



Australian Government

Australian Law Reform Commission

THE KIRBY ORATION

‘The Human Genome: Lessons for Life, Love and the Law’

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A. Thank you ...

First, thank you very much to the Board of the Australian Institute of Health Law and Ethics (AIHLE) and the organisers of this conference, for the great honour of being invited to deliver the opening address.

It is a particularly special honour for me to be asked to do the ‘Kirby Oration’. Justice Michael Kirby was the first and longest serving head of the Australian Law Reform Commission (ALRC). Although it has been nearly two decades, Michael is still a very important figure at the ALRC—he instilled the scholarly and consultative approach to law reform that still informs the ALRC’s processes; and current Commissioners and staff still identify strongly with him (and the feeling appears to be mutual). It is rare that a public institution so clearly bears the stamp of an individual over such a long period. And Michael continues to be a warm, supportive and very generous friend to me.

Justice Kirby is also a leading authority in this field, beginning with his pioneering work at the ALRC that led to the enactment of the Human Tissue Acts in all Australian jurisdictions; he is a member of UNESCO’s Bioethics Committee and the Human Genome Organisation’s (HUGO) Ethics Committee, as well as being the Patron of AIHLE.

If there is anyone in Australia who could make a greater claim to being my ‘guru’ on the ethical, legal and social implications of the New Genetics than Michael Kirby, it would be Professor Don Chalmers—a friend and colleague for over 27 years (beginning at the University of Papua New Guinea), Dean of Law at the

University of Tasmania, AIHLE Board Member, and former Chair of the Australian Health Ethics Committee. So for Don to be person introducing me on this occasion, makes it all the more special.

Finally, my invitation to deliver the Kirby Oration also should constitute recognition of the outstanding team at the ALRC—in particular, Commissioner Brian Opeskin—that helped conduct the recent inquiry into the Protection of Human Genetic Information.

B. Introduction

I have been doing institutional law reform work off and on for nearly 30 years now, in several different countries—but I have no hesitation in saying that the recent inquiry was one of the most challenging, and easily the most intellectually engaging, in which I have ever been involved.

First, we had to learn to work with the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC), in this *joint* reference. This could have been a problem, but (like most arranged marriages, I suppose) we learned to love and respect each other. AHEC brought some excellent complementary skills and features to the inquiry—its experience and expertise in bioethics and ethical oversight, and its links with the broader membership of the NHMRC and its processes. At the personal level, relations between the ALRC and AHEC could not have been warmer or more productive—for which I must pay tribute to the Chair, Dr Kerry Breen, the then Deputy Chair, Professor Colin Thomson, as well as Professor Chris Cordner and Father Bill Uren, who played a major role directly and by way of liaison.

The key lesson for the ALRC in working with AHEC was the constant reminder not to pigeonhole ‘ethics’ as something which is relevant only to the practice of medicine and the conduct of research—rather, the ethical dimension was something that we needed to keep in mind across the full range of human interactions and institutions.

We also had to come to grips with, at least, the basics of modern genetics—

- not only the pure science, but also the praxis, in order to make recommendations for the oversight of research that give comfort to the community *and* accord with the practical realities of life in the lab;
- and also take into account the challenges and practical realities of providing clinical genetic services (by GPs, specialists, genetic counsellors, pathology labs and others).

On the legal side alone, the inquiry had to master up to nine different regimes (in our federal system) dealing with privacy; health privacy; discrimination; occupational health and safety; forensic procedures; insurance; industrial and employment law; evidence, and so on.

Further, we had to come to grips with the nature and operations of the insurance industry—the various ‘products’ on offer; underwriting practices; re-insurance practices; review mechanisms; industry education and training, and so on.

One of the great pleasures of this inquiry—really appealing to the sociologist in me—has been the opportunity to engage with these various sectors, and to get some sense of the way they see the world; create, systematise and communicate their knowledge; organise their work; set their priorities; establish and incorporate their ethics and values; and interact with others.

Finally, it is worth commenting on the very constructive way these various sectors engaged with us throughout the life of the inquiry. Although the inquiry had the potential to step heavily on many toes, we were almost invariably treated with courtesy and candour (which, following some other less happy recent experiences, we no longer take for granted) and given tremendous access to material and great amounts of busy people’s time.

C. *Essentially Yours*

The two-year ALRC-AHEC inquiry culminated in the report *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96, 2003), which was tabled in the Australian Parliament on 29 May 2003 by the then Attorney-General, the Hon Daryl Williams AM QC MP, and the then Minister for Health and Ageing, Senator the Hon Dr Kay Patterson.

It is immensely gratifying that the report has been getting great amounts of attention and high praise over the world—including the United States, Canada, the United Kingdom, New Zealand, China, Korea, Japan—and in international forums, such as the OECD and HUGO.

I cannot resist giving you the flavour of the positive comments made by some of the leading figures in this field. Dr Francis Collins, the Director of the National Human Genome Research Institute (one of the National Institutes of Health in the US) and the head of the international public consortium that conducted the Human Genome Project, recently described *Essentially Yours* as:

a truly phenomenal job ... placing Australia ahead of what the rest of the world is doing.

