence by offering statistical evidence of the improbability that the sample taken from the crime scene could have come from any person other than the defendant.

14.4 The defence may seek to rely on DNA evidence to eliminate the defendant from suspicion, where this evidence establishes that the DNA sample taken from the defendant does not match the sample taken from the crime scene or found on the victim. This form of evidence is also important in appeals against conviction. A convicted offender may rely on DNA evidence to prove that a miscarriage of justice has occurred.

14.5 DNA evidence is also used in criminal proceedings for purposes other than identification. For example, in the US prosecution of Louise Woodward, a nanny accused of the murder of a baby in her care, the prosecution used genetic test results from the blood spots contained on the baby's Guthrie card (see Chapter 9 for more detail on Guthrie cards) to help to exclude the possibility that the baby died a natural death.[1219]

14.6 The admissibility of evidence in court proceedings is regulated by legislation and common law. At the federal level, the *Evidence Act 1995* (Cth) *(Evidence Act)* regulates the admissibility of evidence. New South Wales has enacted legislation based on this federal model, while the remaining jurisdictions have their own evidence regimes applicable to matters arising in state or territory courts.

14.7 To be admissible in court proceedings, evidence generally must be relevant and not subject to an exclusionary rule. The judge will consider the admissibility of evidence in the absence of the jury, in a hearing known as a '*voir dire*'. These hearings are usually held before the main hearing, but may also be conducted once the trial has begun.

14.8 The *Evidence Act* contains the following exclusionary rules relevant to the admissibility of DNA evidence:

1219 The blood spots were tested to determine whether the baby was suffering from particular genetic diseases that could have caused the injuries attributed to the nanny's child abuse: Professor B Scheck, *Proceedings — Legal Issues Working Group Report and Discussion*, National Commission on the Future of DNA Evidence, <http://www.ojp.usdoj.gov/nij/dnamtgtrans7/trans-l.html>, 27 September 1999.

- in the case of opinion evidence, where the opinion is not wholly or substantially based upon the person's specialised knowledge; and

- in a criminal proceeding, where the probative value of the evidence is outweighed by the danger of unfair prejudice to the defendant.

14.9 The *Evidence Act* also gives a discretion to the trial judge in both civil and criminal proceedings to exclude evidence where:

- the evidence has been improperly or illegally obtained; or

- the probative value of the evidence is substantially outweighed by its prejudicial effect, or where it may be misleading or confusing, or where it may result in an undue waste of the court's time.

14.10 There are also a number of warnings that a trial judge may give to the jury regarding the weight to be given to evidence which is admitted into court; for example, a warning as to the potential unreliability of identification evidence.

14.11 Australian courts have considered the admissibility of DNA evidence on a case by case basis. A more systematic approach has been taken in the United Kingdom, where the Court of Appeal has formulated a set of guidelines outlining the obligations of the prosecution and defence in relation to DNA evidence, as well as the role of the scientific expert in criminal prosecutions.[1220]

14.12 Early Australian authorities supported the exclusion of DNA evidence on the basis that its probative value was outweighed by its prejudicial effect.[1221] The concern was that juries might be overly impressed by popular perceptions of the accuracy of DNA evidence, or might be confused by the nature of scientific evidence and its limitations. However, as DNA technology has developed, the courts have tended to admit the evidence, leaving conflicting expert testimony about DNA testing methods and analysis as a matter for the jury to determine, not the judge (provided the jury is appropriately directed by the judge).[1222]

14.13 The main concerns with the admission of DNA evidence in criminal proceedings now relate to:

1220 *R v Doheny v Adams* [1997] 1 Cr App R 369.

1221 See *R v Lucas* [1992] 2 VR 109; *R v Tran* (1990) 50 A Crim R 233; *R v Stokes* (Unreported, Supreme Court of Northern Territory, Mildren J, 16 March 2000).

1222 B Saul, 'Genetic Policing: Forensic DNA Testing in New South Wales' (2001) 13(1) *Current Issues in Criminal Justice* 74, 96; see *R v Jarrett* (1994) 73 A Crim R 160; *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); *R v Milat* (1996) 87 A Crim R 446; *R v Humphrey* (1999) 72 SASR 558; *R v Green* (Unreported, NSW Court of Criminal Appeal, Gleeson CJ, Cripps JA and Abadee J, 26 March 1993); *R v Mitchell* (1998) 98 A Crim R 32; *R v Lisoff* (Unreported, NSW Court of Criminal Appeal, Spigelman CJ, Newman and Sully JJ, 22 November 1999).

- ensuring the integrity of the 'chain of custody' (this issue is outlined in Chapter 13);
- the reliability of DNA tests and analysis;
- the accuracy of procedures for determining the statistical frequency of matches;
- improperly obtained forensic evidence;
- equality of access to testing and analysis; and
- inter-jurisdictional admissibility.

Reliability of DNA tests and analysis

14.14 In Australian criminal proceedings, defence counsel have argued that DNA evidence should be inadmissible because of the novelty of the science; lack of expertise of the forensic scientist analysing the test results; size of the sample analysed; method of statistical analysis (including the size of the statistical database); and the reliability of the testing kits themselves.[1223]

14.15 The scientific analysis of the DNA match and its statistical evaluation is a form of expert evidence. It is only admissible under the *Evidence Act* if the person giving the evidence has 'specialised knowledge' based on his or her training, qualifications or experience, and the opinion is wholly or substantially based on that knowledge.[1224] As noted above, the trial judge also has a residual discretion to exclude evidence that is more prejudicial than probative, or that would tend to mislead or confuse the jury.

14.16 The reliability of forensic scientific evidence in criminal proceedings was brought into serious question in the Chamberlain case.[1225] The 1987 Royal

1223 See H Roberts, 'Interpretation of DNA Evidence in Courts of Law: A Survey of the Issues' (1998) 30 *Australian Journal of Forensic Sciences* 29, 29.

1224 *Evidence Act 1995* (Cth) s 79. The common law jurisdictions apply a different test whereby expert evidence will only be admissible if it is derived from a 'field of expertise'. This test has never been resolved in Australia; courts have applied the *Frye* test of general acceptance in the relevant scientific discipline: see *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); as well as a reliability test: S Odgers (1998), 213.

