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## Use of Genetic Test Information in Life Insurance: An Evaluation of Different Regulatory Models

### Introduction

The new knowledge from the Human Genome Project has created much interest and anticipation of improved health for the population. A significant aspect of this has been the expanded use of genetic testing to identify whether a person has the affected gene and is therefore at risk of developing a particular condition or, in the case of conditions inherited on an autosomal dominant basis, establishing that a person is presymptomatic of a condition that they will almost certainly develop. Whilst knowledge of genetic risk can be of great benefit, in allowing life-planning in the knowledge of that risk, and in some cases, taking of preventative measures, concerns have been generated about the availability of genetic test information, and the use that commercial third parties may seek to make of this information. A particular site of concern has been the life insurance sector, as applicants for life insurance are usually expected to make full disclosure of their health status at the time of application, including the results of any genetic tests that have been undertaken. Life insurers are generally entitled to take health information into account in the process of risk assessment to determine whether to accept the application and if so, whether at standard rates or whether non-standard terms should be imposed. In the context of insurers' use of genetic test information, this has led to allegations of 'genetic discrimination;' that is, discrimination on the basis of genetic status. An assumption often implicit in such allegations is that such discrimination is necessarily unlawful; however, the legal status of the insurers' conduct will depend on the particular regulatory model that is in force, be it anti-discrimination or other legislation. This is an area that has been the subject of much debate and scrutiny in recent years in many of the world's developed countries, and has triggered a variety of responses. The situation remains somewhat fluid against a background of a range of inquiries, reports and their ensuing recommendations, and other steps towards reform.

The aim of this paper is to evaluate different regulatory approaches that have been adopted in a number of countries in relation to insurers' use of genetic test information: in particular, to look at

the current position in Australia and reforms that have been proposed, the moratorium in the United Kingdom on the use of genetic test information by insurers, and developments in the United States where the issue of genetic discrimination has taken broader dimensions, impacting also on health insurance. The approaches taken in these common law jurisdictions will be examined in a wider context, having regard also to the situation in a number of European countries which have legislated to prohibit or severely restrict the use of genetic test information in insurance underwriting. This evaluation of the different regulatory models seeks to explore the relevant issues both from consumer and insurance perspectives, and to determine the strengths and weaknesses of the different approaches that have been taken. In pursuing this analysis, a distinction needs to be drawn between genetic test information which is the subject matter of this paper, and more general family history information which insurers have routinely been taking into account for many years. Whilst this distinction may at times appear an artificial one and certainly has been the subject of critique, the concerns that have arisen about insurers' access to and use of genetic information have centered on the apparently more specific and accurate source of information available through genetic testing, and in the main, this has also been the focus of legislative and other reform initiatives.

### Australia

In Australia, as in most other countries, issues with regard to insurers' use of genetic test information have primarily arisen in relation to life insurance. This is because life insurance operates on principles of individual risk assessment on the basis of the applicant's health status in determining insurance cover, level of premiums etc. Health insurance, in contrast, is governed in Australia by the principle of

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1 National Health Act 1953 (Cth). For discussion see M. Otlowski, 'Is There Scope for Lawful Genetic Discrimination in Health Insurance in Australia?' (2001) 8 *Journal of Law and Medicine* 427.

'community rating' which precludes health insurers from underwriting on the basis of individual risk status.<sup>1</sup> Persons applying for life insurance products, which includes death, trauma/accident and disability cover as well as total and permanent disablement, are legally required to disclose to the insurer all information that would be material to the insurer's decision, including family history and the results of genetic tests that have been undertaken. The application forms of some insurers operating in Australia actually include specific questions about genetic testing.<sup>2</sup>

The peak life insurance body in Australia, IFSA (Investment and Financial Services Association) has been very proactive in this area, developing a policy on genetic testing which is now an industry standard binding on its member companies which comprise the great majority of life insurers operating in Australia.<sup>3</sup> Pursuant to this policy, insurers will not initiate genetic testing, nor create inducements for individuals to undergo testing through offering reduced premiums to those with a 'good' genetic profile. The policy does, however, uphold the right of insurers to have access to existing genetic test results and to take these into account for underwriting purposes. The use in practice by insurers of genetic test results has been closely monitored through ongoing research commissioned by IFSA and undertaken by the Australian Institute of Actuaries, seeking to record all applications for life insurance where a genetic test result has been disclosed.<sup>4</sup> Notwithstanding attempts within the Australian life insurance sector to be measured in its approach and to have regard to consumer issues, there has been growing concern within Australia about insurers' access to genetic test information. These concerns range from general disquiet about insurers having access to this information, and a sense of unfairness that people can be discriminated against on the basis of their genetic make-up, to a more specific concern about the capacity of insurers to accurately underwrite on the basis of this information. This entails a more sophisticated argument which is premised on the terms of the current legislative exemption from disability discrimination for life insurers operating in Australia. This exemption protects insurers from liability provided that they can substantiate their decision-making on actuarial or statistical grounds or, in the absence of such data, provided 'the discrimination is reasonable having regard to any other relevant factors.'<sup>5</sup> Whilst this exemption has not, as yet, been the subject of specific interpretation in the context of genetic test information, it has been argued that insurers currently lack the necessary