At the same conference, Justice Michael Kirby praised the:

breadth and quality’ of the report and hoped that ‘Parliament will examine the [ALRC’s] proposals and not simply put them into the too-hard basket.

Similarly, Senator Natasha Stott-Despoja described *Essentially Yours* as:

an extraordinary accomplishment' providing a 'world-leading platform for policy development.

Leading British medical geneticist (currently the head of clinical genetics in Oman), Professor Sandy Raeburn, commended:

the excellent report of the ALRC—for the most clear and least biased description of genetics and insurance ever produced.

Canadian commentator Professor Trudo Lemmons, of the University of Toronto, has written that:

The balanced and sensible approach conveyed by the title is found throughout the two-volume report and is a reflection of the impressively thorough background work on which it is based ... The final report has benefited from an impressive set of interviews, discussions, and submissions from individual scholars, various organisations and interested citizens from all over the world. The way in which the authors have managed to integrate these contributions is remarkable.

Dr Thomas Murray, currently head of the Hastings Center (for bioethics) in New York and chair of the Human Genome Project's first Ethical, Legal and Social Issues Working Group, has written that:

Despite the difficulties the quest for comprehensiveness must have posed, the ALRC and AHEC have done an extraordinarily fine job of explaining the science, identifying what is important for the people of Australia, and offering sensible advice. ... In its thoroughness, its candour, and its analytical depth, *Essentially Yours* sets a standard for advice to the public and policy makers on how to understand and protect genetic information.

D. Some striking features of the inquiry

I have given many talks recently to various stakeholder organisations summarising the principal findings and recommendations in the *Essentially Yours* report—and I suspect that many members of this audience will have heard one of those addresses. Given the length of the report, we also went to some effort to provide a good [Executive Summary](#), as well as shorter [media releases and briefing notes](#)—all of which are freely available on the ALRC's website (www.alrc.gov.au). Therefore, I thought it would be more interesting for this group—and for me—if I took a somewhat different approach, and tried to highlight some of the main themes that emerged throughout the life of the inquiry.

1. People Are Interested

First, people in Australia are very interested in learning about the ‘New Genetics’, and the implications of this for themselves and their families. The inquiry featured 15 well-attended public forums around Australia in all of the capital cities and major regional centres; over 200 ‘targeted’ meetings and consultations with key stakeholders and community organisations (eg, research labs, doctors, health officials, genetic support groups, counsellors, the insurance industry, employer groups, trade unions, professional associations, academics, students, privacy groups, human rights lawyers and so on); and more than 300 written submissions.

Thus, in just over two years, the inquiry engaged directly with many thousands of Australians (and this is a conservative figure). This included the expected professionals and ‘experts’—but also many more from the general community and from affected communities. Many more Australians followed the development of the inquiry through the media, or by requesting literature from the ALRC, or by consulting our website—which has recorded very heavy usage for the documents associated with the inquiry.

Usage levels appear to correlate significantly with media coverage—unfortunately, it is difficult to feel that the public is not being badly let down by the media in this area, which—with some notable exceptions—too often provides ‘dumbed-down’, ‘gee whiz’ stories which avoid the complexity and the need for balance in policy formation. There also appears to be far too little in the way of corporate memory—for example, stories appearing soon after the release of *Essentially Yours*, and dealing with some of the same issues, fail even to mention that Australia has just gone through a major consultative process and policy development exercise. Instead of following up on the progress of the implementation of the *Essentially Yours* report in Australia, media reports are much more likely to focus on individual cases or to describe parallel developments overseas.

2. Public ambivalence ... and anxiety, but *not* cynicism

Secondly, the inquiry’s experience in dealing with the Australian public confirms the local and overseas literature in respect of social attitudes to the rise of the New Genetics. Put briefly, there are strong—but conflicting—feelings in the community.

On the one hand, there is considerable optimism about potential for genetic research to produce important medical breakthroughs in the diagnosis, treatment and prevention of some terrible debilitating diseases, such as diabetes, Alzheimer’s and Parkinson’s, as well as leading to the development of whole new fields of medicine, such as gene therapy, regenerative medicine, and pharmacogenomics. Although it may give pause to some civil libertarians, it was also evident to the inquiry that there is strong support in the general community for law enforcement uses of DNA analysis.

And indeed, Australia does ‘box above its weight’ in terms of performance in medical research, biotechnology and related fields. While we have only 0.3% of the world’s population, Australia produces 2.7% the world’s medical research, and we are ranked sixth among the top biotechnology countries in the world. Federal

and state governments in Australia have recognised these achievements and have been especially supportive. For example, biotechnology research has been assigned a high priority by the Australian Government in the allocation of competitive research grant funds. In Queensland, Premier Peter Beattie has been a strong supporter of the impressive Institute for Molecular Biosciences (IMB) at the University of Queensland, as evidenced by special funding as well as his vehicle's number plates, which read 'BIOTECH'.

At the same time, there is an (understandable) underlying anxiety in the Australian community about the pace of change—concerns about the loss of control; fears about the beginnings of 'genetic determinism' or perhaps even eugenics; and doubts about the ability of public authorities to regulate this area effectively in the public interest.