1225 The Chamberlain case involved the disappearance of a baby girl, Azaria Chamberlain at Ayers Rock (Uluru), Australia in 1980. Her parents, Lindy and Michael Chamberlain, claimed their baby had been taken from their tent by a dingo. Lindy Chamberlain was subsequently charged with the murder of her daughter and Michael Chamberlain was charged with being an accessory after the fact to murder. They were convicted and appeals to the Northern Territory Supreme Court and the High Court were unsuccessful. Fresh evidence was later adduced — in the form of a missing matinee jacket and tests showing that the 'foetal blood' found in their car was in fact a form of chemical spray common to that make of car. The Northern Territory government established a Special Commission of Inquiry, which found serious doubts and questions as to their guilt and as to the evidence in the trial. The Commission recommended their pardon. In 1988, the Northern Territory Court of Criminal Appeal quashed their convictions: Brown, D (1996), 296–307.

Commission into the convictions of Lindy and Michael Chamberlain highlighted a number of deficiencies in relation to the scientific evidence produced, including the use of inappropriate methodologies, the inadequate quality control assurance systems and unacceptable practices adopted by the forensic scientists involved.[1226]

14.17 The Chamberlain case highlighted the importance of ensuring that forensic evidence in criminal proceedings be based on accurate scientific practices. Subsequently, a number of changes have led to marked improvements in the quality and accuracy of forensic analysis.

14.18 First, forensic science has become more sophisticated, ensuring greater accuracy in analysis. Second, a system of national laboratory accreditation has been established by the National Association of Testing Authorities, Australia (NATA). Forensic laboratories that wish to become and remain accredited by NATA must comply with the NATA requirements — including the international standard ISO/IEC 17025 — 1999, and supplementary criteria in the field of forensic science.[1227] Currently, almost all forensic laboratories in Australia have NATA accreditation.

Reliability of test procedures

14.19 Questions about the reliability of DNA testing kits, and their use by forensic laboratories, have recently been in issue in Australian proceedings.[1228] Currently, all laboratories in Australia involved in forensic investigations use the same testing kit, known as 'Profiler Plus'.[1229] Several United States courts have held that evidence derived from this test kit was inadmissible because the manufacturer refused to disclose the primer sequences used in the kits and the developmental validation data used by the manufacturer in validating the kits. The manufacturer argued that this information was commercially sensitive and therefore confidential. The courts, however, held that because the information was

1226 I Freckelton, 'Problems Posed by DNA Evidence — Of Blood, Babies and Bathwater' (1992) 17(1) *Alternative Law Journal* 10, 11, commenting on the Royal Commission of Inquiry into the Chamberlain Convictions, *Report* (1987), Northern Territory Government Printer, Darwin; see also S Odgers and J Richardson, 'Keeping Bad Science Out of the Courtroom — Changes in American & Australian Expert Evidence Law' (1995) 18(1) *University of New South Wales Law Journal* 108, 112–13.

1227 See 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; Standards Australia, *AS ISO/IEC 17025: 1999 Australian Standard — General Requirements for the Competence of Testing and Calibration Laboratories* (1999), 1999, Sydney.

1228 See *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); *R v Gallagher* (Unreported, NSW Supreme Court, Barr J, 4 May 2001); *R v McIntyre* (Unreported, NSW Supreme Court, Bell J, 11 April 2001); *R v Argue* (Unreported, NSW District Court, Nader ADCJ AC, 1 March 2001); *R v Kami & Kami* (Unreported, NSW District Court, Shadbolt J, 14 May 2001); *R v Rees* (Unreported, NSW Supreme Court, Bell J, 16 June 2000).

1229 *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001), paras 193–194, 198.

not available it was not possible to scientifically validate the test kit in order to determine its reliability, and so the evidence could not be admitted.[1230]

14.20 The defence has subsequently raised this decision in a number of Australian proceedings in efforts to have DNA evidence excluded.[1231] 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.[1232] This decision has been followed in a number of subsequent proceedings.[1233]

14.21 Finally, defence have unsuccessfully sought the exclusion of DNA evidence where the forensic laboratory did not adhere to the manufacturer's guidelines in using the test kit by analysing a sample smaller than the minimum recommended by the manufacturer. The test results were considered reliable.[1234]

Reliability of the forensic analysis

14.22 The defence also may question the competence of the forensic scientist in conducting the DNA analysis. For example, the defence may seek to show that a prosecution expert witness does not have the qualifications or expertise to express opinions on statistical questions, or that his or her evidence is incomprehensible to the jury. In these cases, the courts generally consider the expert's qualifications and experience to determine whether or not he or she is qualified to give the evidence.[1235]

14.23 The objectivity of the forensic science expert may also be questioned.[1236] For example, in the United States a forensic serologist who worked in a police crime laboratory was investigated in relation to the expert evidence he gave in a number of criminal prosecutions. As a result of the investigation, a court ruled that none of the testimony he had given in more than 130 cases was credible. He has

1230 D Smith and G O'Shea, 'Murder Trial Halted as Doubts Raised Over DNA Test Kit', *The Sydney Morning Herald*, 7 February 2001.

1231 For example, see *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); *R v Gallagher* (Unreported, NSW Supreme Court, Barr J, 4 May 2001).

1232 *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001). The court rejected the defence counsel's submission that the court should not allow the issue to be decided by the relevant scientific community because they had a vested interest in the legal acceptance of the technology, having made a substantial financial investment in it.

1233 For example, see *R v Gallagher* (Unreported, NSW Supreme Court, Barr J, 4 May 2001), and *R v Kami & Kami* (Unreported, NSW District Court, Shadbolt J, 14 May 2001).

1234 *R v Rees* (Unreported, NSW Supreme Court, Bell J, 16 June 2000).

1235 For example, see *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); *R v Gallagher* (Unreported, NSW Supreme Court, Barr J, 4 May 2001); *R v Noll* [1999] 3 VR 704.