actuarial, statistical or other data about the mortality and morbidity outcomes of particular genetic test results to justify their use of this exemption. Opportunities to challenge insurance companies decisions are presently limited; individuals can seek to do so through the particular company involved or they can bring a complaint under anti-discrimination legislation, alleging that the insurer's conduct is not protected by the insurance exemption. The onus would then lie on the insurance company to seek to substantiate its decision, providing evidence of the actuarial, statistical or other data relied upon, and they can be legally compelled to provide this information<sup>6</sup>. In practice, however, this is a little used remedy. Notably, although there is an insurance complaints body for the life insurance sector – the Financial Industry Complaints Service (FICS) – its jurisdiction is presently limited and excludes complaints in relation to underwriting decisions, thus precluding it from dealing with complaints arising from the use of genetic test information by insurers.

Debate about insurers' access to and use of genetic test information has been fuelled in Australia by research data which has documented numerous allegations of genetic discrimination by insurers.<sup>7</sup> The publicity that this research data generated was a precipitating factor in the setting up of a major national inquiry into the protection of genetic information, jointly undertaken by the Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council (ALRC/AHEC). The recommendations stemming from the Inquiry's *Essentially Yours* Report<sup>8</sup> support the current framework whereby individuals are required to disclose genetic test results to insurers in applications for life insurance – recognising that mutually rated personal insur-

2 See E. Lynch et al, 'Cancer in the Family and Genetic Testing: Implications for Life Insurance' (2003) 179 *Medical Journal of Australia* 480.

3 Investment and Financial Services Association, Standard No 11.00 Genetic Testing Policy.

4 The most recent issue of this cumulative information is IFSA Genetic Test Survey Report, Period Seven: 1 December, 2003-31 May 2004, Institute of Actuaries of Australia.

5 Disability Discrimination Act (Cth) s 46. Similar provisions exist under state and territory legislation.

6 See Disability Discrimination Act (Cth) s 107(1).

7 K. Barlow-Stewart and D. Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250.

8 Australian Law Reform Commission and Australian Health Ethics Committee of the NHMRC, Report No. 96, *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003).

ance is a voluntary form of insurance premised on a process of underwriting and offered by a sector which must remain commercially viable. However, the recommendations seek to modify the processes for assessment of genetic test results and ensure independent oversight of the sector. In particular, the Report recommends that a standing body be established – the Human Genetics Commission of Australia (HGCA) with appropriate expertise which would be vested with the responsibility of approving genetic tests for underwriting purposes, having regard to their scientific validity and the actuarial or statistical data available to assess the significance of genetic test outcomes. Other significant recommendations contained in the Report include the need for insurers to provide applicants with reasons for adverse decisions in an understandable form, and the creation of an independent appeals mechanism within the sector. These recommendations in relation to insurance were contained within a two volume report of more than 1000 pages, making 144 recommendations across a broad range of areas including health care, employment, research and paternity testing. It is, therefore, perhaps not surprising that the process for implementation of the Report has been slow; at the time of writing, an official response from the Government to the Report which was released in May 2003 is still awaited but expectations are that the key recommendations contained in the Report in relation to insurance will be implemented.

The recommendations in the ALRC/AHEC *Essentially Yours* Report fall short of the protection offered by a complete legislative ban such as exists in Austria, Belgium and Denmark or of a ‘ceiling’ approach as exists in a number of European jurisdictions such as the Netherlands<sup>9</sup> by force of legislation, and also currently applies in the UK by virtue of a moratorium.<sup>10</sup> Under this ceiling approach, the normal insurance rules in relation to symmetry of information between applicant and insurer are modified in such a manner that applicants for life insurance are not required to disclose genetic test results for standard policies below the specified limit. Applicants must only disclose this information if they apply for large life insurance policies which are in excess of the specified ceiling. The rationale for this delineation between standard and large policies (with disclosure of genetic test results only required for the latter) lies in the need to protect insurers from the more expensive effects of ‘adverse selection’ whereby individuals armed with knowledge about their risk seek to take out large amounts of insurance. There would appear to be a sound empirical basis for this, as research has