Judging from the public meetings, it appears that these concerns are based, to some extent, on a 'genetic muddle'—a generalised anxiety which wraps up doubts, misunderstandings and appropriate concerns about genes, genetics, genetic testing, genetic engineering, genetically modified foods, stem cell experimentation, human cloning and xenotransplantation (not to mention Chernobyl, mad cow disease, foot and mouth disease, the Ebola virus and all things deadly).

Another commonly expressed concern was about access and equity—the fear that yet *another* major modern technology with the potential to make life better might, in practice, tend to drive up the costs of healthcare and increase the divide between the 'haves' and the 'have nots'. (These issues also feature in the ALRC's current reference on the intellectual property aspects of genetic materials and technologies, also known as the inquiry into 'Gene Patenting and Human Health', which is exploring the balance between encouraging investment and innovation in biotech and ensuring that further research and the delivery of cost effective clinical genetic services are not compromised.)

At every public meeting, the same concern was expressed in virtually the same words: 'we can see the value of medical research into genetics, and we generally would be happy to participate by giving information, blood or tissue to facilitate this research. However, we are *not* comfortable with the heavy degree of commercialisation of this research, and we definitely do not want our altruism to lead to billion dollar profits for multinational pharmaceutical companies (usually expressed as 'American pharmaceutical companies!'). Perhaps it is no surprise that when John Le Carre needed a new entity to replace the fallen Soviet Union as the 'Evil Empire' in his latest novel, *The Constant Gardener*, he chose 'Big Pharma' for this purpose.

A number of people at the public forums and consultations commented that while 'smart drugs' based on modern pharmacogenomics is ostensibly a good thing, the resulting markets for individualised and customised drugs would be smaller and more fragmented—resulting in more effective drug therapies, but at much higher prices. Concerns were expressed, by indigenous people among others, that this would tend to shape the research programs for drug companies, prompting them to focus more on 'white, middle class, lifestyle diseases' than on diseases associated

with poverty or those which primarily affect indigenous Australians and people in the Third World (eg, malaria)—or the ‘Two-Thirds World’, as I see it is now referred to in the current literature.

Another thing that clearly emerged at the public forums is the atavistic or primal fear among members of the community about their genetic material being sent overseas (again, often expressed as being ‘sent to the US’). So at virtually every event, someone in the audience expressed concern about volunteering for an experiment at an Australian university research lab or teaching hospital, then finding that the researchers had ‘spun off’ into a private biotech company which merged with or was taken over by American interests—and ‘the next thing you know, your DNA is overseas’.

Beyond the implications for the health and well-being of individuals, the New Genetics gives rise to questions as fundamental as what it means to be ‘human’. It is noteworthy that the recent book by American political scientist Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (Allen & Unwin, 2002), contains a plea for strong government regulation of the biotech sector—this from an ardent conservative free marketeer!

However, for all of that—and unlike the situation in Europe—it was still evident in the meetings, consultations and submission Australians have *not* lost faith in the possibility of effective regulation of biotechnology in the public interest. In part, this is as a result of good management to date; in part, it is a result of good fortune, insofar as Australia has not suffered any public health crises, like the Europeans, which have sapped public confidence. This leaves open a precious window of opportunity for Australian governments and policymakers which they should not squander—a matter to which I will return later in this address.

3. The rapid pace of change in genetic science and technology

Third, it is striking how rapidly genetic science and technology has developed—and is continuing to develop—with ‘generational change’ in the knowledge base occurring every few years. The New Genetics is no longer the stuff of science fiction. In just the past few years alone:

- The Human Genome Project has been completed, before schedule and on budget! (The sequencing of the 3.2 billion base pairs cost US\$3.2 billion—for those currently looking for guidance in the preparation of grant applications.)
- Significant progress already has been made on the next phase, the Haplotype Mapping (HapMap) Project—also being undertaken by an NHGRI-led international public consortium, which is committed to making all of its results available on a public access database (subject to a ‘click licence’ to avoid ‘parasitic’ use of this material, according to Dr Collins).
- Work on ‘comparative genomics’ is providing increasingly greater insights, as scientists map a range of species for comparison—the human being; the mouse; yeast; roundworm; *Arabidopsis thaliana* (mouse-ear cress); fruit fly;

bacterium E Coli and *H influenzae*, and so on. It is already part of popular culture that other primates are 97% or more genetically identical to humans, and chimpanzees in particular are about 99% identical. However, even many 'lower order' animals and plants have a significant enough similarity to humans to be valuable in studying gene function. For example, mice and human share about 70-90% of their DNA (an average of 85%)—which is why researchers use 'knock-out mice' (in which certain genes are 'knocked out') in experiments aimed ultimately at understanding the dynamics of human genetics. A fascinating talk delivered at the HUGO Conference in Shanghai in April 2002 by Dr Eric Lander of MIT's Whitehead Institute pointed to both the potential for comparative genomics, and the complexities. Researchers noted that certain genetic sequences may be found across a large number of species and over a long period of time, from basic organisms first appearing billions of years ago to much more complex and contemporary species, including humans. Assuming that nature must value highly such 'highly conserved' sequences, it is logical to assume that these code for proteins with important functions. Researchers then knocked out these genetic sequences in laboratory animals, and found ... no discernable result whatsoever! So, we still have much to learn. Along similar lines, the emerging field of 'epigenetics' suggests there is also a great deal more to learn about *direct* environmental influences on the heritable genome, not merely the interplay between genes and the environment in individuals.

