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**The Executive Director  
Australian Law Reform Commission  
GPO Box 3708 Sydney  
NSW 2001**

## **Response to the ALRC and AHEC Discussion paper 66: Protection of Human Genetic Information**

The Genetic Support Council Western Australia Inc. (GSCWA) is the peak body for genetic support groups in Western Australia. The Council has held a forum with genetic support groups and discussions with a number of representatives from genetic support groups and interested parties. Additionally, many of the issues have been canvassed previously when providing a response to Issues Paper 26. The following reflects the general opinions and views expressed by genetic support groups in Western Australia in relation to both Issues Paper 26 and Discussion Paper 66.

Most of the proposals and questions have been responded to and although at times there is a certain repetition in response, this is to ensure the GSCWA members views were fully represented throughout. Whilst some of the proposals and questions may not have been the subject of direct discussion during the consultation process, every effort has been made to ensure that responses are within the general theme of the discussions that took place.

Throughout the response, on a number of occasions reference is made to “the general thrust” of the GSCWA’S response. This may best be summarised to mean:

- That the highest standards be adopted in the protection of genetic information and individuals privacy.
- That every attempt be made to harmonize legislation and integrate this at State/Territory and Federal levels.
- Consumer/community consultation is paramount in the establishment of any bodies or further development of legislation/regulation.
- That where possible, duplication of roles be avoided.
- That particular attention be given to matters of discrimination in areas such as employment and insurance.

Furthermore, the GSCWA wishes to participate in the process of ensuring that there is effective consumer/community representation by the genetic support community. This is particularly important in relation to Western Australia, but hopefully with the possible development of a national network of peak genetic support bodies in 2003, a much more national perspective will also be available.

## List of Proposals and Questions

### 3. A Standing Advisory Body on Human Genetics

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

**Supported.** *Whilst it is assumed that the proposed HGCA will endeavour to draw together the current “patchwork” of federal and state/territory laws, regulations and guidelines, care needs to be taken that this standing advisory body does actually do this. In choosing a model, it would seem essential to integrate wherever possible the current and future responsibilities for development and regulating the field of genetics.*

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

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

#### **Supported**

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

- identifying genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment — such as through restricted clinical request pathways or through the assignment of a higher risk classification by the Therapeutic Goods Administration;
- approving specific genetic tests for use by the insurance industry for risk-rating purposes, or by employers for compelling occupational health and safety reasons; and
- performing any similar function or providing expert advice on any other matters relating to human genetics, upon the request of the responsible minister or ministers.

#### **Supported**

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

#### **Supported**

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

***Supported, however, strong recommendation that appointments should include community/consumer representation on the HGCA as well as consultation with appropriate communities and stakeholders. The respective genetic support group peak bodies or associated organisations in states and territory's may provide an appropriate vehicle for this process. Certainly, the GSCWA would wish to be involved. It is hoped that in 2003 a national network of such organisations will be established and this may provide further opportunity to provide a more national perspective.***

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

***Supported***

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

***Supported with the recommendation that genetic support groups have the opportunity for input into this process***

## **5. Regulating Access to Genetic Testing**

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

***Yes, legislation should be enacted to require accreditation of laboratories conducting all genetic testing. Whether this should be NATA, the proposed HGCA or some other existing body, needs to be consistent with the idea of minimizing any duplication. The responsible body should have appropriate legislative powers to enforce compliance. The level of sanction for non compliance should be more than loss of accreditation if that only meant the laboratories could successfully continue testing in a private market..***

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

***Yes***

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

***Supported***

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

**Supported**

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

**Supported with appropriate sanctions for non compliance.**

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

**Yes, although whether or not this is enforceable is problematic.**

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

**Supported**

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

**Supported.**

## 7. Information and Health Privacy Law

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

**Supported. It would seem that the discrepancies between states/territory's and commonwealth legislation or lack of as the case may be, is significant.**

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

**Supported. Comment within the report refers to the NSW'S legislation and that the inclusion of body samples as personal information does not appear to have caused insurmountable problems. The GSCWA accepts it does not have all the information to fully test this view but it would seem that the inclusion of body samples as personal information in the Privacy Act may be appropriate.**