shown that whilst insurers could absorb the costs of adverse selection in respect of small to standard policies, they would be vulnerable to its impact in relation to large policies for insurance.<sup>11</sup> The attraction of a ceiling approach is that it reduces the effects of adverse selection within well-defined financial limits. Although there had been considerable support for such an approach within Australia, as reflected in the submissions to the Inquiry, this was ultimately rejected by the ALRC/AHEC Report as an unwarranted interference with normal insurance principles. Instead an approach was preferred which draws to some extent on the UK model (discussed below), whereby an independent body is charged with responsibility for determining which genetic tests are appropriate for use in insurance underwriting. Under the ALRC/AHEC recommendations, the HGCA would carry out this role and insurers would only be permitted to use the results of those genetic tests for underwriting which have been approved for this purpose, but they could continue to take family history information into account. (Notably, the Report also contains recommendations for the development by the insurance sector of policies on the use of family medical history for underwriting.) If implemented, the model proposed has the potential to be effective in protecting applicants from unjustified reliance on genetic test information, provided that the HGCA is vigilant in its role as ‘gatekeeper.’ Significantly, in the UK, where the Genetics and Insurance Committee (GAIC) performs much the same role, but in that jurisdiction, for the more limited purpose of determining which genetic tests can be used for underwriting insurance applications above the ceiling amount, very few genetic tests have been approved.

The significance of other recommendations involving the creation of an independent appeal mechanism and conferring on insurers the obligation to provide understandable reasons for adverse decisions if so requested by applicants should also not be underestimated. These are important strategies to ensure that the sector is kept accountable. Preliminary data from a major empirical research

9 Medical Checks Act 1997 s 5(2).

10 For detailed coverage of the European situation see European Commission, Community Research, H. Nys et al, *Genetic Testing, Patients’ Rights, Insurance and Employment: A Survey of Regulations in the European Union* (2002).

11 A. Macdonald, ‘How Will Improved Forecasts of Individual Lifetimes Affect Underwriting?’ (1997) 352 *Philosophical Transactions of the Royal Society of London, Series B*, 1067.

project in Australia funded by the Australian Research Council into the nature and extent of genetic discrimination (Genetic Discrimination Project- GDP<sup>12</sup>) indicates that very few individuals who believe they have been unfairly discriminated against on the basis of their genetic status pursue these matters through the legal avenues available under anti-discrimination legislation. Establishing an independent appeal body within the sector with jurisdiction over such underwriting decisions would provide a cheaper and more accessible pathway for aggrieved individuals. Independent analysis by the GDP of the data collected by the Institute of Actuaries of Australia on behalf of the peak life insurance body IFSA has shown that relatively few cases involving disclosure of a genetic test result are decided solely on this basis, and that in many cases, other medical or non-medical reasons lie behind the decision. Yet it is easy to see that individuals who have disclosed a positive genetic test result to an insurer are likely to assume that this has been responsible for the adverse decision against them. Guaranteeing better flow of information to applicants through provision of clear reasons for adverse decisions will help to ensure that applicants understand the actual reasons for insurers' decision-making and would also be of assistance to those individuals who wish to challenge the decision.

### United Kingdom

In the UK, following successive inquiries by the Nuffield Council on Bioethics<sup>13</sup> and the House of Commons Science and Technology Committee<sup>14</sup>, which were both opposed to the unrestricted use of genetic test results by insurers, a moratorium has been in force since 1997 which prohibits genetic test information being used for life insurance underwriting. This came about largely through negotiation with the Association of British Insurers (ABI) which was given the opportunity to come up with a response to the growing concerns about unrestricted use by insurers of genetic test information. In its original form, the moratorium announced by the ABI was modest in nature: that for a period of 2 years, its life insurance members would not ask people to take genetic tests when applying for life insurance, or take into account the results of any genetic tests for new applications up to £100,000 directly linked to a new mortgage; for new applications for other life insurance policies, the company will decide whether or not to take the results of previous genetic tests into account.<sup>15</sup>