1236 W Thompson, 'Evaluating the Admissibility of New Genetic Identification Tests: Lessons From the "DNA War"' (1993) 84(1) *The Journal of Criminal Law & Criminology* 22, 53.

since been charged with perjury and several of those convicted as a result of his evidence have had their convictions overturned.[1237]

14.24 Another example involves a scientist who was engaged in forensic work at a police laboratory in the United States for a period of 13 years and is currently under investigation for apparently falsifying her forensic results over that period. After a number of complaints, and the overturning of several convictions on the strength of DNA evidence, the Governor of Oklahoma announced an investigation to re-examine all of the felony cases in which the scientist had been involved. The immediate focus of the investigation is the 23 capital trials in which she gave prosecution evidence. While 11 of those convicted have already been executed, the remainder are currently on death row.[1238]

14.25 The NATA accreditation guidelines provide minimum standards for forensic laboratories and analysis, as well as external oversight in order to acquire and maintain accreditation.[1239] These guidelines may provide some protection against inept DNA analysis or abuse of process by individual forensic scientists. While allegations of scientific misconduct and omission have been made in Australian criminal proceedings, there has not been any finding of fraudulent DNA analysis.[1240]

14.26 There has, however, been a case in which a forensic laboratory's omission to analyse certain DNA samples taken from a crime scene contributed to a miscarriage of justice. In *R v Button,*[1241] a man convicted of rape had his conviction quashed 10 months later, after DNA analysis of the bed linen taken from the crime scene excluded him as the offender. The bed linen had not been analysed by the forensic laboratory prior to trial and the analysis was only conducted at the insistence of his lawyers. Williams JA stated:

> 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 [the forensic laboratory]. 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 … The Director of Public Prosecutions in her submissions to this Court did refer to the fact that the John Tonge Centre is under-resourced, and that is a matter which from time to time

1237 W Rowe, 'Commentary' in E Connors and others, *Convicted by Juries, Exonerated by Science: Case Studies in the Use of DNA Evidence to Establish Innocence* (1996), National Institute of Justice, xvi–xvii.

1238 J Yardley, 'Inquiry Focuses on Scientist Used by Prosecutors', *The New York Times*, 2 May 2001.

1239 See 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, Standards Australia, *AS ISO/IEC 17025: 1999 Australian Standard — General Requirements for the Competence of Testing and Calibration Laboratories* (1999), 1999, Sydney.

1240 See *R v Fitzherbert* (Unreported, Supreme Court of Queensland, Pincus, Davies JJA and Moynihan J, 30 June 2000).

1241 *R v Button* (Unreported, Queensland Court of Appeal, Williams JA, White and Holmes JJ, 10 April 2001).

> has been raised in these Courts … It may well be that laboratory testing is expensive … but the cost to the community of that testing is far less than the cost to the community of having miscarriages of justice such as occurred here.[1242]

14.27 Finally, there has been one reported case of an incorrect match between database indices. In a recent United Kingdom case, an incorrect match was made between a DNA sample found at a burglary scene and an innocent suspect whose DNA profile had been stored on the national database. The incorrect match was said to have a probability of one in 37 million.[1243] However, such inaccuracies appear to be more likely among profiles created from a small number of loci along the DNA molecule. In this case, only of tsix loci had been used to create the profiles, and each of those loci was found to match. However, when the man's lawyer demanded a second test, using 10 loci along the DNA molecule, there was sufficient difference to exclude the man as a suspect in the offence.[1244]

14.28 Early DNA profiling in Australia involved the testing of four loci along the DNA molecule.[1245] However, as noted in Chapter 13, the Profiler Plus test kit system currently used by Australian forensic laboratories tests nine loci (as well as a gender identifying marker).[1246] It appears that the higher the number of loci tested in order to create a DNA profile, the less chance that a random person in the general population will have a matching profile and the higher the forensic value of a match between DNA profiles.

Accessibility of independent forensic analysis

14.29 Due to the small number of accredited forensic laboratories currently established in Australia, logistical problems may arise for defence counsel in gaining access to independent scientific analysis and witnesses. For example, if the defence seeks a second analysis of a crime scene sample it generally will need to send the sample to a laboratory in another jurisdiction. This will have cost and time implications, especially where a defendant relies on legal aid.

14.30 Furthermore, if the defence seeks expert advice to undermine the reliability of an analysis method that is used by all Australian accredited forensic laboratories and their scientists, it may need to rely on overseas experts to do so — with even greater cost implications.

1242 Ibid, 2.

1243 In that case, a man was charged after the DNA database reported a 'cold hit' between the DNA sample found at the crime scene and the man's DNA profile, which was stored on the database. 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. The charges were withdrawn after a retest excluded him as a suspect: see J Chapman, 'DNA: After an Innocent Man is Wrongly Matched to a Crime, Could Thousands in Jail Now Appeal?', *Daily Mail* (London), 9 February 2000; see also L Lee, 'England Man to Sue Police Over DNA Mistake', *Newsbytes* (Minneapolis), 18 February 2000, M Kirby, 'DNA Evidence: Proceed With Care' (2000) 12(8) *Judicial Officers' Bulletin* 57 1.

1244 L Lee, 'England Man to Sue Police Over DNA Mistake', *Newsbytes* (Minneapolis), 18 February 2000

1245 For example, see *R v Jarrett* (1994) 73 A Crim R 160.

1246 (2001).

14.31 The ALRC considered issues relating to the use of expert witnesses in court proceedings in its recent review he civil justice system. It made recommendations supporting a number of improvements to the use of expert witnesses and evidence, including encouragement of parties to agree jointly to instruct expert witnesses, as a matter of course.[1247]

Accuracy of procedures for determining statistical frequency of matches

14.32 If there is a probability that a person other than the defendant may have left the DNA sample in question — at least significant enough to create a reasonable doubt — the evidence of the match will lose its probative value in establishing that the accused is guilty of committing the offence. Therefore, once a forensic analyst has found a match between the DNA sample found at the crime scene and the sample taken from a suspect, he or she will compare the match against a database of other DNA profiles to determine the probability that some other random person could have provided the sample at the crime scene. The statistical analysis involved is complex and there are a number of methods for assessing the probabilities involved.

14.33 Challenges to the admission of statistical evidence have taken three main forms: the statistical validity of the database used; the method of calculation used; and the presentation of the statistics.[1248]

14.34 A main concern in this area is the need for a representative database of DNA profiles against which the crime scene sample may be compared. This raises related concerns with respect to the size of the database and the population groups (and subgroups) represented on it, as well as the methods of analysis used in the statistical evaluation.[1249] Generally, the courts consider that the database should contain profiles of persons within the offender's own racial group (if that is known). If the database is too small, or if it is not sufficiently representative, the statistical calculation may be incorrect, and may mislead the jury into believing that the probability the defendant left the sample at the crime scene is much higher than in fact it is. This may lead to a miscarriage of justice.

14.35 Commentators have suggested that the issue of population sub-groups may not be of major practical importance because comparisons among different

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1247 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), Commonwealth of Australia, paras 6.74–6.130.