- Advances are being made in related new fields, such as proteomics (focusing on the proteins expressed by genes, which is more important to health than the genes themselves); pharmacogenomics (as discussed above); and bioinformatics, which is an attempt to harness super-computing power to explore the genome. As Professor John Mattick, Director of the Institute for Molecular Biosciences at the University of Queensland and one of Australia's leading geneticists, this makes sense not only because high speed computers are useful tools in sequencing and correlating, but also because of the genome itself is so mathematical in nature.

And apart from health and medical applications, very rapid progress has been made in the use of genetic science and technology by law enforcement authorities. DNA analysis—whether to link a suspect to a crime scene, identify human remains, or help prove innocence—is now a major tool of all modern police forces. Indeed, few media accounts of major criminal investigations these days—from the terrorist attacks on the World Trade Center, in Bali and Turkey; to the mass screenings in Wee Waa and Norfolk Island; to the Falconio case in the Northern Territory—do *not* include routine reporting of the collection and analysis of DNA for forensic purposes.

However, it is nevertheless worth sounding a cautionary note at this point, because for all of this amazing progress, we also need to maintain some perspective. Although we are getting close to some exciting breakthroughs in advanced medicine, for much of the Third World—again, at least the 'two-thirds world' in terms of population—there is still no access to fresh drinking water, to basic

healthcare or affordable drugs (although it is looking more promising now that the WTO will finally reach agreement on the production and distribution of cheaper generic drugs).

And in Australia, with our world-class healthcare system and well-managed growth economy, the state of indigenous health is still a matter of national disgrace—and I use that term advisedly. The life expectancy of Aboriginal men is currently 56, or more than 20 years less than for the general population; and there are very high levels of diabetes, eye disease, heart disease, drug and alcohol problems, and related communal violence.

Even in the affluent West, there are significant and growing health problems—although these are primarily the by-products of over-consumption. We read about epidemic levels of adult onset diabetes and juvenile obesity. The *Essentially Yours* report argued for much more community and professional education about genetics, on the basis that an understanding of genetic health information can be empowering. However, even without knowing much about the secrets of the human genome, our community already knows well the secrets to a long and healthy life: eat a good balanced diet, with lots of fresh fruits and vegetables, and get plenty of exercise.

And yet, when it comes to human nature, the double cheeseburger always seems to trump the double helix.

4. The wide breadth of actual/potential applications

The fourth striking feature of this inquiry is the wide breadth of actual and potential applications for the use of human genetic information—which accounts for the ‘super-sized’, two-volume, report of 1200 pages, with its 144 recommendations for reform directed at 31 different actors (governments, industry, educational authorities etc).

It seems to me that the advent of the New Genetics represents one of those fundamental paradigm shifts that occur rarely in human history, forcing us to re-appraise almost every area of social interaction and legal regulation—likely to be similar in kind to the impact of that other contemporary paradigm shift, the Information Technology and Communications (IT&C) Revolution, which has the internet as its leading vector.

As documented at length in *Essentially Yours*, the impact of the New Genetics now extends well beyond science and medicine to such disparate areas as law enforcement; insurance (allegations of genetic discrimination by insurers was one of the main factors leading to the establishment of the inquiry); immigration; the management of tissue banks, genetic registers and databases; family relations (through DNA parentage and kinship testing); the construction of Aboriginal identity; and employment—which I believe will become, in the next few years, the major battleground with respect to the socially (and then legally) permissible uses of human genetic information.

Even in sport—and it is not much of an exaggeration to say we are talking here of Australia’s national religion—advances in genetic science already have begun to raise questions about the value we place on ‘the fair go’, on aspiration and hard work, and the triumph of the human will.

For example, as is well known, the Australian Institute of Sport runs a talent identification program (TIP) to select promising young athletes for its many sporting programs. Would it be proper—and socially acceptable—to incorporate genetic testing and information into the TIP? And if so, what weight should such information be given? Could we tell the best 16 year old athlete in Australia: “I’m sorry –you are currently winning everything in your age group; you are a lovely, ‘coachable’ kid; and you possess a great work ethic. Unfortunately, however, our tests indicate that you don’t have the genetic markers for the proteins found in the elite performers in your sport—so we really shouldn’t waste your time or our resources.”

Our state of scientific knowledge is already such that we can identify some genetic markers which are associated with high performance in certain sports—and there are others which are associated with diseases and conditions relevant to certain sports. For example, Australian researchers have identified a protein (‘ACTN3’) which appears to produce ‘fast twitch’ muscle fibre. It is also known that the ‘ACE’ protein enhances heart function—and the combination of ACTN3 and ACE is found in 95% of world’s elite sprinters and power athletes. (Conversely, a *deficiency* of ACTN3 appears to aid success in the marathon and other high endurance sports.)

