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GENETIC PROFILING: A LEGAL FRAMEWORK TO EMBRACE THE CHALLENGES

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Abstract

The current issues surrounding the use of genetic profiling technologies in New Zealand are analysed and compared with other jurisdictions, resulting in a number of key recommendations for the legal framework. An amendment to the Human Rights Act, review of the Health Information Privacy Code and an increased role for the Insurance and Savings Ombudsman are discussed in light of the developments in other jurisdictions. The implementation of a genetic database registration system and the development of policies to guide employers, insurers and health professionals on acceptable uses of genetic profile information are presented as recommendations to improve the current approaches. The establishment of an Advisory Body would ensure that safeguards against discrimination continue to be fair and effective, keeping pace with the rapid advancements in this field. The increased availability and the more acceptable costing are making the use of genetic profiling technology attractive. This is contributing further to the legal challenges, particularly when combined with the increasing range of applications for the data provided, in such diverse fields as the insurance industry, employment, personalised pharmaceuticals and the use of genetic databases. It is seen as essential that the legal framework promotes and supports the public in their access and use of genetic profiling technologies. These developments promise to be important and at the forefront of future heath care in New Zealand.

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I Introduction

Recent technological advances have resulted in much greater knowledge about genes and an increased ability to test for genetic diseases. The private nature and availability of information revealed by these tests increases the risk of discrimination, with predictable consequences for insurance and employment, wider privacy issues such as the storage of information in Deoxyribonucleic Acid (DNA) Banks and the disclosure of information to related individuals, along with implications arising from pharmacogenetic testing.

Identifying DNA mutations, changes to the chromosome number or protein abnormalities linked to a genetic disease can confirm or eliminate a suspected disease, but can also determine the likelihood of developing or passing on a disease.[1] The public health system currently provides routine testing and counselling for individuals with a family history of genetic diseases, such as breast cancer and neurological conditions.[2] With the cost of some diagnostic procedures being reduced commercially to less than 200 dollars, these technologies are becoming increasingly accessible.[3] Some tests, such as for the diagnosis of Huntington's Disease, can involve reasonably accurate predictions, but those that can reveal predispositions may be influenced by environmental and lifestyle factors leading to incorrect conclusions about the potential risk.[4] Professor Richard Faull, Director of the University of Auckland's Centre for Brain Research, believes that current research will lead to "packages of care tailored to patients' specific needs."[5] The trend towards personalised medicine is likely to include genome profiling and underpin future healthcare options, giving rise to contentious debate about the access to personal information.[6]

This paper analyses the different regulations and policy surrounding the use of information arising from genetic profiling, leading to the conclusion that it is necessary to review the current approaches in New Zealand. This would enable clarification of the ambiguities and ensure that there are sufficient safeguards in place, particularly in light of the implications for access to the rapid advances in medical technology and the range of treatments.

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[1] US National Library of Medicine "What is Genetic Testing" (1 July 2013) Genetics Home Reference<ghr.nlm.nih.gov>.
[2] Nikki Macdonald "Unveiling Your Genetic Compass" (13 April 2013) <www.stuff.co.nz>.
[3] Macdonald, above n 2.
[4] Macdonald, above n 2.
[5] Phil Taylor "Unlocking the Secrets of Our Brains" *The New Zealand Herald* (New Zealand, 07 September 2013) at A22.
[6] Nikki Macdonald "Unveiling Your Genetic Compass" (13 April 2013) <www.stuff.co.nz>.

II Background – Genetic Profiling and Discrimination

All sources of medical information including that available from medical records, family history or as has only recently become possible, through more accurate and comprehensive genetic profiling, can lead to discrimination. A 1998 United Kingdom survey provided evidence further supporting the view that discrimination was a reality in the context of the insurance industry.[7] Prior to the introduction of the 2008 anti-discrimination law in the United States, a significant number of cases of genetic information adversely affecting insurance or resulting in job losses were documented by the Council for Responsible Genetics.[8]

The two competing jurisprudential theories about genetic discrimination are that discrimination is acceptable because it enhances efficiency, as in the formulation of insurance ratings, with the opposing view being that it disadvantages individuals in unavoidable personal circumstances, hence challenging equality principles.[9] "Genetic exceptionalism" underpins these competing considerations, arguing that genetic information is a distinct health information class because it is familial (hence may reveal information about relatives without their consent) and as the genetic code is "fixed and unchangeable," it is outside an individual's control.[10] Some argue that genetic information is no different from other health related information and therefore should be treated as falling under the relevant privacy and anti-discrimination law.[11]

The United Nations endorsement of the Universal Declaration on the Human Genome and Human Rights 1998 (UDHGHR) has a key principle of respect for human dignity, including a general prohibition on discrimination based on genetic characteristics.[12] The Office of the United Nations Commissioner for Human Rights developed an ad hoc expert committee in 2002, to consider priorities regarding human rights due to biotechnological advances, identifying discrimination as a key issue.[13]

The General Conference of the United Nations Educational, Scientific and Cultural Organisation adopted the Universal Declaration on Human Genetic Data (UDHGD) in 2003, reflecting the 1998 Declaration and highlighting the complex nature of

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[7] Lowrence Low, Suzanne King and Tom Wilkie "Genetic discrimination in Life Insurance: Empirical Evidence from a Cross Sectional Survey of Genetic Support Groups in the United Kingdom" (1998) 317 British Medical Journal 1363.
[8] Council for Responsible Genetics "Genetic Testing, Privacy and Discrimination" <www.councilforresponsiblegenetics.org>.
[9] Alexander Somek "Genetic Discrimination" (2003) 40 Society 35 at 37.
[10] Jennifer Molina "Genetic Privacy: Issues in Aotearoa/ New Zealand" (Summer Studentship, Social Science Research Centre, University of Canterbury, 2005) at 9.
[11] At 10.
[12] *Universal Declaration on the Human Genome and Human Rights* A/Res/53/152 (1998), arts 1, 6.
[13] *Report of the Expert Consultation on Human Rights and Biotechnology* (Geneva 2002) at [2].

genetic information due to environmental, social and cultural factors.[14] The UDHGD emphasises the concept of non-discrimination and non-stigmatisation and is intended to guide countries formulating legislation and policies underpinned by respect for human dignity.[15]

III Implications for Insurance

An insurance company collects premium payments from a group and uses this to pay those in the group who make a claim, therefore spreading the financial loss for one individual across the group.[16] Consequently, the premium for an individual is based on the likelihood of a claim being made by assessing risk factors such as age, health, sex and family history, using worldwide statistics.[17] This means that it is inevitable that insurance providers will want to adjust their rates according to new information, such as a predisposition to a disease, obtained by genetic profiling.[18]

The claim that discrimination is acceptable is based on the argument that using this information means a more accurate assessment of risk for the insured and therefore fairer insurance policies for those who have lower risks in that insurance pool.[19] This is in the interests of the insurer and those being insured, therefore arguably justifiable as it results in premiums that more accurately reflect the potential loss of the insured person.[20] A basic principle of insurance is equality of access to relevant information between the insurer and the insured.[21] If insurers did not have the right of access to this information then they would be less able to accurately determine risks and predict the money needed to cater for losses, further challenged by the fact that individuals who know their own high risk due to genetic profiling will seek an increased amount of insurance.[22] This is commonly referred to as adverse selection because it allows high risk individuals to take advantage of the market due to unequal access to information and gain insurance benefits below an appropriate cost that are effectively subsidised by the rest of the insurance pool.[23] Low risk individuals may also seek little or no insurance, leading to an insufficient insurance pool and market collapse.[24]

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[14] *International Declaration on Human Genetic Data*, (32 C/Res 22), arts 3, 4.
[15] Article 7.
[16] Human Rights Commission *Guidelines: Insurance and the Human Rights Act 1993* (November 2007) at 5.
[17] At 5.
[18] Somek "Genetic Discrimination", above n 9, at 36.
[19] At 37.
[20] At 37.
[21] At 37.
[22] At 37.
[23] Andru Isac "Latent Defects in Human Capital: Regulating Genetic Testing and the Insurance Market" (2003) 9 NZBLQ 315 at 318.
[24] At 318.