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

**The GSCWA does not consider that it is qualified to make comment on the more technical aspect of this question. It is important that any legislative change be consistent with the general thrust of the GSCWA overall response.**

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

**As with proposal 7.1**

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

**There is considerable need to ensure that any legislation is complementary. The GSCWA is not in a position to express an opinion on how this may be achieved given the legalistic nature of the debate. Suffice to say, that the important issue to be addressed is maintaining an appropriate level of privacy in relation to body samples.**

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

**Yes. It would seem appropriate to maintain such standards**

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

**No comment**

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

**Key issues for the genetic support groups in terms of the storage of human genetic information were issues of privacy and confidentiality. They repeatedly voiced their view that protection needs to be given to "my right to have my information kept confidential". They strongly believed that researchers should only work with de-identified samples, and that a code of practice for de-identifying donor samples should be drafted at the federal level to ensure uniformity in practice. However they noted that more information on the de-identification process and what it means would be useful for the groups. Furthermore, the groups expressed the view that genetic information should not be stored for research purposes for longer than a period of 2 years. It is acknowledged that 2 years is not helpful to longitudinal studies and improving technologies may provide very valuable outcomes over time.**

**Current guidelines for the collection and use of genetic information for research purposes were seen as too weak by the genetic support groups. In particular, the issue of how consent can be properly obtained for future research purposes when those purposes are not known at the time of consent being given, was important. The groups believe that written consent from the individual should be obtained every time the genetic information is being used for a different purpose. The question of how different the research may be needs to be qualified to make such a position workable.**

**Although it might not be possible to obtain individual consent every time the information is used, the notion that greater individual control over their own genetic information was expressed strongly by the groups. Therefore, the groups support the concept that individuals have a form of property right over their own genetic material in order to protect the privacy of this material. Genetic samples and information of deceased persons needs to be treated in the context of the above viewpoint.**

**The GSCWA believes that its members take this view out of a strong sense of the need for personal privacy and ownership of their own genetic information.**

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

**Supported**

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

**Supported**

## **8. Anti-Discrimination Law**

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

**Supported**

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

**Yes**

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

- define ‘disability’ in the DDA and define ‘impairment’ in the regulations made under the *Human Rights and Equal Opportunity Commission Act 1986* (Cth) (HREOC Act) to clarify the application of the legislation to discrimination based on genetic status;
- define ‘impairment’ in the regulations made under the HREOC Act to clarify the application of the legislation to a disability that may exist in the future;
- insert a definition of ‘disability’ in the *Workplace Relations Act 1996* (Cth) to conform with federal anti-discrimination legislation, as amended by these proposals.

**Supported**

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

**Agreed**

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

**Words to the effect “Genetic Condition” and “genetic Predisposition” may be appropriate and or reference to the hereditary nature of many conditions may also be advisable.**

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

**Yes**

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

**Agreed**

## **11. Enforcing Compliance with the National Statement**

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

**Supported**

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

**Most likely a broad term such as ‘human genetic research’ or similar would be appropriate to avoid the problem of interpretation and definition. Austin and Peyser (2000) define “genetic research” in terms of genetic and molecular epidemiology, pathobiology, statistical genetics, bioinformatics, ecogenetics and pharmacogenetics, health behaviour and health education as an indication as to how complex this becomes.**

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

**Sanctions should be significant and directed at an individual level as well as at an organisational/corporate level.**

## **12. Human Genetic Research and Consent**

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

**Supported**

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

**Sufficient information to enable the AHEC to make a judgement as to the appropriateness or otherwise of the waiver of consent. Whilst this may be after the HREC has approved a project, it would provide some checks and balances**

**on the HREC. There needs to be some process so that the AHEC can set standards for the justification of waiver of consents if this is not already the case.**

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

**Any change would need to be consistent with the overall thrust of the GSCWA'S response.**

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

**Supported.**

### **13. Encouraging Best Practice in Human Genetic Research**

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

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

**Supported with appropriate community/consumer consultation**

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

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

**Supported with appropriate community/consumer consultation**

### **15. Human Genetic Databases for Research**

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

**Supported with appropriate community/consumer consultation where appropriate.**

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

**Yes**

- would a licensing or registration scheme be preferable?