1248 L Chapman (2001), 5.

1249 *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001); *R v Pantoja* (1996) 88 A Crim R 554; *R v Noll* [1999] 3 VR 704; *R v Rees* (Unreported, NSW Supreme Court, Bell J, 16 June 2000); *R v Humphrey* (1999) 72 SASR 558; *R v Jarrett* (1994) 73 A Crim R 160; *R v Milat* (1996) 87 A Crim R 446; *R v Mitchell* (1998) 98 A Crim R 32; *Latcha v R* (1998) 104 A Crim R 390; *R v Sopher* (1992) 74 A Crim R 21. See also H Roberts, 'Interpretation of DNA Evidence in Courts of Law: A Survey of the Issues' (1998) 30 *Australian Journal of Forensic Sciences* 29, 32–34.

ethnic groups within the major races have not found significant differences between them.[1250] However, it has been suggested that because of the similarities in DNA between close relatives, the possibility that an innocent person may be convicted when the actual offender is a relative is a more serious problem.[1251]

14.36 Another concern is that due to the complex nature of the statistical analysis, the jury may be 'dazzled by statistics' and by the statement of probabilities in terms of large numbers (eg 'one person in 90 billion'). It is argued that in such circumstances the jurors may not be in a position to evaluate such evidence fairly and critically.[1252]

14.37 One problem that may arise is known as the 'prosecutor's fallacy'.[1253] This arises when the prosecution's expert witness misrepresents the probative value of the DNA evidence and thereby misleads the jury. Alternatively, the evidence may be presented correctly but the trial judge or prosecution counsel may commit the fallacy in summing up. An expert witness may generally only give his or her opinion as to the probability that the defendant's DNA sample matches the sample left at the crime scene. The fallacy arises where the expert witness instead gives evidence of the probability that the defendant is *innocent*, given that his or her DNA sample has matched the sample found at the crime scene.[1254] This is overstepping the role of the expert witness; consideration of the defendant's innocence or guilt is a matter for the jury alone.

14.38 At the same time, if a number of tests have been conducted, it is important that the jury be given a balanced view of the results. In *R v Pantoja*,[1255] the prosecution's expert witness testified that the probability of a match occurring at random was one in 792,000. Another scientific witness, using different markers and methods, positively excluded the suspect.[1256] If the jury were given only the evidence of the first expert, they would have been misled as to the probative value of the evidence.

14.39 It is also important to ensure that every party to criminal proceedings — the judge, prosecution and defence counsel and the jury — has a proper

1250 B Hocking and others, 'DNA, Human Rights and the Criminal Justice System' (1997) 3(2) *Australian Journal of Human Rights* 208, 216–17, 235; H Roberts, 'Interpretation of DNA Evidence in Courts of Law: A Survey of the Issues' (1998) 30 *Australian Journal of Forensic Sciences* 29, 33–34.

1251 B Hocking and others, 'DNA, Human Rights and the Criminal Justice System' (1997) 3(2) *Australian Journal of Human Rights* 208, 217.

1252 For example, see I Evett, 'DNA Profiling: A Discussion of Issues Relating to the Reporting of Very Small Match Probabilities' (2000) *Criminal Law Review* 341; see *R v Karger* (Unreported, Supreme Court of South Australia, Mullighan J, 29 March 2001).

1253 See D Balding and P Donnelly, 'The Prosecutor's Fallacy and DNA Evidence' (1994) *Criminal Law Review* 711, 711–712, 716.

1254 Ibid , 711–712, 716.

1255 *R v Pantoja* (1996) 88 A Crim R 554.

1256 B Hocking and others, 'DNA, Human Rights and the Criminal Justice System' (1997) 3(2) *Australian Journal of Human Rights* 208, 234.

understanding of the scientific basis of the DNA evidence involved. Judges and juries may need some form of education or training to consider properly the relevance and weight of the evidence in particular proceedings. Additionally, legal practitioners may need training to competently present the DNA evidence and identify any issues regarding reliability or admissibility.[1257] Issues relating to the education and professional development of the judiciary were dealt with in the Commission's report, *Managing Justice: A Review of the Federal Civil Justice System* (ALRC 89).[1258]

14.40 Finally, the current approach of Australian courts is generally to admit this statistical information into evidence so that the jury may consider it, provided that there is sufficient evidence as to the validity of the database used to make the calculation, and the judge gives a clear direction about the use the jury should make of the evidence.[1259]

Question 14–1. What measures should be undertaken to ensure that juries are better informed about DNA science in order to understand and evaluate DNA evidence?

Admissibility of improperly obtained forensic evidence

14.41 The admissibility of DNA evidence that has been improperly obtained is dealt with specifically in the *Crimes Act*, and generally in the *Evidence Act*. These provide:

- a judicial discretion to exclude forensic evidence that has been obtained in breach of the provisions relating to forensic procedures in the *Crimes Act*[1260]

1257 For example, judges could seek formal training through particular judicial conferences, or the publication of judges' handbooks on this area. Juries could be given introductory training about DNA evidence prior to the beginning of a trial where such evidence will be admitted. Legal practitioners could undergo continuing legal education in the science and law involved in forensic DNA, or could receive such training as a standard part of a university law degree: see generally, The Hon Justice E Mullighan (2001).

1258 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), Commonwealth of Australia, Recommendation 8. Currently, in the US a non-governmental 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 genetic evidence: see the Einstein Institute for Science Health and the Courts, *Website*, <http://www.einshac.org>, 24 September 2001.

1259 See *R v Mitchell* (1998) 98 A Crim R 32. In *R v Humphrey* (1999) 72 SASR 558, the court held that the judge has a discretion to reject the frequency evidence if the statistical validity of the evidence is so problematic that there is a real risk that it will be given undue weight by the jury.

1260 This applies to evidence of forensic material, or evidence consisting of forensic material taken from the individual by a forensic procedure; evidence of any results of the analysis of the forensic material; and any other evidence made or obtained as a result of or in connection with a forensic procedure: *Crimes Act 1914* (Cth) s 23XX(3).