Compulsory genetic profiling could provide a solution to this problem by enabling more accurate classification of risks.[25] Insurance provides protection from unpredictable events and it is unreasonable to restrict insurers from taking into account increasingly predictable risks.[26]

The argument against discrimination is that it would be "manifestly unfair" because there is nothing that an individual can do to avoid a predisposition which is "inherited and immutable".[27] A further consideration is the risk of genetic information being used in an uninformed way. Distinction needs to be made between monogenic disorders such as Huntington's Disease (whereby onset is inevitable) and complex polygenic disorder predispositions (whereby the likelihood and seriousness of any disease is much more uncertain).[28] Uninformed use of data has been revealed in studies such as one Australian case, which involved a 22 year old woman who tested positive for a predisposition to bowel cancer and was subsequently declined travel insurance.[29] Genetic discrimination may discourage individuals from having necessary medical tests, in order to avoid compromising the financial position of the entire family.[30] The heritable nature means that diagnosis of one individual has implications for an entire family who may be at risk of "red flagging by insurers".[31]

A New Zealand Law

Human rights are protected in New Zealand by a legislative regime including the New Zealand Bill of Rights Act (BORA), Human Rights Act (HRA), Health and Disability Commissioner Act 1994 (HDCA) and the Privacy Act 1993.[32] BORA, HRA and the HDCA all make it unlawful to discriminate on certain prohibited grounds including a disability, but it is unclear whether the definition of a disability would include a genetic predisposition.[33] The adequacy of the existing framework depends on New Zealand's view of "genetic exceptionalism" (due to the familial nature and lack of individual control as discussed above) or whether genetic information can be "lumped together" with general health information.[34]

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[25] Somek "Genetic Discrimination", above n 9, at 37.
[26] Michael Kinsley "Genetic Discrimination: Unfair or Natural?" (2008) <www.time.com>.
[27] Isac, above n 23, at 319.
[28] At 317.
[29] At 317.
[30] At 318.
[31] At 316.
[32] Human Rights Commission *Human Rights in New Zealand Today: Biotechnology and the Developments Arising from the Study of the Human Genome* (2004) at ch 19.
[33] At ch 19.
[34] Mark Henaghan and others *The Regulatory Implications of the Human Genome Project for New Zealand: Phase 1* (Human Genome Research Project, Dunedin 2003) at 9.

The National Health Advisory Committee on Health and Disabilities produced a report on Molecular Genetic Testing in New Zealand (2003), acknowledging the "social and ethical issues in genetic testing and the implications for insurance and employment" but did not explore this in any depth.[35] The Human Rights Commission Report in 2004 found that in order to comply with its international obligations, New Zealand needed to ensure non-discrimination by considering the effectiveness of the HRA and BORA in preventing genetic discrimination within the insurance industry and whether legislative amendment was necessary.[36] The Bioethics Council and an independent study undertaken by Otago University (which considered the consequences of the human genome project for New Zealand) led the investigation into the implications of genetic profiling.

New Zealand has not enacted legislation in response to this issue. The insurance industry is governed by a self-imposed voluntary moratorium (through the Investment Savings and Insurance Association (IAI)) preventing an insurer requesting a genetic profile.[37] However, where a genetic profile has already been undertaken, the insurer can request that information and disclosure is required of the insured person.[38]

Section 19 of the BORA provides the right to be free from discrimination under the prohibited grounds of discrimination set out in s 21 of the HRA, including sex, religion, age and disability, among others.[39] Section 44 of the HRA makes it unlawful to discriminate in the provision of goods and services and "facilities by way of insurance" and therefore insurers cannot refuse to provide insurance or treat them less favourably by reason of any of the prohibited grounds of discrimination (both directly and indirectly) in s 21.[40] As insurance is about classification of risk, there is an exception in s 48 that allows distinctions on the grounds of sex, disability and age, based on actuarial data.[41] There is no provision prohibiting discrimination by insurers on the grounds of genetic profile results and even if this is included under the definition of disability (which has not yet been considered by the courts), s 48 would allow an exception, therefore the HRA does not prevent discrimination on the grounds of genetic information.

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[35] *Molecular Genetic Testing in New Zealand* (National Health Advisory Committee on Health and Disabilities, October 2003) at 9.
[36] Human Rights Commission, above n 32, at ch 19.
[37] Human Rights Commission, above n 16, at 14.
[38] Human Rights Commission *Discussion Paper: Review of the Guidelines on Insurance and the Human Rights Act 1993* (2006) at 13, 14.
[39] New Zealand Bill of Rights Act, s 19; Human Rights Act, s 21.
[40] Sections 44, 65.
[41] Section 48; Human Rights Commission, above n 16, at 5.

The Human Rights Commission published Guidelines on Insurance and the HRA in 1997 to assist the industry and the public in understanding how human rights relate to insurance but did not address the issue of genetic information.[42] A 2007 review of these guidelines was conducted in response to issues such as the increasing availability of genetic profiling. The review noted that the current self imposed moratorium approach is consistent with adverse selection concerns because it recognises the need for insurers to have access to the same information about an applicant's health as the actual applicant, although there is uncertainty about whether this is a realistic concern.[43] However, the need to balance discrimination based on genetic status to avoid excessive premiums or exclusion from insurance was also highlighted.[44] The review questioned the current approach, noting the flexibility and ease of implementation but also its non binding and voluntary nature, raising the idea of changes to the legislation, such as the inclusion of genetic status as a prohibited ground under the HRA or (as in the United States) by a completely separate piece of legislation.[45]

Feedback was generally positive, with the New Zealand Society of Actuaries and the Medical Assurance Society recommending that the current moratorium be compulsory for all insurance companies but also that there should be a review as genetic profiling increases.[46] The Mental Health Foundation raised the issue of discrimination linked to genetic profiling for existing or possible future development of mental illness.[47] While the moratorium is currently seen as effective in New Zealand, the Human Rights Commission believes there is an opportunity to monitor international best practice development and promote debate of future options.[48]

B Comparative Approaches

1 Legislative Approaches

Countries that have introduced regulation restricting the use of genetic profile information in insurance through either privacy legislation or antidiscrimination laws

[42] Human Rights Commission, above n 16, at 7.
[43] At 13, 14.
[44] At 13.
[45] Human Rights Commission, above n 38, at 4.
[46] New Zealand Society of Actuaries *Submission to the Human Rights Commission on the Review of the Guidelines on Insurance and the Human Rights Act 1993 Discussion Paper* (2006) at 6.
[47] Mental Health Foundation of New Zealand *Submission to the Human Rights Commission on the Discussion Paper: Review of the Guidelines on Insurance and the Human Rights Act 1993* (2006) at 3.
[48] Human Rights Commission, above n 16, at 14.

generally focus on whether genetic profiling can be compulsory and whether an applicant can be required to disclose genetic test results for risk analysis.[49]

The United States and some European Countries have taken the approach of prohibiting insurers from requesting genetic profile information, generally under the right to privacy.[50] The European Convention on Human Rights and Biomedicine 1997 prohibits "any form of discrimination against a person on the grounds of his or her genetic heritage".[51] Austria, Belgium and Norway are countries that have acted to implement this convention but with the exception of Austria, this is rarely addressed in one consolidated statute.[52]

The United States passed the Genetic Information Non-Discrimination Act (GINA) in 2008 to prohibit the requirement of genetic tests and prevent discrimination in insurance coverage or premium costs (or employment) based on genetic profile results.[53] This was seen by the National Human Genome Research Institute as necessary for biomedical research and personalised medicine to advance,[54] but this legislative measure does not extend to cover life or long term care insurance which is already creating problems for some who have undergone genetic profiling.[55] The difficulty of using anti-discriminatory laws is that insurance markets have been traditionally predicated on the ability of insurers to rationally discriminate between individuals based on their own risk.[56] There is confusion over the definition of genetic information and genetic profiling in some countries, such as Austria, Israel and Denmark, where legislative prohibition prevents insurers from seeking genetic information.[57]

2 Voluntary Moratorium

The United Kingdom currently relies on a voluntary moratorium similar to that in New Zealand. However the United Kingdom approach involves a compromise moratorium allowing applicants to refuse to reveal information if the policy is below a

[49] Isac, above n 23, at 319.
[50] Human Rights Commission, above n 38, at 13.
[51] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine CETS 164 (opened for signature 4 April 1997, entered into force 1 December 1999), art 11.
[52] Isac, above n 23, at 319, 320.
[53] Section 1.
[54] David Resnick "A Big Step Toward Personalised Medicine" (2008) <www.masshightech.com>.
[55] Rob Stein "Scientists See Upside and Downside of Sequencing their own Genes" (2012) <www.npr.org>.
[56] Isac, above n 23, at 316.
[57] Human Rights Commission, above n 16, at 14.

certain amount.[58] One recommendation by the Human Genetics Commission was that the United Kingdom legislation incorporate the principle that "we affirm that humans are born equal, that they are entitled to equality of opportunity and that neither genetic constitution nor genetic knowledge should limit that equality". [59] The British Insurance Industry argument is that insurance operates to benefit everybody by balancing its ability to assess risk on the basis of all relevant information while not discouraging testing due to fear of eligibility or costs.[60] The Genetics and Insurance Committee was set up in 1999 as an independent review body to ensure that genetic information for insurance purposes is used only where relevant and supported by scientific and actuarial evidence.[61]