**The most important aspect would seem to be that appropriate standards are required to be either licensed or registered and that there are appropriate sanctions for breach of standards. This may be by monetary penalty and/or loss of licence/being deregistered.**

- how should human genetic research databases be defined for the purposes of licensing or registration?

**In recognition of the uniqueness of genetic information, the genetic support groups felt that genetic information should be held at a "higher standard", reflected in specific legislation dealing with the collection, use and disclosure of genetic information. This legislation should apply to research, the workplace, and in the storage of human genetic information particularly**

- what conditions should attach to licensing or registration?

**Those conditions that meet the standards implied above.**

- what form of independent scrutiny of database operations should be involved?

**No comment**

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

**Provided this is not a duplication of any existing roles. As previously mentioned every effort should be made to integrate and harmonize the field.**

## **16. Human Tissue Collections**

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

**Supported with appropriate community/consumer consultation where appropriate.**

## **17. Ownership of Human Genetic Samples**

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

**Supported**

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

### **Supported**

## **18. Health Professionals and Family Genetic Information**

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

***There is considerable concern regarding developments in this area and pressure to allow health professionals to disclose genetic information to relatives in these circumstances. This proposal is not supported for several reasons. Firstly, it is suggested that there is limited empirical information to support the view that there is a significant number of cases that fall into this situation. Furthermore, there is likewise little information to sustain the view that with proper counselling, individuals will not disclose such information to genetic relatives. A similar proposal was debated when the HIV/AIDS outbreak occurred in Australia. Changes to confidentiality were not implemented and it would seem the outcome has been positive even without such changes. Should there be compelling evidence to the contrary then the GSCWA and its members may have a different view.***

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

### **18.1 is not supported and as such neither is 18.2**

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

***This would only be relevant if proposal 18.1 was adopted and at this time it is strongly opposed. Should however, circumstances change or proposal 18.1 is adopted regardless of the views put here, then appropriate community/consumer consultation should be an essential part of the process.***

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

### **As per 18.3**

## **19. Genetic Registers and Family Genetic Information**

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

***The GSCWA believes a PID has been made recently to this effect.***

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

**Supported.**

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

**Yes**

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

***As mentioned earlier, key issues for the genetic support groups in terms of the storage of human genetic information were issues of privacy and confidentiality. They repeatedly voiced their view that protection needs to be given to "my right to have my information kept confidential". They strongly believed that researchers should only work with de-identified samples, and that a code of practice for de-identifying donor samples should be drafted at the federal level to ensure uniformity in practice. However they noted that more information on the de-identification process and what it means would be useful for the groups. Furthermore, the groups expressed the view that genetic information should not be stored for research purposes for longer than a period of 2 years. It is acknowledged that 2 years is not helpful to longitudinal studies and improving technologies may provide very valuable outcomes over time.***

***Current guidelines for the collection and use of genetic information for research purposes were seen as too weak by the genetic support groups. In particular, the issue of how consent can be properly obtained for future research purposes when those purposes are not known at the time of consent being given, was important. The groups believe that written consent from the individual should be obtained every time the genetic information is being used for a different purpose. The question of how different the research may be needs to be qualified to make such a position workable.***

***Although it might not be possible to obtain individual consent every time the information is used, the notion that greater individual control over their own genetic information was expressed strongly by the groups. Therefore, the groups support the concept that individuals have a form of property right over their own genetic material in order to protect the privacy of this material. Genetic samples and information of deceased persons needs to be treated in the context of the above viewpoint.***

***The GSCWA believes that its members take this view out of a strong sense of the need for personal privacy and ownership of their own bodies.***

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

**Yes**

## 20. Genetic Counselling and Medical Education

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

### **Supported**

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

### **Supported**

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

**Supported conditionally if there is appropriate involvement of community/consumer representation to ensure genetic counselling is responsive to the needs of genetic support groups and individuals with genetic conditions or genetic predispositions.**