(this is similar to the general discretion to exclude improperly obtained evidence, provided in s 138 of the *Evidence Act*); and

- that any forensic material that is required to be destroyed under the *Crimes Act* will not be admissible in evidence against the individual to which it relates, unless introduced by that person.[1261]

14.42 In relation to improperly obtained forensic material, the trial judge must not admit this evidence unless he or she is satisfied 'on the balance of probabilities' that its admission is justified in spite of the breach of procedure.[1262] The probative value of the evidence does not itself justify its admission into evidence.[1263] If the judge decides to admit the evidence, the judge must inform the jury of the breach of the procedure and give the jury whatever warning is appropriate in the circumstances.[1264]

14.43 The improper obtaining or retention of forensic material has been raised in a number of cases in Australia. In *Lednar v Magistrates' Court*,[1265] the Supreme Court of Victoria held that a Victorian Magistrates Court order compelling three prisoners to provide DNA samples was invalid. The magistrate had acted improperly by making the order 'in chambers', rather than in open court. As the DNA samples had already been taken, the Court ordered that they be destroyed.

14.44 In *R v Braedon*,[1266] the Northern Territory Supreme Court considered the admissibility of a DNA sample taken from an Aboriginal suspect while in a police car. The suspect argued that he had not consented to the procedure and the evidence had therefore been improperly obtained. He said he had provided the sample only because he felt he must obey the instructions of police officers. The court found that the suspect had not understood that he could refuse the request to provide a DNA sample, but found that the police had not acted unlawfully or improperly in obtaining the sample.

14.45 The improper retention of forensic material was also considered in a recent case before the UK House of Lords.[1267] A man's DNA sample was taken in relation to an offence for which he was later acquitted. Contrary to the legislation, his sample was not destroyed after his acquittal and his DNA profile remained on the national database. The police later identified him as a suspect in a rape case as a result of a match between the DNA sample left at the crime scene and his profile on the database.

1261 Ibid s 23XY.
1262 Ibid ss 23XX(4)(b) and (5).
1263 Ibid s 23XX(6).
1264 Ibid s 23XX(7).
1265 *Lednar v Magistrates' Court* (Unreported, Supreme Court of Victoria, Gillard J, 22 December 2000).
1266 *R v Braedon* (Unreported, Supreme Court of Northern Territory, Martin CJ, 31 August 2000).
1267 *Attorney-General's Reference (No 3 of 1999)* [2001] 1 All ER 577.

14.46 The House of Lords considered that although the original sample should have been destroyed, the evidence derived from that sample should have been admissible. The Court's decision was partly based on the 'public interest' in the effective investigation and prosecution of serious crime.[1268] It is possible that Australian courts will take a similar approach in relation to DNA evidence that has been improperly obtained or retained, emphasising the public interest in resolving serious crimes, rather than strict compliance with due process.

Inter-jurisdictional admissibility

14.47 The framework for sharing forensic material and information between jurisdictions, and the privacy concerns raised by such sharing, have been dealt with in detail in Chapter 13. Information sharing also raises concerns as to the admissibility of forensic material obtained from other jurisdictions, as well as the resulting fairness of the trial if such evidence is admitted.

14.48 As noted above, in criminal proceedings the trial judge has a general discretion to exclude evidence that has been improperly or unlawfully obtained,[1269] as well as a specific discretion under the *Crimes Act* to exclude forensic evidence obtained in breach of Part 1D in relation to forensic procedures.[1270] One reason for the judicial discretion is the public interest in maintaining the fairness and integrity of criminal investigations and trials. Where DNA evidence has been obtained in breach of the federal legislation, the trial judge has a discretion to exclude the evidence — unless he or she is satisfied on the balance of probabilities of matters justifying its admission.

14.49 However, the *Crimes Act* specifically provides that forensic material or information that was lawfully taken under a state or territory law may be retained or used for evidentiary purposes of the Commonwealth.[1271] This allows federal investigators to use DNA evidence that has been obtained from a state and territory jurisdiction in their own criminal investigations. It also would seem to allow the admission of that DNA evidence in a criminal trial under the *Crimes Act*.

14.50 The DNA evidence obtained from these other jurisdictions will not be considered to have been improperly or unlawfully obtained, and therefore open to exclusion, even if it has been obtained by a procedure that does not comply with the *Crimes Act*. Provided the evidence was obtained lawfully in the original jurisdiction it may be retained or used for federal purposes.

1268 See *Police and Criminal Evidence Act 1984* (UK) s 64(3B).
1269 *Evidence Act 1995* (Cth) s 138.
1270 *Crimes Act 1914* (Cth) s 23XX(4).
1271 Ibid s 23YP(2).

14.51 This raises concerns in relation to jurisdictions whose forensic procedures legislation differs markedly from the federal *Crimes Act*. For example, is it appropriate that a DNA profile may be obtained in relation to a minor offence in the Northern Territory, and forwarded to the Australian Federal Police (AFP) to be used in a criminal investigation in the federal jurisdiction? If the AFP has no legal power to obtain that evidence directly from the individual, should it have the power to obtain the evidence by a 'back door' method from Northern Territory police?

14.52 The inter-jurisdictional admissibility of forensic material and information also raises concerns as to the fairness of criminal proceedings, as it appears to remove the trial judge's discretion to exclude such evidence as illegally or improperly obtained.

Question 14–2. In relation to the admissibility of unlawfully or improperly obtained DNA evidence in criminal prosecutions, are the exclusionary rules set out in the *Evidence Act 1995* (Cth) and Part 1D of the *Crimes Act 1914* (Cth) sufficient to discourage improper practices in obtaining such evidence?

Question 14–3. Should forensic material, or information obtained from it, be admissible in Commonwealth criminal proceedings where it otherwise might have been excluded as having been improperly or illegally obtained, because of the operation of s 23YP(2)-(3) of the *Crimes Act 1914* (Cth)?

Equality of access to justice

14.53 The use of DNA evidence in criminal prosecutions raises a number of associated issues in relation to equity and access to justice. These include issues about access to (often very expensive) DNA testing for defendants and convicted offenders, on equal terms with police and prosecuting authorities.

14.54 For example, in *R v Button*[1272] (noted above), the court quashed a man's conviction on the basis of DNA evidence that had been available at trial, but had not been tested. This led the President of the Australian Council for Civil Liberties, Terry O'Gorman, to comment that while DNA testing is available and affordable to prosecuting authorities, it is not as accessible to defence teams who often have to rely on legal aid.[1273]

14.55 There are a number of concerns in this area. First, in order to ensure the fairness of a criminal trial in which the prosecution seeks to admit DNA evidence,

1272 *R v Button* (Unreported, Queensland Court of Appeal, Williams JA, White and Holmes JJ, 10 April 2001).