While Australia also has a voluntary moratorium, it is only in the context of life insurance.[62] The Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council published a Report in 2004 "Essentially Yours", following a comprehensive inquiry into Australia's regulatory framework.[63] Recommendations were wide in scope, dealing with privacy (disclosing information to relatives), ethical oversight of research, discrimination by employers and insurance, DNA data sharing, along with many other issues and included the establishment of a Human Genetics Advisory Committee (HGAC) to advise the government.[64] Following this, "disability" was redefined in the Disability Discrimination Act 1992 (Cth) (DDA) to include a disability that may arise due to a genetic predisposition.[65] The Report also recommended that the Investment and Financial Services Association improve the underwriting process to include scientific reliability (the link between the mutation and the expression of the disease) and its actuarial relevance (the link between the expression of the disease and increased morbidity or mortality). This has been implemented by introducing policy standards, the increased training of underwriters and the establishment of an independent body by the HGAC, to ensure the reliability of the data.[66]

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[58] HM Government "Concordat and Moratorium on Genetics and Insurance" (2011) <www.gov.uk>; Human Rights Commission, above n 16, at 13, 14.
[59] Molina, above n 10, at 12.
[60] At 12, 13.
[61] Wellcometrust "The Genetics and Insurance Committee" The Human Genome <www.welcome.ac.uk>.
[62] Mark Henaghan and others *Genes Society and the Future Volume 3* (Human Genome Research Project, Dunedin 2009) at 345.
[63] Australian Law Commission and the National Health and Medical Research Council *Essentially Yours: The Protection of Human Genetic Information in Australia (ALRC Report 96)* (30 May 2003).
[64] Australian Law Reform Commission *Protection of Human Genetic Information* (19 July 2012).
[65] Australian Law Reform Commission, above n 64; Section 4(j).
[66] Australian Law Reform Commission, above n 64.

3 Critique

Regulatory models based on privacy laws confirm genetic exceptionalism. An opposing argument is that the current disclosure of family health history and general medical information is no different from genetic information.[67] In addition, privacy based laws cannot be reconciled with the fundamental common law duty of disclosure which ensures insurance contracts achieve the equality of access underpinning the establishment of insurance premiums.[68]

A model based on antidiscrimination is also contradictory because insurance is based on the ability of an insurer to use discrimination for effective pricing.[69] As noted, discrimination already occurs using family history and non-genetic tests to indicate the likelihood of getting a disease or suffering from adverse health.[70] An exception banning discrimination based on genetic information that is supported by actuarial data may be difficult to justify.[71]

D Recommendations for New Zealand

Due to the complex, uncertain nature of genetic information and the potential impact it can have on insurance accessibility, this paper argues that the present approach in New Zealand is inadequate. If the moratorium is retained, legislation making this compulsory needs to be initiated along with a mechanism for enforcing compliance.

Whether or not the current approaches in New Zealand are able to adequately provide actuarial data for genetic information is one question raised by the New Zealand Law Commission and also referred to in the Human Rights Commission discussion paper. [72] Following the Australian approach of implementing an independent regulatory body to rule on such decisions could be an effective means of monitoring and avoiding the creation of a disincentive against using genetic profiling technologies. Increased training for insurance providers about the implications of profiling would be beneficial.

If genetic status discrimination is to be dealt with under the HRA antidiscrimination law, this paper recommends that a distinction is made between pre-symptomatic disabilities and the pre-disposition genetic conditions with the potential to be

[67] Isac, above n 23, at 324.
[68] At 324.
[69] At 324.
[70] At 324.
[71] At 324.
[72] Human Rights Commission, above n 38, at 14.

influenced by environmental conditions and lifestyle choices.[73] If genetic status is included in the HRA legislation, this may have further implications for other areas that are covered by the Act resulting in broader policy questions that need to be addressed.

It would also be useful to reconsider the role of the Insurance and Savings Ombudsman (ISO) in receiving complaints about discrimination based on genetic profiling. This would be binding on the participants of the ISO scheme and therefore could be one mechanism for providing a complaints system that is free for consumers, prior to the expensive exercise and time consuming exercise of pursuing litigation in the courts.[74] However there would need to be changes to the ISO responsibilities, as current procedures would not be permit complaints to include issues about discrimination leading to higher premiums or consider underwriting decisions and whether the insurer had used the information in an unfair way.[75] One possibility would be to expand the role of the ISO, to enable consideration of discrimination and inappropriate use of genetic information. It would be necessary to increase public awareness of any changes to the complaints process.

This paper proposes that it would also be useful to establish an Advisory Body similar to that in Australia to review the approaches taken in other jurisdictions and monitor the developments in New Zealand. This would be assisted by including genetic status as a prohibited ground of discrimination, given that the social implications of using genetic information in other areas are significant, such as in employment discussed below.

This section has focused on the issues that have arisen in the insurance industry, analysing the different regulatory approaches to genetic privacy and leading to the conclusion that New Zealand's current approach of a voluntary moratorium needs to be reviewed. This is supported by the underlying argument that law and policy needs to encourage access to new technologies, such as genetic profiling, by ensuring that the public can be confident in their expectation that there are adequate safeguards in place to protect individuals against any potentially negative consequences.

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[73] At 14.
[74] Insurance and Savings Ombudsman "complaints the ISO can Consider" ISO <www.iombudsman.org.nz>.
[75] Insurance and Savings Ombudsman, above n 74.

IV Implications for Employment

Allowing employers to discriminate on the basis of genetic profiling may be valid on economic, health and safety grounds but balancing these against the autonomy of the employee or applicant is seen as essential. Employment decisions may inevitably involve some discrimination on such grounds as education, previous work experience, personality and in today's environment, increasingly psychometric testing.[76] Genetic profiling could allow employers to recruit with more certainty and to avoid the costs associated with employees who are likely to become ill, require leave or need to be replaced due to poor health. Genetic profiles could be used for health and safety concerns such as may arise, for example when the test results for a pilot revealed an increased risk of heart attack. Legal restrictions may be necessary to prevent employers seeking to exclude individuals from the workplace considered to have an unfavourable genetic profile. [77]

Decisions based on genetic information can also lead to employment discrimination on the grounds of race, sex or disability.[78] If an employer refuses to employ an applicant due to a genetic disposition to a disease associated with the female gender, such as breast cancer, this could be perceived as sexual discrimination. Where there is a strong link between a genetic disposition and a particular population group, such as the disease sickle cell anaemia link with Afro-Caribbean discussed below, refusing to employ people belonging to that group could amount to racial discrimination.[79] If a genetic condition is likely to develop into a disease, it may also lead to different employment conditions amounting to disability discrimination.[80]

Genetic profiling in the workplace could involve control and coercion by the employer, as they can be used to refuse an applicant, dismiss an employee or demote them to a different job as a consequence.[81] In addition, privacy and other issues may arise if health details are used inappropriately or disclosed to other parties and emotional and psychological distress may occur from test results that indicate the problem is significant.[82] The Human Rights Commission reported that the use of information from genetic profiling did not appear to be a current factor in

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[76] James Desmond K Gardner-Hopkins "Unemployable Genes: Genetic Discrimination in the Workplace" (2001) 9 Auckland UL Rev 433 at 347.
[77] At 348.
[78] Human Rights Commission, above n 32, at ch 19.
[79] At ch 19.
[80] Phillipa Gannon and Charlotte Villiers "Genetic Testing and Employee Protection" (1999) 4 MedicalLInt 39 at 44.
[81] At 40.
[82] At 40.

employment disputes.[83] However concerns were raised that it may be used in future recruitment decisions, and that there was a need to protect third parties with respect to occupational health and safety matters.

A New Zealand Law

The BORA, s 19 includes the right to be free from discrimination on the grounds set out in the HRA.[84] Section 21 (HRA) prohibits discrimination on the grounds of disability, race and sex and s 22 makes it unlawful for an employer to refuse or terminate employment or offer less favourable terms by reason of any of the prohibited grounds of discrimination.[85] Under s 23 it is unlawful to make an inquiry about an applicant for employment, which could be reasonably understood to indicate any intention to commit a breach of s 22.[86] An exception to the prohibition of discrimination against people with disabilities set out in s 22 is provided in s 29, where the person could only perform the duties satisfactorily with the aid of special services or facilities which it would not be reasonable to expect of the employer, or that the work conditions mean a possible risk of harm to themselves or a third party.[87] This is subject to s 29(2) that the employer could not, without reasonable disruption, take measures to reduce the risk to an acceptable level.[88] The Employment Relations Act 2000 provides that an employee who has been discriminated against during employment may pursue personal grievance,[89] with the prohibited grounds of discrimination being those provided for in s 21 of the HRA (above) and exceptions in s 29 (above),[90] unless justified on the grounds of being fair and reasonable actions.[91]

