

Executive Summary of Discussion Paper 66 from alrc

Part A: Introduction

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

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

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

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

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

From the beginning, the Inquiry has recognised the need for public engagement and widespread consultation, involving the general community as well as experts and interest groups. Between the release of IP 26 and the publication of this

Discussion Paper (ALRC Discussion Paper 66, or ‘DP 66’), the Inquiry conducted 15 public forums around Australia, held well over 100 meetings with interested parties, and received 168 written submissions.

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

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

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

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

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

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

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

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

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

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

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

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

Part B: Genetic testing and genetic information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Part C: Regulatory Framework

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

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

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

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

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

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

Part D: Medical and other human research

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

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

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

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

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

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

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

Part E: Human Genetic Databases

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

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

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

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

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

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

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

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

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

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

Part F: Health services

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

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

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

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

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

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

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

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

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

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

Part G: Insurance

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

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

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

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

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

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

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

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

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

Part H: Employment

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

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

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

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

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

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

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

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

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

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

Part I: Other contexts

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

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

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

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

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

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

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

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

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

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

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

Part J: Law Enforcement and Evidence

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

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

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

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

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

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

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

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

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

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