There is also good scientific research indicating that the protein ApoE4 is a major risk factor for degenerative brain diseases, including Alzheimer’s. Not surprisingly, there is grave concern that a person with the genetic marker for ApoE4 may be significantly predisposed to brain injury if they participate in the sport of boxing (leading to the so-called ‘punch-drunk syndrome’). The Victorian Boxing Council has floated the idea that it might require anyone seeking a professional boxing licence in that State to undergo a genetic test for ApoE4—but it has not followed up on this. The AIS also runs a boxing program. Should it require its young athletes to undergo a genetic test? What if the public liability insurer for the Victorian Boxing Council or the AIS begins to insist upon this as a condition for providing coverage? It is already the case that the AIS employs genetic screening for some athletes—notably in the basketball and volleyball programs—for Marfan’s Syndrome (which can result in a rupturing of the aorta, and sudden death).

In *Essentially Yours*, the inquiry recommended that the AIS establish policies and guidelines governing the use of genetic testing and information in its programs—and to its credit, the authorities at the AIS have taken this to heart and established a Reference Group to develop draft policies and guidelines to be taken to the Australian Sports Commission for formal adoption. (I am member of that Reference Group.)

E. An Action Plan for Implementation

As mentioned, *Essentially Yours* contained 144 recommendations for reform, some of them containing multiple dot points, addressed at a wide range of actors. (For the first time, the ALRC included an ‘Implementation Schedule’ as well as a consolidated list of recommendations, in order to enable the various government agencies and other stakeholders to see clearly which particular recommendations applied to them, as well as to facilitate subsequent monitoring of the implementation effort.)

The ‘10-point Action Plan’ I am about to set out is not intended as a summary or prioritised list of the many recommendations in *Essentially Yours*; rather, this is an attempt to identify the major philosophical underpinnings for those recommendations.

First, all public policy developed in this area must incorporate a strong ethical dimension (the ALRC did listen to AHEC).

Second, we must place a very high premium on the dignity of the individual. Thus, *Essentially Yours* recommends that we should:

- take the concept of ‘informed consent’ seriously (including when it is used in the context of criminal law and procedure); and
- create a new *criminal* offence of submitting another person’s genetic material for testing without their consent or other lawful authority (eg statutory authority or a court order);
- take a firmly interventionist approach to the use of genetic testing and information in the employment area—we need to decide what sort of society we want: the one depicted in *Brave New World* or ‘GATTACA’, or one in which Australian people are free to pursue their full human potential; and
- also take this seriously in the area of parentage testing, and resist the attempts of fathers’ rights groups to promote the validity of non-consensual testing of children (while recognising their grave reservations about the processes of the Family Court of Australia—particularly given the ALRC’s strong criticism of the management culture and procedures of the Family Court in the *Managing Justice* report).

Third, we should *not* accept notions of genetic essentialism or genetic determinism, or incorporate these into policy. People are worth more than the sum total of their genetic sequence. People are not ‘gene machines’.

This is easy to articulate now, but it may become increasingly hard to remember as ‘behavioural genetics’ develops—particularly in the hothouse atmosphere of law and order campaigns conducted during elections or by crusading media organisations. For example, in future, how will we calculate the legal—and moral—effects of a scientifically established predisposition to drug and alcohol use? Or a predisposition to ‘risk-taking’ behaviours? Or a predisposition to violence? Will our traditional common law emphasis on free will and *mens rea*

preclude or diminish criminal responsibility for someone found to be acting under such a genetic predisposition? Or conversely, will we get calls for compulsory genetic testing to be associated with ‘Megan’s Law’ procedures (registration of child sexual assault offenders), to identify and deal with people *predisposed* to criminality, *before* they commit the offence, or before they re-offend (whether this means isolation, tracking or treatment).

For those interested in beginning to explore these questions further, I commend the report of the Nuffield Council on Bioethics, *Genetics and Human Behaviour: the ethical context* (October 2002).

Fourth, we should *not* develop policy and practice on the basis of genetic *exceptionalism*. A threshold question for the inquiry was whether we should embrace notions of ‘genetic exceptionalism’—that is (as expressed in ALRC 96):

the idea that genetic information is so fundamentally different from, and more powerful than, all other forms of personal information that it requires different and higher levels of legal protection.

The initial public policy responses to the New Genetics largely followed this approach, most clearly represented by the work of Professors Annas, Glantz and Roche of the Boston University School of Public Health, who produced the influential Model Genetic Privacy and Non-Discrimination Bill—which was introduced into the federal Parliament by Senator Stott Despoja in 1998, a first attempt to debate these issues in Australia.

In the words of Professors Annas, Glantz and Roche,

genetic information is uniquely powerful and uniquely personal, and thus merits unique privacy protection.

This approach is predicated on the basis that one’s DNA amounts to:

a coded probabilistic future diary’ [which] describes an important part of a person’s unique future.