The HRA provisions have been described as problematic in relation to genetic discrimination in employment for several reasons. In the first instance, it is ambiguous as to whether the definition of "disability" as provided in s 21 would be wide enough to include discrimination on the ground of genetic pre-disposition (discussed in Part III with respect to insurance).[92] If it does, s 22 would therefore include the prohibition of discrimination against an employee or applicant on the grounds of their genetic predisposition and s 23 would appear to prohibit the

[83] Human Rights Commission, above n 32, at ch 19.
[84] Section 19.
[85] Sections 21, 22.
[86] Section 23.
[87] Sections 29(1)(a), 29(1)(b).
[88] Sections 29(1)(a), 29(1)(b), 29(1)(c).
[89] Sections 102, 103.
[90] Section 105.
[91] Section 103A.
[92] Human Rights Commission, above n 32, ch 19.

requirement that an applicant undergo genetic profiling.[93] However the exception in s 29 creates ambiguity in relation to those genetic profile results that reveal an increased likelihood of harmful effects from exposure to workplace toxins.[94] Whether or not this is discrimination would depend on the interpretation by the court of "reasonable" in s 29. It has been suggested that this use of genetic profiling would be interpreted as being similar to the current practice of physical stress tests to determine likelihood of contracting asthma from exposure to substances in a workplace.[95]

The Health and Safety in Employment Act 1992 intersects with the HRA. Section 6 imposes a duty on employers to be responsible for providing a safe work environment for their employees and s 15 provides that the employer must take all practicable steps to ensure that the employee does not harm any other person who is not an employee.[96] "All practicable steps" are defined as "all steps to achieve the result that it is reasonably practicable to take in the circumstances", having regard to what is known about the severity, likelihood, financial constraints, effectiveness and availability of means to address the potential harm.[97] The Human Rights Commission indicated that it is conceivable that this responsibility could extend to using genetic profiling for the identification of employees susceptible to work place hazards or who create a danger to others.[98] It is likely that the outcome would again depend on the interpretation of "reasonably practicable" by the court.[99] It is even possible that the requirement of a genetic test to determine the risk of harm from workplace toxins may be required of an applicant or employee as part of the "all practicable steps" provision, should profiling be considered to be information that "ought reasonably" be known by the employer, as access to this technology increases.[100]

The lack of clarity in the law has the possibility of resulting in two less than desirable outcomes. Employers may find themselves caught between the requirement of "all practicable steps" to protect the health of employees, on the one hand, and the prohibition against discrimination on the basis of disability, on the other.[101] Employees or potential employees may find themselves required to provide a genetic profile as a precondition of employment or before undertaking particular tasks,

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[93] Joanna Goven *Implications of Genetic Testing for the Workplace and ACC Research Report No. 8* (Constructive Conversations, The Foundation for Research, Science and Technology, Canterbury, 2005) at 9, 10.
[94] At 10.
[95] At 10.
[96] Sections 6, 15.
[97] Section 2A.
[98] Molina, above n 10, at 12.
[99] Goven, above n 93, at 11.
[100] Section 2A; Goven, above n 93, at 11.
[101] Goven, above n 93, at 12.

perhaps as a result of an employer endeavouring to take "all practicable steps".[102] While this may be seen as a positive step towards improving workplace health and safety, the concerns discussed in the beginning of this section would be contentious. Issues such as the sensitive and predictive nature of this information, the potential implications for family members, as for insurance, sit alongside the ultimate consequence that the individual may be left without employment.[103] The other concern, similar to that highlighted with respect to insurers in part III, is that employers may misinterpret the genetic information. There is potential for misuse by assuming that the result means a definitive conclusion about the likelihood of an individual developing a disease. Further, genetic profiling may shift the focus away from improvements that would make the workplace safer for everyone, toward ignoring a problem through the removal of particularly susceptible workers.[104]

In New Zealand, the Accident Compensation Corporation (ACC) policies are also likely to be relevant in relation to the practice of genetic profiling in employment as the ACC provides cover for "'personal injury caused by work-related gradual process, disease, or infection".[105] Of significance to the ACC is geno-toxicological testing, a type of genetic profiling that targets genetic variation associated with greater or lesser susceptibility to harm from exposure to known toxins.[106] Genetic profiling was not mentioned in the Workplace Health and Safety Strategy for New Zealand to 2015, published by the Department of Labour in 2005.[107] It appears that the ACC has not considered that results could potentially be used as evidence of a link between the illness and exposure by employers claiming accident compensation, or alternatively tests could be required by the ACC to dispute a link.[108] It could argued that the ACC system means that employers in New Zealand have little incentive to use genetic profiling to screen employees as ACC compensates and rehabilitates injured workers.[109]

However there is still scope for genetic profiling as some employers already use medical screening in ways that parallel the potential use of genetic profiles (such as with the exposure example above) and could be seen as another step on the continuum.[110] Further, at least 25 per cent of employees in New Zealand currently work for employers who have opted through the ACC Accredited Employer

[102] At 12.
[103] At 12.
[104] At 12.
[105] Accident Compensation Act 2001, s 30.
[106] Goven, above n 93, at 7.
[107] At 18.
[108] At 7.
[109] At 12.
[110] At 12.

Programme to self-insure for workplace injury and illness.[111] The Programme allows the employer to act on behalf of the ACC for an employee's work related injuries, which would negate the ACC considerations with respect to gene profiling and employment.[112]

B Comparative Approaches

Although there is little evidence of genetic profiling in New Zealand workplace, there are numerous examples in other jurisdictions. In the 1970s, carriers of the sickle cell disease, present in seven per cent of Africans but less than one per cent of Europeans, were unnecessarily excluded from a number of occupations as it was believed they may be adversely affected by certain chemicals.[113] In the United States, this led to screening programs to identify carriers of the gene as illustrated by the screening currently used to sort applicants for aircrew training in both the British and American military due to the serious health risks faced by carriers at high altitudes.[114]

The United States history of workplace discrimination from the use of genetic information is highlighted by the 2013 lawsuit, *Equal Employment Opportunity Commission v Fabricut Inc,* which sought to enforce genetic non-discrimination rights under Title II of GINA 2008.[115] Following a pre-employment medical examination, Fabricut required an applicant for a clerk position to obtain additional testing to rule out Carpal Tunnel Syndrome (CTS), after initially offering the appointment.[116] The testing ruled out CTS but Fabricut still withdrew the job offer on the grounds of the medical examination and the company view that the applicant had CTS.[117] Damages of United States $50, 000 were agreed to by the company along with an undertaking to take corrective action that included a non-discrimination notice to employees (required by GINA) and non-discrimination training for all staff involved in hiring decisions.[118]

In Australia, widespread problems associated with employers misusing genetic information have not been reported but this does not necessarily rule out discrimination. The fear of victimisation following the lodging of a complaint is a real issue which is compounded by people being unaware of their rights. A 2003 review

[111] At 12.
[112] ACC "ACC Accredited Employer Programme" (12 December 2012) <www.acc.co.nz>.
[113] Gannon and Villiers, above n 80; Desmond, above n 76, at 441.
[114] Gardner-Hopkins, above n 76, at 441.
[115] US Equal Employment Oppurtunity Commission "Fabricut to Pay $50 000 to Settle EEOC Disability and Genetic Information Discrimination Lawsuit" <www.eeoc.gov>.
[116] US Equal Employment Oppurtunity Commission, above n 115.
[117] US Equal Employment Oppurtunity Commission, above n 115.
[118] US Equal Employment Oppurtunity Commission, above n 115.

found considerable uncertainty about the nature and extent of discrimination in employment but at the time, was awaiting the empirical research being undertaken by the Genetic Discrimination Project Team.[119]

As early as 2001, an Australian study into genetic discrimination did identify situations where genetic profiling was required as a pre-requisite of employment and examples of discrimination against asymptomatic employees.[120] An illustration of this is the situation in which a young woman applicant for a public service position was informed that a negative genetic profile result for familial adenomatous polyposis was to be a condition of her employment because regular colonoscopies for early signs of bowel cancer suggested to the employer that she was in fact, at risk of the disease.[121] As the test results came back positive, the applicant did not proceed with her job application.[122]

1 Prohibition of Use

Some jurisdictions have addressed the potential impact of genetic profiling in the context of employment by legislating against the use of genetic information. This has been in the form of either complete or partial prohibitions with specific exceptions for third party safety or to protect an employee. The European Convention on Human Rights and Biomedicine could be interpreted to mean that workplace testing will only be acceptable if it is to benefit the health of the employee.[123] The accompanying explanation states that genetic profiling by insurers or employers offers no health benefit to the individual and therefore is an invasion of privacy that will only be permitted on the grounds of the interests of third parties or the wider public good.