1273 S Balogh, 'DNA Test System Labelled Unfair', *The Australian*, 12 April 2001.

the defendant will need access to adequate funding for legal representation and expert advice. Second, defence counsel should have a good understanding of the DNA evidence involved, as well as access to scientific experts in order to properly test the weight of the evidence.[1274] For example, the prosecution may seek to admit DNA evidence obtained as a result of unreliable scientific procedures. If the defendant does not have funding for legal representation and expert scientific advice in order to scrutinise this evidence, a miscarriage of justice may occur.

14.56 Third, access to DNA analysis is equally important for those who have been convicted of criminal offences, but who wish to establish their innocence. The power of genetic testing technology has advanced markedly since DNA sampling and analysis was first introduced to criminal investigations in the mid-1980s.[1275] Individuals who were previously convicted on the basis of an outdated DNA analysis may now wish to have those samples retested or analysed. Alternatively, individuals who did not have access to DNA analysis at the time of conviction may now wish to undergo testing.

14.57 One model for post-conviction access to DNA testing is the Innocence Panel that has been announced by the NSW Police Minister.[1276] The Panel will consider applications by NSW prisoners for access to DNA evidence for use in their appeals against conviction. Where the evidence exists, the Panel may arrange for a comparison of the applicant's DNA with the DNA taken from the crime scene. It is understood that the results will be available for use in a subsequent appeal against conviction, however it is not clear whether the NSW government intends to provide further funding for legal representation during this process.[1277]

14.58 Finally, each jurisdiction has statutory time limits for lodging an appeal against conviction. Where an individual later seeks to rely on DNA evidence to

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1274 I Freckelton commented in 1992: 'The result of lawyers' lack of acquaintance with other disciplines is poor utilisation of their own experts, from selection to examination-in-chief, as well as cross-examination that rarely grapples effectively with the complexities of the experts' techniques, theories and methodologies … The system is not structured in such a way that expert witnesses, particularly in the criminal field, will regularly be subjected to rigorous and well-informed cross-examination likely to test the quality of the scientific work that they have undertaken or the propriety of the protocols followed by them or their laboratory.': I Freckelton, 'Problems Posed by DNA Evidence — Of Blood, Babies and Bathwater' (1992) 17(1) *Alternative Law Journal* 10, 10.

1275 At first, forensic laboratories mainly relied on Restriction Fragment Length Polymorphism (RFLP) testing which required a large quantity of good quality DNA; most laboratories now use tests based on the Polymerase Chain Reaction (PCR) method, which can generate reliable data from very small amounts of DNA: see National Commission on the Future of DNA Evidence, *Postconviction DNA Testing: Recommendations for Handling Requests* (1999), National Institute of Justice, Washington DC.

1276 The Hon Paul Whelan MP (NSW Minister for Police), 'DNA Justice Project to Help the Innocent, Press Release', 16 August 2000.

1277 The Panel will be headed by District Court judge, John Nader, and will include representatives of the NSW Police Service, the Director of Public Prosecutions, the NSW Privacy Commissioner and victims of crime. It is understood the Panel will commence operation in October 2001: 'DNA Innocence Panel', *The Sydney Morning Herald*, 1 May 2001; The Hon Paul Whelan MP (NSW Minister for Police), 'DNA Justice Project to Help the Innocent, Press Release', 16 August 2000; R Wainwright, 'Innocent Prisoners Face Six Month Wait for Freedom', *Sydney Morning Herald*, 19 September 2001.

which he or she did not have access within this time limit, is it fair to exclude the individual from access to an appeal? Furthermore, if DNA testing results were available at trial but were not disclosed to the defence, will this evidence be considered 'fresh evidence' nonetheless? This issue is of obvious importance to the integrity of the criminal justice system.

Question 14–4. In light of the capacity for DNA evidence to 'establish innocence', should Part 1D of the *Crimes Act 1914* (Cth) be amended to provide a legislative framework for post-conviction review in relation to DNA evidence?

Question 14–5. As a practical matter, do defendants currently have sufficient access to independent DNA testing and analysis services and expert advice?

Use of DNA evidence in establishing paternity

14.59 Evidence in relation to paternity is currently relied upon in court proceedings relating to child maintenance and custody, as well as rights of succession to property. Where the parentage of a child is in issue in proceedings under the *Family Law Act 1975* (Cth) *(Family Law Act)*, the court may order that the child, the mother and the putative father undergo a 'parentage testing procedure'.[1278] The court also may order such tests in order to give a 'declaration of parentage'.[1279]

14.60 The testing procedure involves sampling blood or DNA,[1280] however DNA analysis provides more accurate results. In one case, this improved accuracy led to reconsideration of a maintenance application, which previously had been dismissed on the basis of a less accurate blood paternity test. The woman made a subsequent application for a DNA parentage test against the putative father of her child on the grounds that current testing provides a higher degree of probability as to parentage. The court ordered the DNA parentage test in spite of the earlier proceedings, on the basis that paternity and child support are such serious matters that the court should ensure that the correct decision is made.[1281]

14.61 The courts have also received applications for access to the tissue samples of putative fathers for DNA parentage testing purposes. In one case,[1282] a

1278 *Family Law Act 1975* (Cth) s 69W(1).
1279 Ibid s 69VA. This declaration may be made in the absence of other family law proceedings, and the declaration of parentage is conclusive evidence of parentage for the purposes of all Commonwealth laws.
1280 *Family Law Regulations 1984* (Cth) r 21C.
1281 *JFL v TP* (1999) FLC para 92-870.
1282 *Roche v Douglas* [2000] 22 WAR 331.

deceased man had undergone surgery prior to his death. Certain body specimens were taken from him during surgery and stored at a pathology laboratory. After his death, the man's putative daughter successfully brought proceedings for access to the specimens in order to conduct DNA parentage testing. In future, commentators believe that there may be more court applications for access to stored human tissue and embryonic specimens, for the purpose of paternity testing.[1283]

14.62 The results of a parentage testing procedure will be admissible only in proceedings under the *Family Law Act* if the procedure was carried out by a laboratory accredited for this purpose by NATA.[1284]

14.63 Not long after this inquiry commenced, ABC TV's *7:30 Report* carried a story on 'a ticklish issue about DNA and paternity'.[1285] The program focused on the issues surrounding a Melbourne man said to be suing his ex-wife for fraud and damages (based upon child support payments made) after he allegedly discovered — through DNA testing — that he was not the father of the two children concerned. The program also referred to late night TV advertisements in Melbourne for a company offering 'quick, cheap tests' that consumers can arrange themselves.