At about the same time, the Human Genetics Advisory Commission had identified genetic testing

for insurance as a priority issue for consideration. Following an inquiry during 1997 involving extensive consultation with interested groups and individuals, the Commission published a report in December 1997 on the implications of genetic testing for insurance.<sup>16</sup> The report recommended a moratorium of at least two years on insurers asking prospective clients for their genetic test results. This was justified on the grounds that it is far too early to be able to reach any conclusions about how genetic testing can be used to predict life expectancy or the onset of ill health. The Commission recommended that a requirement to disclose results of specific genetic tests as a condition of purchasing a specific type of insurance product would only be acceptable when a quantifiable association had been established between a given pattern of test results and events actuarially relevant for a specific insurance product. Thus, it was thought appropriate for the moratorium to continue, pending agreement that the actuarial base in relation to any particular test is secure. The report called for co-operation between the government and the insurance industry in order to monitor the situation and to actively promote research on how to interpret test results. It was recommended that the burden of proof to justify the lifting of any element of the moratorium should lie primarily with the insurance industry, and that it was the responsibility of the government, in consultation with the industry and the Commission, to put in place a mechanism for achieving this. It was acknowledged that as part of this mechanism, it may be necessary to protect companies from adverse selection in the case of exceptional sums assured, thus giving indirect support to a 'ceiling' approach. As a result of further agreement between the British Government and the ABI, a more substantial 5 year moratorium was announced in October 2001, with the aim of providing the breathing space required in which to reach

12 This is an inter-disciplinary project by a team comprising the writer together with *Dr Sandy Taylor* (fellow Chief Investigator) and *Dr Kristine Barlow-Stewart* (Partner Investigator). For information about the project see [www.gdproject.org](http://www.gdproject.org).

13 Nuffield Council on Bioethics, Report, Genetic Screening: Ethical Issues (1993).

14 House of Commons, Science and Technology Committee, Human Genetics: The Science and Its Consequence, Third Report (1995).

15 Association of British Insurers, Policy Statement, February 1997.

16 Human Genetics Advisory Commission, The Implications of Genetic Testing for Life Insurance (1997).

a consensus on long-term policy. Pursuant to this agreement, all but the largest policies of insurance are covered, enabling applicants to obtain up to £500,000 life insurance and £300,000 critical illness, income protection and long term care insurance without having to disclose any genetic test results. For policies in excess of these amounts, insurers are entitled to use genetic test results for underwriting purposes but only for those tests authorised by the Genetics and Insurance Committee (GAIC) – a body created by the government specifically for the purpose of vetting genetic tests and determining which are suitable for use in insurance underwriting. It is GAIC's role to assess evidence submitted by applicants on the clinical, technical and actuarial relevance of genetic tests. To date, GAIC has only given permission for insurance companies to use the results of genetic tests for Huntington's Disease for underwriting policies in excess of the ceiling amounts but other applications are still pending. Notably, the House of Commons, Science and Technology Committee, in its Report released in March 2001, had emphasised the need for insurers to be able to take account of *negative* genetic test results in the underwriting of policies as they can be significant in countering unfavourable family history information. Indeed, this was suggested to be the *only* justifiable use that can currently be made of genetic test results in the light of the scientific and actuarial evidence presently available.<sup>17</sup>

By the end of this current moratorium period which expires in November 2006, UK consumers will have had 7 years of moratorium protection from disclosure of genetic test results with the exception of larger policies. Significantly, however, there has been the additional safeguard of the GAIC which has operated as a very effective gatekeeper on authorisation of genetic tests for insurance underwriting. Although a moratorium is more temporary in nature compared with legislative protection, legislative reforms can always be repealed or amended. A defining feature of the UK developments has been the strong co-operation between the government and the ABI in reaching these successive moratorium agreements, although the prospect of more intrusive legislative intervention if satisfactory agreement could not be reached has no doubt been a powerful inducement. A key advantage of the moratorium approach has been the flexibility in its development using a threshold-based approach, and its adaptability to change over time. As the end date of the moratorium looms closer, the key question in the UK will be whether the moratorium will be extended after 2006 and if so, on what terms,

and for what duration. In view of the cautious approach taken to date, it would appear unlikely that the situation has changed sufficiently for the government to now be satisfied that adequate scientific and actuarial evidence exists to allow insurers unrestricted access to genetic test results. Indeed, the existence of a moratorium on the use of genetic test information arguably restricts the capacity of insurers to develop their actuarial experience in this area. Nor does defined legislation circumscribing the rights of insurers in their use of genetic test results in underwriting seem likely in all the circumstances unless this is accepted by the insurance sector. The most probable scenario, therefore, is that the moratorium will be continued for a further period of time.