The examples of total prohibition on the use of genetic information seen in Austria, France and Norway are confined to genetic profile results and exclude family medical history.[124] An example is Norway, where it is unlawful for an employer to request or use any information derived from a genetic profile.[125] The United States has also prohibited the use of genetic information in employment with the 2008 enactment of the GINA. The position in the United States is complicated by the fact that employers usually provide health insurance, consequently employees with medical conditions

[119] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.23], [30.24].
[120] At [30.24].
[121] At [30.27].
[122] At [30.27].
[123] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine, above n 51, arts 11, 12; Gannon and Villiers, above n 80, at 59.
[124] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.35].
[125] At [30.35].

create higher costs for the employer.[126] Title II of GINA focuses on employment, protecting individuals from genetic discrimination and banning the use of genetic information by employers in hiring decisions.[127]

Jurisdictions that have prohibitions subject to specific exceptions include the Netherlands, Denmark and Israel.[128] These models vary in both the scope of exceptions and the type of genetic information covered, although exceptions are generally related to the use for occupational health and safety reasons such as screening for workplace susceptibilities or conditions that place third parties at risk.[129]

2 Permission Subject to Exceptions

The current Australian and United Kingdom regulatory frameworks are similar to New Zealand. Employers are permitted to collect and use both applicant and employee genetic information, subject to limits imposed by occupational health and safety, anti-discrimination and privacy legislation.[130]

The Australian regulatory framework has relevant pieces of legislation. The Human Rights and Equal Opportunity Commission Act 1984 (Cth) (HREOC) provides that the HREOC may inquire into any practice affecting the equality of opportunity or treatment in employment. This is seen as a possible mechanism for reviewing discrimination on the basis of genetic status in the future.[131] The DDA prohibits an employer from discriminating against an applicant on the basis of a disability and the "Essentially Yours" Report recommendation that this definition be extended to include discrimination on the basis of genetic status, has been implemented.[132] The employment provisions of the DDA balance the interests of employers, employees and the community, acknowledging that it is not unlawful to discriminate if a person is unable to carry out the "inherent requirements" of a job because of their disability or if it would impose an "unjustifiable hardship" on the employer if required to provide such services or facilities.[133] The Sex Discrimination Act 1984 (Cth) and the Racial Discrimination Act 1975 (Cth) prohibit discrimination in the selection process, the terms of employment including training and promotion opportunities and

[126] Gardner-Hopkins, above n 76, at 435.
[127] Molina, above n 10, at 13.
[128] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.38].
[129] At [30.38].
[130] At [30.40].
[131] At [30.4].
[132] At [30.7]; Explained above in pt III.
[133] Sections 15.4, 21A, 21B; Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.8].

termination conditions, where the genetic information under consideration falls under race or gender.[134]

The Australian Workplace Relations Act 1996 (Cth) (WRA) also prohibits discrimination on a range of grounds when terminating employment, including race, sex and disability, except where they are unable to fulfill the "inherent requirements" of a particular position, with the onus on the employer to establish a valid reason for dismissal.[135] The Occupational Health and Safety Legislation (present in all Australian States and Territories) also overlaps with the antidiscrimination regime because employers may use genetic information to assist meeting their obligations under the legislation.[136] The relationship with the DDA is set out by the HREOC and provides that meeting health and safety legislation requirements must be accepted as being among the "inherent requirements" of any job.[137]

Protection from unlawful discrimination is also provided for in several statutes in the United Kingdom. The Race Relations Act 1976 and the Sex Discrimination Act 1975 define discrimination as the treatment of another less favourably on racial or sexual grounds.[138] Both Acts include antidiscrimination provisions in employment covering all parts of employment from the application, through to training, transfer or dismissal.[139] The Disability Discrimination Act 1995 defines a disability as a "physical or mental impairment which has a substantial and long term adverse effect on the ability of a person to carry out normal day to day activities".[140] It is unclear whether this would include a person with an asymptomatic genetic disorder. Schedule 1 of the Act may cover a future disorder, as para 8 includes a person who suffers a substantial adverse effect where a progressive condition impairs or is likely to impair the ability to perform daily activities, suggesting the person must have already encountered some difficulty.[141] The House of Commons Science and Technology Committee suggested that the Act would not be an appropriate means of protection against discrimination resulting from genetic profiling.[142]

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[134] At [30.5].
[135] Sections 170CK(2)(f), 170CK(3); At [30.6], [30.11].
[136] At [30.14].
[137] Human Rights and Equal Opportunity Commission "Frequently Asked Questions: Employment" (19 February 2003) <www.hreoc.gov.au>; Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.18].
[138] Race Relations Act (UK), s 1 (1)(a); Sex Discrimination Act (UK), s 1(1)(a).
[139] Gannon and Villiers, above n 80, at 44.
[140] Section 1.
[141] Schedule 1(8); Gannon and Villiers, above n 80, at 47.
[142] Gannon and Villiers, above n 80, at 47.

The United Kingdom Health and Safety at Work etc Act 1974 places a general health and safety duty on an employer.[143] Section 2(2) sets out specific requirements which are not directly related to genetic profiling but are relevant as they require the employer to take reasonable care to ensure that the systems of work and the articles that the employee comes into contact with are safe and do not create any risk to health.[144] The employer could argue that it is reasonably practicable to reduce the risk to health and safety by removing employees that are more susceptible to harm.[145] An employee dismissed may seek remedy for unfair dismissal under the Employment Rights Act 1996.[146] One of the grounds for dismissal is capability, which is assessed by reference to skill, health or any other physical or mental quality.[147] The health and safety obligations of an employer could therefore be used as a reason to exclude the employee who has an unfavorable genetic profile.[148]

An employer may be able to justify discrimination in certain circumstances, such as excluding job applicants with the sickle cell trait if the job involved being an air pilot, as there are the considerations of public safety and personal harm but it is unclear to what extent justifications would be seen as acceptable by the court or tribunal.[149] *Page v Freight Hire (Tank Haulage) Ltd* shows the combined application of the laws concerning discrimination and health and safety, in the context of the removal of a woman of child bearing age from a job considered dangerous due to a chemical, despite her statement that she did not want to have children and was willing to risk the exposure.[150] The Court held that the employer had acted in the interests of safety under s 2(2)(b) of the Health and Safety at Work Act 1974, emphasising the views of the employer rather than the employee, by denying the employee the right to choose where to work rather than requiring the employer to change work practices to accommodate the employee.[151]

It has been argued that the United Kingdom law is insufficient in its development with regard to workplace testing, with some existing rules on discrimination but none that are specific to genetics.[152] Both the Nuffield Council on Bioethics and the House of Commons Science and Technology Committee recommended that genetic profiles should only be used where there is strong evidence of a clear connection between the

[143] Section 2.
[144] Section 2(2).
[145] Gannon and Villiers, above n 80, at 43.
[146] Section 98.
[147] Sections 98(2)(a), 98(3)(a).
[148] Gannon and Villiers, above n 80, at 41, 44, 45.
[149] At 44.
[150] *Page v Freight Hire (Tank Haulage) Ltd* [1981] ICR 299.
[151] Gannon and Villiers, above n 80, at 46.
[152] At 40.

working environment and the disease that the test is seeking to detect.[153] It is also recommended that the tests should be limited to diseases that seriously endanger the health of the employee or present a serious risk to a third party and could not be eliminated by the employer taking reasonable measures to modify environmental risks.

There was support for legislative action by several advisory bodies in the United Kingdom, such as in the 2002 Report of the Human Genetics Commission (the former independent advisory body on social and ethical issues) which recommended that employers should be prohibited from requiring genetic profiling as a pre-requisite to employment.[154] The Commission noted that this should remain under review, in particular with relation to occupational health and safety issues.[155] A Joint Statement of Concern presented in 2006 to a House of Commons Cross Party Group from forty-six organisations and individuals called on the Government to legislate against the use of test results in employment and insurance. As a consequence, the use of genetic profiles by employers is now regulated by the Equality Act 2010, restricting questions that employers can ask in pre-employment medical checks. In practice, this means that employers can only ask for information that is directly relevant to the applicant's ability to carry out the work, or needed to make "reasonable adjustments" to the workplace to enable the employment of a particular person.[156]

3 Critique

The regulatory schemes in Australia and the United Kingdom have advantages and disadvantages but do allow the use of genetic profiling as it becomes more appropriate, in order to ensure health and safety obligations are met in the employment context. Both regimes are complex and ambiguous, involving many intersecting pieces of legislation. The "Essentially Yours" Report scrutinised the method of regulation in Australia and recommended a number of changes to improve the protection currently offered by the legislation surrounding anti-discrimination and occupational health and safety.[157]

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[153] At 52.
[154] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.39]; Human Genetics Commission *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002).
[155] Australian Law Commission and the National Health and Medical Research Council, above n 63, at at [30.39]; Human Genetics Commission, above n 154.
[156] GeneWatch "Genetic Testing in Insurance and Employment"<www.genewatch.org>.
[157] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.41].