Now that the ‘Shock of the New’ has passed, however, the inquiry firmly concluded that an ‘inclusivist’ approach was much to be preferred, in which we: (a) refrained from making artificial and unproductive distinctions between ‘genetic’ and ‘non-genetic’ information; and (b) adapted existing laws and practices to meet the special features and challenges of genetic information, rather than creating new, specialist regimes.

For example, we can build upon what we as a community have learned in recent years from dealing with the challenges of HIV-AIDS, in terms of privacy and non-discrimination/non-stigmatisation; as well as in terms of community education, pre- and post-test counselling, sound laboratory practices, and effective public health administration. Similarly, we can adapt existing privacy laws and safeguards (for example, to cover genetic samples, and to recognise the familial dimension of genetic information—see below), as well as anti-discrimination laws and watchdog

bodies, rather than establish new ones expressly to cover disputes arising out of one's real or perceived genetic status.

Dr Thomas Murray has written that this ALRC-AHEC rejection of genetic exceptionalism is:

the single most courageous and wise judgment in the report. Genetic information remains mysterious and threatening to many. Our judgment is easily skewed by its novelty and our suspicions of its occult powers, Yes, genetic information can be misused either through misunderstanding or malevolence. ALRC 96 offers cogent and thorough recommendations to guard against both'.

Fifth, what *are* those special features of genetic information that require some acknowledgment in practice? Genetic information:

- is ubiquitous—unlike most other forms of sensitive personal information, we are constantly leaving behind genetic material (saliva, blood etc) that can be tested and analysed;
- is very stable—as evidenced by the ability to test DNA from dinosaurs and from disasters like Bali and the World Trade Centre;
- is very personal and sensitive—but this is also true of HIV status, STDs, depression, cancer and so on;
- is uniquely individual, on the one hand—since each person's 3.2 billion base pair genetic sequence will be different;
- has a very strong familial dimension, on the other—indeed, we share 99.9% of our genome with all other human beings, and an even high percentage than 99.9% with members of our families and communities; and
- has a powerful predictive capacity in certain circumstances, and this will only increase with our growing understanding of genetics—but, these predictions are highly complex, interactive and contingent (and so this is only enabling if used intelligently).

Sixth, good public policy in the area of genetic information will involve a careful balancing of interests—and the language of absolute 'rights' will *not* be useful, since interests inevitably will compete, conflict and collide across the whole spectrum.

One matter identified by the inquiry that I believe requires urgent public debate, and perhaps fundamental rethinking, is the powerful preference in Western societies (especially in the English-speaking world) to focus entirely on the individual, and the primacy of the doctor-patient relationship. Yet, as already mentioned, genetic information is by definition *shared* information—with family members, with communities, and with all other humans (to the extent of 99.9%).

The inquiry heard often from doctors and, especially, familial cancer registries that they ‘lived in dread’ of the day they would receive a telephone call from a person dying of cancer, who said: “You treated my sister, whose test showed a predisposition to a cancer that runs in families (such as BRCA1, or colon cancer, or FAP), but we are estranged and she never told me about it. However, you are a health professional and all *you* had to do was make one phone call and I would have sought my own medical advice—and I probably wouldn’t be in the terminal stages of cancer now.” People expressed concern about both the legal ramifications of this scenario as well as the ethical and moral dimensions.

The late Professor Dorothy Wertz of the University of Massachusetts conducted a number of fascinating cross-cultural empirical surveys, which revealed a marked divergence in approach among differing cultures. For example, in response to questions about whether it would be proper to reveal to genetic relatives the fact that a patient tested positive for Huntington’s disease (HD) or for a familial cancer mutation, health professionals in Northern Europe, Western Europe and most especially the English-speaking countries (including Australia, the United States, the United Kingdom, Canada and New Zealand) placed their focus squarely on the individual doctor-patient relationship and were reluctant to breach this confidence, whatever the consequences for other family members.

By way of contrast, health professionals in African, Asian, Latin American, Middle Eastern, Eastern European and Southern European societies were much more likely to value familial and communal interests over individual autonomy. This was echoed in a recent conversation I had with Dr Dae-Sil Lee, a leading Korean geneticist, who said that his research work strongly confirmed his Confucian beliefs and values, demonstrating the interconnectedness of life, and the central importance of tradition, family, and community. (I have heard Dr Francis Collins say similar things about how genetic science has confirmed—not challenged—his deep Christian faith.)

In a similar vein, I believe that it is important for us to have a public debate in Australia about how we wish to proceed with work on population genetics—especially in relation to the use of collected genetic material (such as neonatal blood spots cards, although known as ‘Guthrie cards’). The use of such material—in the case of Guthrie cards, virtually a complete national collection for the last 40 years, even if unsystematised—for epidemiological purposes would have beneficial society-wide effects in terms of research, planning and public health administration. But, of course, this would mean some trade-offs against privacy protection for individuals. Would that be a price we are happy to pay?