### United States

As noted, the issues in relation to the use of genetic test information in insurance in the US have arisen in a somewhat different context to other jurisdictions such as Australia and the UK where the focus has been on the life insurance sector. In the US, the main site of concern and debate has been in the health insurance arena, and the implications for the life insurance sector have been of secondary importance. For the majority of Americans, access to private health insurance is gained through their employment whereby insurance is provided as part of a group policy. Only a minority (approximately 10%-15%) of individuals obtain insurance through the individual market, and it is in respect of this group that concerns about insurers' use of genetic testing have largely focused.<sup>18</sup> The concerns are potentially significant as there is no national health care system in the US, and denial of access to health insurance consequently has ramifications for access to health care. Health care is widely seen as a primary, even essential social good that people should be entitled to without discrimination and, in this respect, differs from life insurance which is regarded as an optional good which in practice less than half of the population takes up. Understandably, therefore, concerns about the impact of genetic discrimination have taken on greater proportions in the US. This helps to explain why this was the first jurisdiction

17 House of Commons, Science and Technology Committee, Fifth Report, March 2001.

18 N. Kass, 'The Implications of Genetic Testing for Health and Life Insurance' in M. Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) (New Haven: Yale University) 299.

to identify the 'problem' of discrimination on the basis of genetic status,<sup>19</sup> and the significant legislative and other efforts in that jurisdiction directed to addressing the problem. After extensive but rather *ad hoc* legislation activity by individual states, progress was made at the federal level with the enactment of the *Health Insurance Portability and Accountability Act of 1996* which provides some protection against genetic test information being used to deny or limit health insurance coverage. However, because of perceived shortcomings of this legislation (for example, it does not provide protection in all cases for individuals who seek insurance in the individual or self-employment market, and it does not prevent health insurers from disclosing, or demanding access to genetic information), further federal bills have been proposed which seek to give individuals more comprehensive protection. The legislation which is seen as holding most promise is the Genetic Information NonDiscrimination Bill 2003. If enacted, this legislation will prohibit genetic discrimination by public and private health insurance providers, preventing them from denying coverage or imposing higher premiums on the basis of genetic status, or from asking applicants to undertake genetic testing. It also seeks to prohibit genetic discrimination in employment. Whilst this has been unanimously passed by the US Senate, it has still not received the necessary endorsement from the US House of Representatives to bring it into law. It remains, therefore, to be seen whether these central concerns about genetic discrimination in health insurance in the US will be addressed in the immediate future. In comparison with other jurisdictions such as Australia and the UK, the preoccupation with the health insurance in the US has undoubtedly deflected attention away from other areas where legitimate concerns have been raised about the use of genetic test information in insurance underwriting. As a result, there has been less progress towards reform in respect of the life insurance sector in that jurisdiction. Significantly, the Genetic Information NonDiscrimination Bill 2003 includes no protection from genetic discrimination in respect of life insurance underwriting.

## Conclusion

It is clear from this review of the position in Australia, UK and the US that although in some respects, these problems in relation to the use of genetic test information in insurance underwriting are universal ones, somewhat different issues have arisen in different jurisdictions, particularly the US where there have been different priorities, and

health insurance has been almost exclusively the focus of attention. Viewed in the broader European context, where the *European Convention on Human Rights and Biomedicine* has clearly been influential in shaping national responses to these issues, differences in degree of government intervention and initiative of the insurance sector have also resulted in a number of different approaches being taken, ranging from complete legislative prohibition on the use of genetic test information by insurers such as exists in Austria, for example, to moratoria such as existed in France which preclude such use, or voluntary agreements or codes which implement a ceiling approach such as exist in Germany and Sweden. In this light, the initiatives adopted or proposed in the countries considered here would certainly appear on the conservative side: the most protective, at the present time, is the moratorium in the UK but this is due for review in 2006; in Australia, where there are currently no restrictions on insurers' access to genetic test results, the approach proposed is more guarded, seeking to preserve the fundamentals of insurance underwriting as applied to genetic test results but providing for vetting of the tests used by an independent body; in the US whilst expectations for federal reform are now raised, the scope is limited and does not extend to life insurance.

This wide range of reform strategies provides a useful opportunity to monitor and assess developments in the various jurisdictions over time, including the impact of these strategies on the life insurance industry. This will be particularly relevant in jurisdictions where access to genetic test information has been completely precluded in view of insurance sector's claims that this approach risks undermining the viability of the industry over time due to adverse selection. Clearly, there are competing interests in this area which need to be carefully balanced. Whilst safeguards may be required for the insurance sector to protect against the impact of adverse selection (eg through a ceiling approach), ultimately, the protection of individuals from unfair genetic discrimination should be a key priority and would certainly be a significant step towards ensuring 'genetic equity.'<sup>20</sup>

19 P. Billings et al, 'Discrimination as a Consequence of Genetic Testing' (1992) 50 *American Journal of Human Genetics* 476.

20 For analysis of this concept see J. Harris and J. Sulston, 'Genetic Equity' (2004) 5 *Nature* 796.