The complete prohibition such as introduced by GINA in the United States may mean that employment use of genetic profiling is limited. The Australian Inquiry concluded that a complete prohibition on the use of genetic information in employment is not justified, as increased availability is likely to result in an opportunity for more balancing of the interests of employers, employees and the public.[158] The recommendations for amending the current regulation included the aforementioned changes to the DDA to ensure it is clear that an employer is prohibited from requesting genetic information from an applicant or an employee unless reasonably required for a legitimate purpose. Legal discrimination may arise in situations such as when necessary to ensure an employee is able to perform the "inherent requirements" of the job or in relation to occupational health and safety issues.[159] Allowing the use of genetic profiles to meet health and safety obligations could result in practices called "victim blaming," as it may allow an employer to avoid the alteration of the workplace or removal of dangerous substances, but rather choose not to employ a higher risk individual.[160] The "Essentially Yours" Report found that in the Health and Safety context, the genetic information should only be used in the limited circumstances that are subject to the oversight of the Human Genetics Commission of Australia.[161]

C Recommendations for New Zealand

Research has indicated that in other jurisdictions it is expected that employers will increasingly come under pressure from insurance companies (where employment is linked to health, life, or disability insurance) or compensation schemes (directly or through the cost of premiums) to use genetic profiles to screen employees.[162] New Zealand employment law and practices are not the same as in other countries, such as the United States and there is less intersection with the insurance issues. Different social practices and starting points may result in different sets of implications and may call for different policy responses.[163]

In New Zealand, there have been minimal regulatory responses to genetic profiling in the employment context. As outlined in Part III with respect to insurance, New Zealand needs to consider the effectiveness of the Human Rights Act 1993 (HRA) and the Bill of Rights Act 1990 (BORA) in preventing genetic discrimination in employment and whether legislative amendment is necessary to comply with

[158] At [30.52].
[159] At [30.53].
[160] Gannon and Villiers, above n 80, at 41.
[161] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [30.53].
[162] Goven, above n 93, at 6.
[163] At 6.

international obligations.[164] It is proposed (in Part III) that an amendment to clarify a "disability" is necessary. A distinction should be made between pre-symptomatic disabilities and the pre-disposition genetic conditions, which may depend on environmental conditions and lifestyle choices. Doubts have also been raised as to whether the HRA and health and safety legislation will provide adequate protection against discrimination in employment.

The relatively infrequent use of genetic profiling currently occurring in New Zealand, arguably does not justify enacting specific legislation. It is recommended that New Zealand implements an Advisory Body, similar to that recently set up in Australia, to consider an appropriate response in a New Zealand context and to supervise and advise policy governing the use of genetic profiling in the workplace. The Health and Safety (Pike River Implementation) Bill, introduced to Parliament in June 2013, will set up WorkSafe New Zealand as a new agency of health and safety (expected to be in place by December 2013).[165] WorkSafe New Zealand is able to establish Advisory Groups to provide a "forum for dialogue" and advice, representing the views of "Government, employers and employees" to WorkSafe New Zealand on health and safety as well as other matters relating to its functions.[166] It is therefore proposed that the establishment of an Advisory Body could come within this new structure.

Appropriate policy should include a requirement that employee autonomy be recognised as far as possible, by giving the option of whether to undergo genetic profiling or at least enable participation in any decisions made by being fully informed about the relevance of the condition in the employment context.[167] However the exercising of employee autonomy may be restricted due to the affect on third parties or the potential to result in a decision to accept dangerous work that is not in the best health interests of the employee.

It is also necessary to consider the stigma, particularly with respect to genetic information involving sensitive personal issues that may affect family members beyond the employment relationship.[168] Prior to the carrying out of genetic profiling the minimum expectation would need to be that the employer seek to alter work procedures in order to eliminate any possible risks linked to genetic diseases. Pre-test counselling would need to be given so that employees are provided with an explanation of any available scientific evidence of links between genetic conditions

[164] Human Rights Commission, above n 32, at ch 19.
[165] Health and Safety (Pike River Implementation) Bill 2013 (130-1), cl 5; Ministry of Business, Innovation and Employment "Health and Safety (Pike River Implementation) Bill" (28 June 2013) <www.mbie.govt.nz>.
[166] Health and Safety (Pike River Implementation) Bill, cl 8.
[167] Gannon and Villiers, above n 80, at 53.
[168] At 54.

and workplace practices. Independent testing facilities would be required to conduct the tests. Post-test counselling would be necessary with a full explanation of the results and their implications, including a range of options for the employee to consider should the tests reveal problems in the particular work place.[169]

The issues that have arisen in the employment context and an analysis of the different approaches that have been taken to address the concerns about discrimination have been presented in this section. The conclusion is that the current legislation is ambiguous and unclear due to the failure to adequately address the concerns raised for the future of genetic profiling in employment. Recommendations stop short of an overall legislative provision relating to all the issues raised but include amendments and a proposal that an Advisory Body be established by WorkSafe New Zealand, with a role in monitoring employment changes and providing advice on the issue of genetic profiling in the context of employment.

V Genetic Databases

Human tissue samples are stored in various places in New Zealand such as District Health Boards, pathology laboratories, universities, commercial enterprises, diagnostic laboratories and private research collections.[170] These samples can be used to perform genetic profiling and thus obtain information about the donor. That information is then stored in genetic databases (sometimes referred to as DNA Banks), which are used in both the public and the private sector for clinical, research and public health purposes (along with other nonrelated functions such as identification of the remains of soldiers, prosecution through DNA fingerprinting of suspects and paternity disputes).[171]

Concerns have been raised about the relatively uncontrolled access to genetic information. A common fear, addressed above, is that access to such information could potentially lead to discrimination by insurance companies and employers. However, it is also of concern to some people that parts of their "unique genetic makeup" may be used for purposes other than that for which the original consent was given.[172] In a New Zealand context, Maori and Pacific peoples may have specific interests in genetic information and the implications for whakapapa or genealogy.[173]

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[169] At 53.
[170] Henaghan and others, above n 62, at 224.
[171] Lawrence O Gostin "Genetic Privacy" (1995) *23 Journal of Law, Medicine and Ethics 320 at 322.*
[172] *Review of the Regulation of Human Tissue and Tissue-Based Therapies: Discussion Document* (Ministry of Health, 2004) at 58, 59, 60.
[173] At 58, 59, 60.

Public health and research communities would benefit from using existing tissue samples to create new genetic databases, such as seen in the United Kingdom Biobank. Between 2006 and 2010, the Biobank recruited 500 000 volunteers to provide samples and other medical information which was made available to public and private researchers providing that the research met scientific and ethical approval and was in the public interest.[174] The aim was to improve the health of the United Kingdom public by integrating findings into the health care system and encouraging and advancing research directed towards locating susceptibility genes for certain diseases.[175] Results are available in a database accessible to all researchers, pharmaceutical and other health based companies (where using it for an approved purpose) but not insurers or employers.[176] Relatives, police and lawyers cannot access the information unless compelled by the courts.[177] Although the information is anonymous, the confidentiality is contentious as genetic information is arguably in itself a personal identifier.[178]

Using previously stored samples derived from genetic profiling (or through other measures) is another method for providing samples to researchers. The problem identified in this situation is that, due to new and future technologies, the tissue may be used for purposes without the consent of the person who provided the sample.[179] The law and policy must balance the public interest in using these samples against the privacy and autonomy of the individual. There is a large public interest in researchers having the scientific freedom to access genetic information gathered from stored samples to improve health and prevent diseases. The public interest argument must be balanced against the reality that, due to inequalities in access to health care, those able to take advantage of the treatment and procedures resulting from the research may not be the same group that contributed. Other potential problems and controversial aspects of genetic databases that are relevant include the privacy and autonomy of individuals and public confidence that safeguards will protect any information that does arise from the testing of stored samples. Issues similar to those identified earlier in this paper, including discrimination in insurance and employment, along with stigmatisation as well as concerns about commercialisation.[180]

Although genetic databases have the possibility of being a useful tool for catching criminals, there is a danger of this being inconsistent with the presumption of innocence that exists in the criminal justice system, a risk of false accusations and

[174] UK Biobank "About UK Biobank" (2013) <www.ukbiobank.ac.uk>.
[175] UK Biobank, above n 174.
[176] UK Biobank, above n 174.
[177] UK Biobank, above n 174.
[178] UK Biobank, above n 174.
[179] Gostin, above n 171, at 246.
[180] Henaghan and others, above n 62, at 232.

possible intrusion into the privacy of relatives of suspects due to the familial nature of DNA.[181] Use of genetic databases for criminal purposes therefore requires strict quality control and assurance measures.[182] Given the scope of this paper, analysis is limited to the regulation of samples and information derived from genetic profiling of those samples, when being used for research.