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

**Supported, Given that this relates to genetic services, it is strongly recommended there is appropriate involvement of community/consumer representation from the genetic support field to express needs of groups and individuals requiring this service.**

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

### **As per 20-4**

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

### **As per 20-4.**

## 21. Population Genetic Screening

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

**Yes. The proposed HGCA could play a role provided this is not a duplication of any existing roles. As previously mentioned every effort should be made to integrate and harmonize the field.**

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

**Supported, recommended there is appropriate involvement of community/consumer representation**

## 24. Genetic Discrimination in Insurance

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

**Supported**

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

**Supported**

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

***It would seem that genetic information should only impact on underwriting personal insurance if there is real increase in risk over and above that within the normal population. It is felt that reasons given by insurers for the perceived increase risk should be clear and meaningful and that they explain the actuarial or statistical basis for the risk. It would seem desirable to prohibit the use of genetic information outside these confines. Public subsidy for poorer risks would seem desirable if an individual cannot obtain insurance or the cost of premiums are excessive.***

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

***It is difficult to see how information like this could be withheld if it would have a bearing on the level of risk. If however, the test was negative or did not constitute an increase in risk in relation to the insurance being sought, then emphatically no. There would need to be some safeguard for a situation where the person did not know they had undergone a test or did not have access to the results.***

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

**Supported**

**Question 24–3.** Would Proposal 24–3 be implemented most effectively through an industry code or legislation? If the latter, should this be through amendment to: (a) the insurance exemption in anti-

discrimination legislation; (b) the duty of disclosure in the *Insurance Contracts Act 1984* (Cth); or (c) both?

***It is felt that Industry codes have generally been found to be somewhat limited. Legislation is strongly recommended as the most effective means of achieving an appropriate outcome. The most important aspect of any legislation is that it is effective, that it does what it proposes to do which sometimes isn't the case, and that it can be easily enforced. Additionally, sanctions should be meaningful. Whether or not either of these pieces of legislation are the most appropriate to meet this need or new legislation is required may best be addressed by others better qualified in these matters.***

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

### **Supported**

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

### **Supported.**

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

### **Supported**

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

### **Supported**

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

- conducted in a timely and efficient manner;

### **Supported**

- undertaken by a panel of individuals, each of whom is independent of the insurer that made the decision;

### **Supported**

- carried out by suitably qualified individuals with a demonstrated understanding of insurance law and anti-discrimination law, underwriting practice, and clinical genetics; and

**Appropriate community/consumer involvement should be included in this process to ensure the views of genetic support groups and their members are considered.**

- binding on the insurer but not on the complainant.

### **Supported**

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

### **Supported**

## **25. Insurance and Genetic Privacy**

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

### **Supported**

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

**Due to the complexity of genetic information and the need for individuals to clearly understand what is required by the way of genetic information it would seem desirable that such requests are clear and concise. Relevant forms and documentation by insurers need to be presented in such a way as to enable informed decisions to be made. Currently this is not always the case.**

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

**A PID may have far reaching implications in terms of obtaining insurance and needs to be considered with great care. Adequate safeguards need to be considered for third parties unless these safeguards are in place, then the proposal is not supported.**

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

**The GSCWA does not have any evidence to support the view that genetic information is shared in this manner. Protection of a individuals privacy of genetic information is a serious concern and if this can take place then legislation needs to be enacted to prevent the practice. The sharing of general non identifiable information is another matter.**

## **27. Genetic Discrimination in Employment**

**Proposal 27–1.** Employers should be able to collect and use genetic information in relation to their employees only where this is reasonable and relevant within the terms of anti-discrimination and

occupational health and safety legislation, and subject to the limitations set out in the proposals in Chapters 28–30.