14.64 Concerns were raised on the program by, among others, the Minister for Health and Aged Care, the Honourable Dr Michael Wooldridge, the Deputy President of the Australian Medical Association, Dr Trevor Mudge, and leading family lawyer, Michael Taussig, about matters of ethics, informed consent, quality control, post-test counselling, and privacy in relation to 'mail order paternity testing' by private laboratories.

14.65 Proceedings have also been brought by individuals wishing to gain access to dead bodies, and stored tissue samples held in laboratories, for the purpose of identifying paternity. This has raised the question of property in such samples. This issue is dealt with in detail in Chapter 7.

Question 14–6. Should genetic testing to establish paternity be regulated so that it may be conducted only by accredited laboratories, or only under the

1283 See B Brown, 'Symposium: Reconciling Property Law With Advances in Reproductive Science' (1995) 6 *Stanford Law & Policy Review* 73.

1284 *Family Law Regulations 1984* (Cth) r 21D. The NATA requirements for paternity testing specify that: in cases where no exclusion can be determined, a relative chance of paternity of 99.5% must be reached; and non-paternity can be declared only if there have been at least two tests inconsistent with paternity: see B Atchison and N Redman, 'Interpreting DNA Evidence in Paternity Cases' (2000) 32 *Australian Journal of Forensic Sciences* 75, 75.

1285 Report, *DNA and Paternity Case May Set Mammoth Precedent: Transcript.*, ABC-TV, 5 March 2001. See also T Lewin, 'In Genetic Testing for Paternity, Law Often Lags Behind Science', *The New York Times*, 11 March 2001.

supervision of the courts, in order to meet concerns regarding informed consent, counselling and quality control?

Use of DNA evidence in civil proceedings

14.66 DNA evidence may be used in civil proceedings relating to such matters as:

- assessment of damages in negligence claims; and
- proof of causation in toxic tort or medical negligence claims.[1286]

14.67 The use of genetic test results in civil actions outside of family law is still relatively rare. However, commentators have suggested that as the predictive quality of genetic tests gain greater acceptance in the scientific and medical communities, these tests increasingly will be used.[1287]

14.68 Genetic information may be relevant to both parties in a negligence claim. A defendant may rely on genetic tests to limit the damages payable to the plaintiff, or to dispute a claim that its actions caused the particular injury.

Example 14-1.[1288] Anna is a 35 year-old neurosurgeon with an annual income of $400 000. She is run over by a delivery truck as a result of the driver's negligence. She is rendered a quadriplegic and can no longer practice medicine. Anna sues the delivery company for negligence. The court finds that the driver was negligent and considers the amount of damages that should be paid.

Usually, the court would consider the income Anna would have earned over the following 30 years until reaching retirement age. However, Anna is in the presymptomatic stage of Huntington's disease — which will radically limit the number of years she could have expected to practice medicine, as well as reducing her life expectancy. The delivery company therefore has a strong economic incentive to discover any available information about

1286 See R Weiss and others, 'The Use of Genetic Testing in the Courtroom' (1999) 34 *Wake Forest Law Review* 889, 890.

1287 N Kording and J DuMontelle, 'An Overview of Admissibility of Genetic Test Results in Federal Civil Actions: an Uncertain Destiny' (1998) 19 *Whittier Law Review* 681, 683.

1288 This example is based on an example provided in 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, 878.

Anna's genetic health, in order to limit its liability for her loss of future earnings.

Example 14–1 cont'd

This raises a number of ethical questions. Should a defendant have the right to seek to limit its liability in civil proceedings by discovering the plaintiff's genetic risk to premature incapacity or mortality?[1289] If so, should the defendant have the right to seek orders that a plaintiff undergo genetic testing? Should the plaintiff's 'right not to know' be protected?

14.69 Alternatively, genetic tests may be used in future in tort claims involving exposure to carcinogens in the workplace, or some other context (also known as 'toxic tort' cases).[1290] For example, an employee may rely on genetic testing to show that the working environment for which the employer was responsible has caused particular mutations in his or her genes, in order to show that the employer is liable for any illness suffered by the employee (or his or her children).[1291]

14.70 At the same time, an employer could rely on genetic testing to limit its liability by showing that the employee had a genetic predisposition to these mutations.[1292] This effectively shifts the focus of inquiry from the dangerous product or environment to the individual's own genetic makeup (and even that of his or her family).

14.71 In the United States, negligence cases have been brought in relation to children born with health defects as a result of their parents' exposure to toxic substances. In a number of these cases the courts have ordered the production of personal records (such as employment, educational and medical records), as well as physical and mental examinations of the individual bringing the claim, and his or her relatives. This broadens the scope of the proceedings to non-parties. The potential impact of such discovery on these relatives may be a significant deterrent to individuals bringing legitimate claims against the organisations responsible for

1289 Ibid, 878; see also N Kording and J DuMontelle, 'An Overview of Admissibility of Genetic Test Results in Federal Civil Actions: an Uncertain Destiny' (1998) 19 *Whittier Law Review* 681, 689. Rothstein cites the US case of *Pettyjohn v Goodyear Tire v Rubber Co.* Civ. A. No.91-Cv-2681, 1992 WL 105162 (E.D. Pa. Apr. 29, 1992), in which the plaintiff attempted to recover damages for personal injuries caused by the explosion of a tyre. When reviewing the plaintiff's medical records, the defendant found a notation indicating that he was HIV positive. To limit its liability for future earnings, the defendant requested that the court order that the plaintiff undergo HIV testing. The court agreed and ordered that he undergo the HIV test, or forego any claims for future damages: 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, 890.