A New Zealand Law

The Code of Health and Disability Services Consumers Rights 1996 (the Code), as it applies to health consumers and researchers, is of relevance in this context. Right 7(9) provides that a decision may be made about the return or disposal of a sample and Right 7(10) provides that no sample may be stored for use other than with the prior informed consent of the consumer or for the purposes of research approved by the Ethics Committee.[183] Therefore data can be used where there is no consent in some circumstances, in contrast to the former Code which required informed consent in all circumstances. This was introduced because it may be contrary to the public interest if too strict.[184]

The Code also interacts with an exception in the Health Information Privacy Code 1994 (HIPC), established under the Privacy Act 1993, which allows health information to be used without consent, if the information is to be used for research purposes.[185] Approval by an ethics committee may be required and publication is not permitted in a form that could reasonably be expected to identify the individual concerned. The Hazardous Substances and New Organisms Act 1996 amended the Health Act 1956, s 121 to allow regulations made under the Act to apply to both health information and specimens, defined as "a bodily sample or tissue sample taken from a person".[186] Given the complexity of the law, the Ministry of Health undertook consultation and a review, adopting the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes 2007, to support researchers. These guidelines require that consent to the collection of a sample must be distinct and separate from consent provided to the future unspecified use.[187]

The Human Tissue Act 1964 was reviewed by the Ministry of Health in 2005 and replaced by the Human Tissue Act 2008 after identifying a number of Act

[181] Molina, above n 10, at 14.
[182] Molina, above n 10, at 14.
[183] Code of Health and Disability Services Consumers Rights 1996, right 7.
[184] Henaghan and others, above n 62, at 254.
[185] Henaghan and others, above n 62, at 254.
[186] Privacy commissioner *Health Information Privacy Code 1994* (2008), at 18.
[187] Ministry of Health *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* (2007) at 5; Henaghan and others, above n 62, at 261.

shortcomings. Among others, this included the need to clarify obligations and procedures in relation to "historical tissue collections".[188] The former Human Tissue Act required the person lawfully in possession of the body to establish that there is no objection to the use of tissue from a deceased person.[189] The 2008 Act provides that consent is required to use human tissue collected from a living person for a "secondary purpose" after that person's death.[190] However, informed consent is not required where analysis has received Ethics Committee approval.[191]

Amendment to the HIPC was made in 2013 to improve "legal protections" around the bloodspot sample of newborn babies, collected as part of the National Newborn Metabolic Screening Programme.[192] The Privacy Commissioner has raised the concern that the development of DNA technologies means requests to use these samples as part of a national DNA database are a possibility.[193] The amendment therefore restricts how information derived from the samples can be used.[194]

The Operational Standard for Ethics Committees 2006 provides for the protection of the interests of the participants in research, safeguarding of the interests of Maori culture and promotion of awareness of the ethical principles and practices to the wider community.[195] Although the Operational Standard states that research may not proceed without obtaining consent from the individual, an exception is allowed where it is not practicable or where the Ethics Committees is satisfied that the potential public benefit outweighs the need to protect the right of an individual to consent.[196]

The use of samples without consent may happen in New Zealand where the safeguards are met. However the complex framework with interlocking provisions from statute and ethical guidelines has been identified as a problem. Calls have been made for data collections to fall under stricter regulation and overview, in particular, with regard to recognition of Maori and other cultural perspectives.[197]

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[188] *Review of the Regulation of Human Tissue and Tissue-Based Therapies: Discussion Document*, above n 172, at 36.
[189] At 36.
[190] Section 19
[191] Section 20.
[192] Privacy Commissioner "Privacy Commissioner Amends Health Code to Protect Newborn Bloody Samples" (press release, 20 March 2013).
[193] Privacy Commissioner, above n 192.
[194] Privacy Commissioner *Health Information Privacy Code 1994 Amendment* (2013), at [7], [8], [9].
[195] Ministry of Health *Operational Standard for Ethics Committees* (2006) at [10].
[196] At [36].
[197] Henaghan and others, above n 62, at 265.

B Comparative Approaches

The International Declaration on Human Genetic Data art 14 provides for the protection of privacy and confidentiality in relation to human genetic data.[198] This includes an obligation for researchers not to keep such data in a form that allows the research participant to be identified "for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed".[199] Additionally, human genetic data should not be disclosed or made accessible to third parties such as employers, insurance companies and relatives. An exception exists in limited circumstances if it is necessary for "an important public interest reason" provided for by domestic law consistent with the international law of human rights, or with the "prior, free, informed and express consent" of the persons concerned.[200] Article 17 provides that some "stored biological samples" may be used to produce human genetic data with the prior, free, informed and express consent of the person concerned.[201] This is subject to an exception for significant "medical, and scientific research purposes" which may be used for these purposes where there is ethics committee approval.[202]

The storage and use of samples and information held in DNA data bases in Australia is also regulated by a combination of legislation, guidelines and standards including the protection of health information in the Privacy Act 1988 (and other state and territory legislation), the Human Tissue Act, the Ethical Guidelines in the National Statement and the Human Genetics Society of Australasia (HGSC) Guidelines for Human DNA Banking. The Privacy Act protects an individual's personal information and the right to control how it is collected, used and disclosed.[203] The legislation extends to genetic information and is identified as an important element in regulating the operation of research databases.[204] The "Essentially Yours" Report in Australia, recommended that the Privacy Act be extended to cover genetic samples, rather than just the information derived from the samples.[205]

The various Australian Human Tissue Acts set out the consent procedure.[206] Tissue from a live donor requires verbal consent for specific use, whereas tissue of a deceased person may be used for other purposes providing that no objections were

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[198] *International Declaration on Human Genetic Data*, above n 14, art 14(c).
[199] Article 14(c).
[200] Article 14(b); Henaghan and others, above n 62, at 239.
[201] Article 17.
[202] Henaghan and others, above n 62, at 242.
[203] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [18.26].
[204] At [18.28].
[205] At [18.36], [18.37].
[206] At [18.41].

expressed during the person's lifetime and that the next of kin gives consent.[207] The National Health and Medical Research Council National Statement has general provisions which are relevant to the operation of databases. Researchers are required to ensure the confidentiality and privacy of stored information, research protocols must make clear whether the information is to be stored and in what form (coded or anonymous) and individuals should be informed about this intention.[208] Further, the National Statement generally requires consent to the use of human tissue samples, genetic material and genetic information in medical research.[209] The "Essentially Yours" Inquiry recommended an additional chapter to provide further ethical guidance on the operation of human genetic research databases, specifically with respect to consent for unspecified future research.[210] The Inquiry was of the view that this would provide a valuable ethical baseline against which the operation of human research genetic databases could be measured.[211]

The Guidelines for Human DNA Banking mainly address storage of DNA in the context of clinical health services but also state that researchers have obligations to the families involved in studies.[212] Guidelines recommend the establishment of a central directory of DNA Banks storing material for both clinical and research services, with the register to be maintained by one regional clinical service.[213]

C Recommendations for New Zealand

Genetic databases often include the samples as well as the information derived from them and both are used in close association to facilitate research. Under the current law, individual privacy rights cannot be asserted by the individuals who gave the samples.[214] It would be beneficial to incorporate an amendment in the HIPC, as in Australia, which currently covers any information given in association with, or derived from, body parts or bodily substances, but does provide protection for the actual tissue sample from which genetic information may be gathered.

The former Human Tissue Act required no objection to the use of tissue from a deceased person during their lifetime. This has been updated in the 2008 Act to reflect informed consent and as such is in line with recommendations in the Australian

[207] At [18.43].
[208] At [18.47].
[209] At [18.49].
[210] At [18.74].
[211] At [18.75].
[212] At [18.51].
[213] At [18.52].
[214] At [18.36], [18.37].

Inquiry.[215] The secondary principle is consistent with Right 7(10) of the Code because tissue with no informed consent can only be used with approval by an Ethics Committee. The Human Tissue Act does not regulate storage, use or transfer of samples as part of genetic databases.[216] The Australian Inquiry noted the option of the addition of new provisions to cover these gaps in the Australian Acts, but came to the conclusion that the law relating to genetic samples and information should be dealt with by building on health privacy legislation rather than under the Human Tissue Acts.[217] Although the recent updates to the Human Tissue Act in New Zealand have provided a more comprehensive piece of legislation, there are still similar gaps still to be addressed.