I would hope that such a national discussion also would address the preoccupation with *biological* parenting, at the expense of social parenting. For example, the inquiry received many submissions from ‘Dads’ groups’ which started off arguing that ‘every child needs two parents’ (a jibe at the perceived bias of the Family Court against fathers), but then moved on to urge a *laissez faire* approach to genetic testing—that is, the knowledge and consent of the other parties should not be required, nor should paternity testing labs be required to be accredited. In effect, the argument seems to be, do not place any impediments (even ethical

ones) in the way of challenging biological parentage—even if this has potentially explosive results for existing *social* relationships.

And while we are on the subject, wouldn't it be great if we could use these national debates—assuming we can get them started—to promote the genetic basis for tolerance? One of the major findings of the Human Genome Project is that there is no genetic foundation for 'race', which is a social construct. Genetic research increasingly appears to verify the 'out of Africa' theory of human origins, with the very low degree of genetic variation among humans (only 1 SNP per 1300 bases, which is much lower than other complex species) tending to confirm that we have all emerged from a small 'starter population'.

What this means, is that every Palestinian and every Israeli; every Hindu and every Muslim in India; every Catholic and every Protestant in Northern Ireland; every Bosnian and every Serb; and every Hutu and every Tutsi in Rwanda, is 99.9% genetically identical. What a tragedy that the 'genius' of the human race seem always to be able to find the murderous potential in that 0.1%.

Seventh, we need to develop flexible approaches that can respond to the rapid changes in science and technology, and a broad mix of regulatory strategies tailored to the needs and circumstances of each context—not 'one size fits all' solutions, or 'Big Law'. The strategies useful for ensuring more effective oversight of medical research are not necessarily the same as those which work in overseeing the work of law enforcement officials, or ensuring best practice in testing laboratories,

Thus, as mentioned, the inquiry pushed for strong intervention in the employment context, to avoid the creation of a 'genetic underclass' in Australia of people fit and willing to work, but with some predisposition that employers may use to rule them out. However, in the area of risk-rated, private insurance (eg life insurance and critical illness insurance, but *not* private health insurance, which is 'community rated'), the inquiry did not favour government intervention, preferring instead to call on the industry to provide more effective regulation, more adherence to scientific and medical advances (and their actuarial implications), more transparency and more responsiveness to legitimate consumer interests.

Eighth, we have a clear need for *much* more community and professional education about how to deal with the New Genetics. There are some sobering surveys available for those who may doubt this need. For example, a Eurobarometer survey conducted in EU countries in March 2003 put the following proposition: 'ordinary tomatoes do not contain genes, while genetically modified tomatoes do'. 60% of respondents agreed with this. (Perhaps they are from the 'Old Europe').

The inquiry also heard consistent complaints from members of the affected community (patients, genetic support groups, etc) about doctors' lack of knowledge of genetics—and this included not only GPs but also (or perhaps *especially*) leading specialists (in fields other than medical genetics).

In surveying the literature about how to communicate risk to patients, I was fascinated by the many published studies of how members of the community understand and apply concepts of risk and probability. The short answer is, they *don't*—even the well educated do very poorly, yet this is essential for coming to grips with the predictive power of genetics. Some of this literature emerges from the health and medical context, while some of it comes from researchers in logic and mathematics—however, the conclusions are mutually reinforcing insofar as most people are unable to distinguish between good risks and bad risks in the surgery or at the casino.

This points very strongly to the need for increasing the availability of qualified genetic counsellors in Australia. I have said on a number of occasions that if a 'hero' emerged in the course of this inquiry, it would have to be the genetic counsellor. We heard story after story, from individuals and families, about learning through a diagnosis, test or family history that were affected by a genetic disorder. In the initial stages, this rarely involved much accompanying information, since so many doctors do not possess the necessary level of knowledge about clinical genetics, or do not have the communications skills to explain to lay people concepts like penetrance, predisposition, and probability.

So, in the normal way of the modern world, people go home, type the name of the condition into 'Google'—and then scare themselves witless. It is only *after* they have been able to meet with a genetic counsellor that affected individuals and their families get some real sense of their position, their prospects and options. Often they are put in touch with genetic support groups, which also play an extremely important role—providing support, information, practical advice, advocacy services and a sense of community. In the case of rare genetic conditions, *virtual* communities emerge and engage through the internet. The inquiry was told very often about how reassuring it was for affected people to meet others who are experiencing the same feelings and dealing with the same issues.

Apart from those people dealing with serious genetic health issues, it will be necessary to empower health consumers more generally, since 'lifestyle' genetic tests and products are already beginning to be marketed—and this will only increase. For example, the UK company Sciona directly markets a 'do-it-yourself' genetic testing kit for £120, which includes a buccal swab used to collect cheek cells and then to be posted to the laboratory for analysis. The test, sold as 'You and Your Genes', is said to look for particular SNPs on nine genes that may have some health consequences. Much of the marketing is now being conducted via the internet—the Body Shop stores initially carried the product, but apparently no longer do, and a number of major pharmacy chains have rejected it.

The CEO of Sciona has defended the direct marketing of these tests in the following terms:

There is already a lot of information out there recommending, for instance a diet high in fruit, broccoli and grains and low in char-grilled red meat, smoked and preserved foods and alcohol. Consumers find

this advice daunting, as they are not sure to what extent it pertains to them as individuals.