1290 R Weiss and others, 'The Use of Genetic Testing in the Courtroom' (1999) 34 *Wake Forest Law Review* 889, 897.

1291 See the Chernobyl example cited in Chapter 10.

1292 R Weiss and others, 'The Use of Genetic Testing in the Courtroom' (1999) 34 *Wake Forest Law Review* 889, 911–12.

the injury or illness suffered.[1293] Commentators have advised caution in this area, in light of the speculative nature of genetic information.[1294]

14.72 The main concerns here are with the potential breach of individual privacy, the individual's 'right not to know', and the fear that juries will give genetic information more weight than it deserves. If damages for negligence are discounted because of a plaintiff's genetic information, this could constitute a windfall to the defendant who will pay less compensation in spite of being found liable.[1295]

14.73 There have been additional uses of genetic information in medical negligence claims. Failure to inform patients of the risks of having children with serious genetic disorders, as well as negligent conduct of genetic tests, have already led to negligence suits in the United States. In one case, the parents of a girl born with Tay-Sachs disease sued a laboratory for negligence as a result of its incorrect test results. The parents had employed the laboratory to determine whether they were carriers of the disease. As the test revealed they were not carriers, they conceived and carried the foetus to full term without prenatal testing. Only once the child was born did they discover that she had inherited the disease.[1296]

14.74 Indeed, as genetic testing becomes more sophisticated, and less expensive, advice to take certain genetic tests may become part of the standard of care owed by doctors to their patients.[1297]

14.75 Finally, genetic information has been used in some unusual contexts in a number of civil cases in the United States. For example, a woman introduced evidence of the DNA samples taken from her bed sheets in family law proceedings, as evidence that her husband had been unfaithful to her. The woman was seeking to enforce an infidelity clause in their pre-nuptial agreement which provided for a penalty sum if her husband committed adultery.[1298] In another case, a man who was convicted of rape and imprisoned for more than four years successfully sued his former lawyer for negligence for failing to seek a DNA test that would have

1293 J Wriggins, 'Genetics, IQ, Determinism and Torts: the Example of Discovery in Lead Exposure Litigation' (1997) 77 *Boston University Law Review* 1025, 1057–1067. The Australian Law Reform Commission considered the role of discovery as an important aspect of effective case management in its review of the federal civil justice system: Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System*, Report 89 (2000), Commonwealth of Australia.

1294 N Kording and J DuMontelle, 'An Overview of Admissibility of Genetic Test Results in Federal Civil Actions: an Uncertain Destiny' (1998) 19 *Whittier Law Review* 681, 690.

1295 Ibid , 690–91.

1296 R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 332, citing *Curlender v Bio-Science Laboratories*, 165 Cal Rptr 477 (California Court of Appeal, 1980).

1297 R Weiss and others, 'The Use of Genetic Testing in the Courtroom' (1999) 34 *Wake Forest Law Review* 889, 912–13.

1298 S Harris, 'How DNA Creates Bodies of Evidence', *The Sunday Telegraph* (Sydney), 25 February 2001.

excluded him as a suspect. He won the negligence suit and was awarded US $2.6 million in damages.[1299]

Question 14–7. Given the familial and the predictive nature of genetic information, should the procedural and evidentiary rules about discovery of medical and education records be reviewed? (For example, should a defendant in negligence proceedings be entitled to require that a plaintiff undergo genetic testing — or should a defendant be entitled to discover records relating to a plaintiff's family members — in order to disprove causation or minimise damages for injury?)

Use of behavioural genetics in court proceedings

14.76 Scientists are currently researching whether there is a genetic component to various traits relating to an individual's behaviour and personality; these may include intelligence, aggression, antisocial behaviour, anxiety, alcoholism, addiction, obesity and homosexuality.[1300]

14.77 Research into behavioural genetics has raised concerns of a renewed interest in the notion of 'genetic behavioural determinism'. This is the belief that an individual's genetic makeup may determine his or her behaviour, or personality traits.[1301] This is a controversial area, with many commentators stressing the importance of environment and free will, as opposed to genetics, in individual behaviour. In fact, it has been suggested that 'the greater mistake is not to equate determinism with genes, but to mistake determinism for inevitability.'[1302]

14.78 If these deterministic theories become widely accepted, this may have a number of implications for criminal and civil proceedings and society at large. Defendants in criminal proceedings may seek to rely on behavioural genetics theories to prove that they are not responsible for their behaviour. For example, a defendant may admit that he assaulted the victim, but may argue that it was not his fault because he had a genetic predisposition to aggression and violence. If this predisposition was so compelling that he could not overcome it he may be found

1299 M Hansen, 'The Great Detective' (2001) *American Bar Association Journal* .

1300 Nuffield Council on Bioethics, *Genetics and Human Behaviour: The Ethical Context* (2001), Nuffield Council on Bioethics, London, 3.

1301 M Rothstein, 'New Discoveries in Genetics, Including Behavioural Genetics, Will Raise a Host of Legal Questions Requiring Careful Scrutiny by the Courts' (1999) 83 *Judicature* 117, 117; see also R Dreyfuss and D Nelkin, 'The Jurisprudence of Genetics' (1992) 45 *Vanderbilt Law Review* 313, 320.

1302 M Ridley (1999), 307.

not guilty.[1303] These arguments have been raised in a number of criminal trials to date, without success.[1304]

14.79 In civil proceedings, genetic behavioural determinism may impact upon our understanding of the 'reasonable person' test, and therefore alter our current attitudes toward delineating acceptable and unacceptable behaviour. The lawfulness of an individual's conduct is generally determined by reference to an objective standard of behaviour of the 'reasonable person'.[1305] It is possible that evidence of an individual's predisposition to certain behaviour may result in the imposition of higher or lower standards according to the particular trait involved. For example, should an individual with an 'intelligence gene' be held to a higher standard of behaviour?

14.80 However, it is also possible that those individuals who might seek to rely on the 'genetic behavioural determinism' defence might receive more severe punishment on the basis that they should have known of the predisposition to, say, violence and acted to prevent the situation arising.[1306]

1303 M Johnson, 'Genetic Technology and its Impact on Culpability for Criminal Actions' (1998) 46 *Cleveland State Law Review* 443, 470.

1304 For example, *Nelio Adelino DaSilva Serra v R* (Unreported, Court of Criminal Appeal of Northern Territory, Kearney, Angel and Priestley JJ, 24 February 1997). Wells has commented that the criminal law has been remarkably resistant to notions of excuse based on individual characteristics or circumstances. She notes that excuses create problems of line drawing, and threaten the social control and managerial functions of the criminal justice system: C Wells, ''I Blame the Parents': Fitting New Genes in Old Criminal Laws' (1998) 61(5) *The Modern Law Review* 724, 734–35.

1305 M Rothstein, 'New Discoveries in Genetics, Including Behavioural Genetics, Will Raise a Host of Legal Questions Requiring Careful Scrutiny by the Courts' (1999) 83 *Judicature* 117, 118.

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