***Not supported unless there is a clear and obvious OHS issue with relation to the employees' ability to carry out their current job at that time. There would seem to be no reason for employers to collect and use genetic information as a matter of course.***

## **28. Inherent Requirements of the Job and Related Issues**

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

***Strongly supported. Genetic information should not be required by an employer unless it effects the current ability of the employee to perform the inherent requirements of a job. If this is not covered by current legislation then it should be.***

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

### ***Supported***

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

### ***Supported***

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

***Supported, recommended there is appropriate involvement of community/consumer representation from the genetic support field to represent view of the sector.***

## **29. Occupational Health and Safety**

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

- there is strong evidence of a clear connection between the working environment and the development of the condition;

### ***Supported.***

- the condition may seriously endanger the health or safety of the applicant or employee; and

### ***Supported.***

- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

**Supported.**

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

**Supported, recommended there is appropriate involvement of community/consumer representation from the genetic support field to represent view of the sector.**

- specify the genetic tests that have been approved for use;

**Supported.**

- provide guidelines for interpreting test results;

**Supported.**

- indicate the circumstances in which family medical history may be collected and used;

**Supported.**

- make provision for genetic counselling for those undergoing screening;

**Supported.**

- provide for the confidentiality of test results; and

**Supported.**

- indicate appropriate responses by employers where genetic screening reveals relevant susceptibilities.

**Supported.**

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

- there is strong evidence of a clear connection between the working environment and the development of the condition;

**Supported.**

- the condition may seriously endanger the health or safety of the employee; and

**Supported.**

- the danger cannot be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risks.

**Supported.**

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

**Supported, recommended there is appropriate involvement of community/consumer representation from the genetic support field to represent view of the sector.**

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

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

**Not supported in its current form. This proposal provides serious concerns regarding confidentiality and privacy. It is difficult to envisage circumstances whereby an individual would continued to be employed in such a situation and as such why would the need arise to pass on this information. There are similarities to this proposal as those raised in proposal 18.1. There is no doubt that an employer has certain responsibilities under OHS legislation to the safety of all employees and it is not suggested that this should be diminished. It is, however, important to have appropriate safeguards should a process exist for passing on this information.**

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

**Not supported unless concerns outlined in response to proposal 29-5 are addressed.**

### 30. Employment and Genetic Privacy

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

**Any change of definition should not diminish in any way the protection and privacy of the employees genetic information.**

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

**This should be consistent with response to 30-1.**

### 31. DNA Parentage Testing

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

**Supported**

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

**Supported, recommended there is appropriate involvement of community/consumer representation**

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

**Supported, recommended there is appropriate involvement of community/consumer representation**

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

**Supported**

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

**Control of information on the internet is becoming increasingly difficult. Regulation of this form of advertising is highly desirable to ensure that individuals receive proper information, are able to make informed decisions and have access to support and counselling. Whether it is achievable is beyond the GSCWA ability to comment.**

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

**Supported**

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

**Supported**

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

**Supported**

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

**Supported**

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

**Supported, recommended there is appropriate involvement of community/consumer representation to convey the views of the genetic support sector.**

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

**Supported**

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

**Supported.**

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

**Supported.**

- inform all persons who provide genetic samples of the availability of counselling, both at the time the samples are submitted for testing and at the time the results are made available; and

**Supported**

- forward test results to an independent person who has the skills to counsel the tested individuals and other relevant family members. Such a person should be nominated by each individual who has provided a genetic sample, and might be a qualified counsellor, social worker, minister of religion, medical practitioner, lawyer or court officer.

**Supported**

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

**Yes**

**33. Immigration**

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

**Supported**

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

### **35. Harmonisation of Forensic Procedures Legislation**

**Proposal 35–1.** The Commonwealth, States and Territories should work together to achieve harmonisation in Australian forensic procedures legislation, in particular in relation to the collection, use, storage, destruction and index matching of forensic material and the DNA profiles created from such material. Inter-jurisdictional sharing of forensic material and DNA profiles, whether on a bilateral basis or via the national DNA database system, should be permitted only after such harmonisation has been achieved.

#### ***Supported***

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

#### ***Supported.***

*For your consideration, please do not hesitate to contact the Council should you require any further information. Attached also please find attached copy of the International Huntington Association “Guidelines for the molecular genetics predictive test HD” as requested at our meeting.*

*Yours Faithfully*

*Terry Keating  
Executive Director.*