In my own view, it strains credibility to suggest that people who have difficulty processing simple health messages like 'eat more salads' and 'avoid fatty foods' will benefit significantly from the highly complex and contingent information that would be derived from analysis of their DNA. This trade is probably not of sufficient importance or harm as to necessitate heavy-handed regulation—such 'curiosity' testing simply may be the Genetic Age's equivalent of 'mood rings', requiring only some public education that instils a healthy sense of 'buyer beware'.

Ultimately, I am optimistic that it is possible to mount an effective, comprehensive, public education campaign about the New Genetics. As a career academic, I have a strong stake in maintaining the belief that people are educable. And my personal experience over the past two years also suggests that the public will be engaged by developments in genetic science and technology, and that there are interesting ways of disseminating this information widely.

When I visited the United Nations in August to speak to Pacific Islands Ambassadors, UN officials told me that the most 'clued-in' country in the world about these issues is Brazil. Why? Apparently, the highest rating show on Brazilian TV is a prime time soapie called 'El Clon' ('The Clone')—and this has prompted a national debate about the ethical and social implications of the New Genetics. (I have suggested to Carla Zampatti, Chair of the Board of SBS-TV, that the broadcaster try to buy this series for Australia.)

Ninth, we need to start planning *now* for the imminent time when 'all medicine will be genetic medicine'? The advances in gene chip technology and bio-informatics will lead to a rapid expansion in the number and scope of genetic tests available and a substantial decrease in unit cost—which in turn will dramatically increase the pressure for access to and use of genetic tests (and not only in the medical/health context). To provide an example of the sort of advances that are being made in this regard, the Australian media recently reported the story of a University of New South Wales PhD student's success in making correlations among 15,000 mouse genes. This took the 'Barossa' supercomputer 32 hours; a standard desktop computer would take 5700 years to complete the same calculations.

A recent Canadian Government report estimated that '60% of all Canadians will experience a disease with some form of genetic component during their lifetime'. If you factor in family, friends, employers and so on, we are already talking about an impact of close to 100%—and there is no reason to think that Australia is any different in this respect. At present, only three genetic tests are listed on the Medical Benefits Schedule, but in only five years or so, we have the reality of the '\$1000 genome'—that is, most Australians will be able to afford to have their genome fully sequenced and recorded on a CD.

If we wish to take full advantage of this science and technology, it is critical that our health systems immediately begin strategic planning to: address cost issues and training needs; prepare family doctors to be the key 'gatekeepers' for genetic

testing; develop an integrated genetics education program running through from university medical schools to the Royal Colleges and other institutions; provide (much) more resources for genetic counseling and genetic support groups; and manage more effectively the protection and use of genetic databases.

Tenth, all of these initiatives need to be pulled together by a Human Genetics Commission of Australia (HGCA), as recommended in *Essentially Yours*—and as already exists in the United Kingdom, and less formally in Canada (the Ontario Genetics Advisory Committee) and the United States (the Secretary’s Advisory Committee on Genetics, Health and Society). The HGCA is envisaged as a broad-based body capable of providing cutting edge advice to governments, industry and the general community about the scientific and technological advances in human genetics (including those ‘over the horizon’) as well as about the ethical, legal and social implication of these advances.

The HGCA also would have important roles to play in coordinating community and professional education at the national level; setting standards for insurers and employers about the permissible uses of genetic tests and information; advising regulators (such as the Therapeutic Goods Administration) on best practice standards; monitor international developments; and liaising with other relevant bodies, such as the NHMRC, the TGA, the Office of the Gene Technology Regulator (OGTR, which handles plant and animal genetics); and the Australian Health Ministers Advisory Committee (AHMAC, which comprises the federal, state and territory health ministers), to help ensure that Australia maintains clear, consistent and high national standards in this area.

F. Conclusions

It may well be human nature—and perhaps it is even genetic—to leave everything to the last minute and to react to emerging events rather than to plan ahead. However, good management requires that we anticipate and prevent problems—and we currently have an excellent opportunity to make policy based on sound principle, rather than on crisis management.

The area of genetic research, testing and information is so sensitive that it is critical we get this right—and do so *now*—to avoid the crisis of confidence and the public backlash that inevitably would follow from poor or unethical practices, as it has elsewhere.

What we proposing is not radical. In 1997, the then Governor of Texas, George W. Bush, praised and signed into law a bill prohibiting genetic discrimination in the workplace and in group health insurance plans—this, in the spiritual epicentre of the free market. *President* Bush now supports a similar law that recently passed through the US Senate with all-party support.

These initiatives are broadly similar to what we have recommended for Australia (although our comprehensive public healthcare system and community-rated

private health insurance mean that the landscape is different). However, I believe that the reforms recommended in *Essentially Yours*:

- are much more comprehensive;
- are more finely-tuned; and
- extend well beyond legislation, to involve many more stakeholders than government(s).

Thus, we also have a real opportunity now in Australia to be an international pacesetter in the protection and intelligent use of human genetic information. *Essentially Yours* has attracted significant interest overseas, and the report will be studied by governments and policymakers around the world—starting, we hope, at home.