The Inquiry also investigated the idea of subjecting the human genetic research databases to a licensing or registration regime. A licensing regime would require all research databases to obtain a licence to operate, or the alternative "light touch" approach would be to implement a system of registration.[218] This approach would require the operators to report to the Australian Health Ethics Committee (AHEC) to gain approval for research being undertaken, with the AHEC responsible for ensuring compliance with the National Statement. Some researchers were concerned about the practical limitations of such a reform as it may be costly and ineffective due to the "fluid" nature of research and that documentation would require twice as many staff and impose an "unsupportable burden" on research.[219] The Inquiry was of the belief that genetic databases in a research setting were adequately regulated by the existing Human Research Ethics Committees but proposed that a registration system would provide "greater transparency and accountability" without subjecting the institutions to onerous compliance costs.[220]

Incorporation of a registration regime in New Zealand could be a useful step in providing accurate and comprehensive information to the proposed Advisory Body. An additional function could be to keep the public informed about the nature of research being undertaken and provide an assurance that privacy, legal and ethical standards are being met. This would be a means of safeguarding against the negative consequences of a lack of transparency such as a general fear or distrust within the public about using advancing technologies, which may in turn be detrimental to

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[215] *Review of the Regulation of Human Tissue and Tissue-Based Therapies: Discussion Document*, above n 172, at 40.
[216] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [18.44].
[217] At [18.45].
[218] At [18.79], [18.80].
[219] At [18.84].
[220] At [18.97].

public health, if it was to limit research resources vital to advancing biomedicine and genetic profiling.

VI Disclosure to Relatives

Disclosure of genetic information to relatives may prevent serious or imminent threat to their life or health resulting in the issue of defining the responsibility of health professionals with respect to the duty to inform relevant members of a patient's family. However this needs to be balanced against the autonomy, confidentiality and privacy of the individual that traditionally has been the starting point for regulating health information. This discussion is largely underpinned by consideration of genetic exceptionalism.[221] One argument is that genetic information is not sufficiently different to other medical information to justify the development of an alternative legal framework. The law protects confidentiality with exceptions for certain circumstances and further, where a patient poses a risk to another individual the courts have accepted that limited disclosures of confidential information may be justified in order to avoid that harm.[222] It could be argued that the existing law surrounding confidentiality already provides a framework for disclosure to be permitted if the health of another person is at risk. The absence of a specific statutory duty to warn the third party in New Zealand results in an uncertain legal position for a doctor who discloses genetic information to the relatives of a patient.[223]

The shared nature of genetic information, respect for the privacy of persons and confidentiality of personal information are recognised in key international instruments. The UDHGHR states that "the human genome underlies the fundamental unity of all members of the human family" and recognises it in a symbolic sense as the heritage of humanity.[224] The International Declaration on Human Genetic Data provides that genetic information has special status because it is predictive of predispositions, the nature of it is familial, it may have cultural significance and it may contain information that is not known or significant at the time when samples are collected.[225] Respect for the privacy of persons and the confidentiality of their personal information is recognised in the Universal Declaration on Bioethics and Human

[221] Explained above in pt II.
[222] Dean Bell and Belinda Bennett "Genetic Secrets and the Family" (2001) 9 MedLRev 130 at 158.
[223] Graeme T Laurie "Challenging Medical-Legal Norms: The Role of Autonomy, Confidentiality and Privacy in Protecting Individual and Familial Group Rights in Genetic Information" (2001) 22 JLegMed 1 at 26.
[224] *Universal Declaration on the Human Genome and Human Rights*, above n 12, art 1.
[225] *International Declaration on Human Genetic Data*, above n 14, art 4.

Rights, stating that such information should not be "used or disclosed for purposes other than those for which it was collected or consented to".[226]

The decision in the United States in *Tarasoff v Regents of the University of California* imposed a duty of a health professional to warn a third party where there was serious danger or violence.[227] Arguably this could be applied to a situation in which a health professional has an obligation to warn a family member of a patient about their risk of developing a disease.[228] The United States Courts have been divided on the application of this to the genetic context, with the Supreme Court of Florida finding that a duty of care was owed to the children of a patient treated for Medullary Thyroid Carcinoma in *Pate v Threlkel* but that the duty was satisfied by warning the patient of the risk to relatives.[229] The narrow approach to satisfying the duty of care was not adopted by the Superior Court of New York in *Safer v Pack*, which recognised that the duty to warn the plaintiff after treating the father for polyposis was separate to the relationship that the health professional has with the public and that the duty of care to the third party might override the patient's right to confidentiality.[230] In addition to those cases, the Supreme Court of Minnesota, in *Molloy v Meier*, has held that "a physician's duty regarding genetic testing and diagnosis extended beyond the patient, who was a minor with fragile X syndrome, to biological parents who foreseeably may be harmed by a breach of that duty."[231]

A New Zealand Law

The Health Information Privacy Code (HIPC) 1994 governs the collection, storage and access to health information. It is concerned with protecting the privacy of individuals and their personal information that is necessary with health care. The HIPC applies to health information, a subset of personal information. The HIPC defines health information as information about an identifiable individual, which includes information about an individual's health including medical history, disabilities and information provided by testing samples.[232] The HIPC also recognises that there is a public benefit in allowing access to some information for particular

[226] *Universal Declaration on Bioethics and Human Rights* 32 C/Res 24 (2005), art 9.
[227] *Tarasoff v Regents of University of California* 551 P 2d 334 (Cal 1976); Bell and Bennett, above n 22, at 135, 136.
[228] *Tarasoff v Regents of University of California*, above n 227; Bell and Bennett, above n 22, at 135, 136.
[229] *Pate v Threlkel* 661 So 2d 278 (Fla 1995); Bell and Bennett, above n 22, at 150, 151, 152.
[230] *Safer v Pack* 677 A 2d 1188 (NJ Super Ct App Div 1996); Bell and Bennett, above n 22, at 150, 151, 152.
[231] *Molloy v Meier* 679 NW 2d 711, 719 (2004); Richman Wee "Disclosure of Genetic Information to At-Risk Relatives: Privacy Law and Professional Guidance in New Zealand" (2011) 3 Journal of Primary Health Care 237 at 238.
[232] Privacy commissioner *Health Information Privacy Code 1994* (2008), at 5.

purposes and provides in r 10 that consent by an individual is not required for disclosure of health information if the health practitioner "believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the individual" and (until recently) "the disclosure of the information is necessary to prevent or lessen a serious and imminent threat to public safety or the life or health of the individual concerned or another individual."[233] In April 2013 the HIPC was amended in accordance with the Privacy Amendment Act 2013, removing the requirement of "and imminent," in order to make the decision on whether to disclose information easier.[234] Serious threat is defined in the Privacy Act 2013 as having regard to "the likelihood of the threat being realised," the "severity of the consequences" and "the time at which the threat may be realised."[235]

The New Zealand Medical Association Code of Ethics requires medical practitioners to "keep in confidence information derived from a patient" and this can only be breached where the law requires otherwise.[236] The limits to confidentiality between a doctor and patient, with regard to human immunodeficiency virus (HIV) patients, recognised by New Zealand Medical Association protocols, could arguably be extended to genetic diseases.[237] New Zealand case law on medical confidentiality determining whether a breach has occurred includes questions such as whether there was an imminent risk of harm to the third party.[238] The test developed by the courts requires that the risk be major (an immediate danger to the life of the third party) and that this belief must be fairly and reasonably held.[239] It is therefore possible that if a health professional disclosed genetic information about a relative of a patient, the public interest exception could be used as a defence.[240] Whether or not there is a legal duty to warn a third party in common law about a genetic disease is likely to depend on proximity and likelihood (*Anns* test*)*.[241] This may be covered by the Accident Compensation Scheme, avoiding civil proceedings against the health professional.[242] However, the complexity of the interaction with the ACC means that analysis is beyond the scope of this paper.

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[233] Privacy commissioner, above n 186, at 58, 59.
[234] Privacy Commissioner, above n 194, at [3].
[235] Section 2(1), definition of "serious threat."
[236] New Zealand Medical Association *Code of Ethics* (2008) at [14]; Michael Heron and Amy Jordan "Health Professionals and Mandatory Reporting" [2001] NZLJ 139 at 140.
[237] R J Patterson "Aids, HIV Testing and Medical Confidentiality" (1991) 7 Otago LR 379 at 379, 378.
[238] *Furniss v Fitchett* [1958] NZLR 396.
[239] *Duncan v Medical Practitioners* [1958] NZLR 396; Patterson, above n 237, at 394.
[240] Patterson, above n 237, at 395.
[241] *Anns v Merton London Borough Council* [1978] AC 728 (HL) at 758, 759.
[242] Patterson, above n 237, at 399, 403, 404.

The Privacy Commissioner conducted a review of the HIPC and concluded that disclosure to at-risk relatives can be made under the existing rule.[243] This means that the patient would have to be informed during pre test counselling that results may be disclosed to relatives.[244] Health professionals would be required to have a plan should disclosure be necessary and ensure intentions are made clear during informed consent discussions and pre test counselling.[245]

The Medical Council of New Zealand provides guidance for best practice, outlining the expectation that health professionals should treat all information as "confidential and sensitive", noting the exception to be found in r 10 of the HIPC.[246] The Council has also proposed ethical considerations to aid desirable and proper disclosure.[247] Further, health professionals should limit the information that is disclosed to only that which is necessary in the circumstances, keep comprehensive records and the involve colleagues in the making of decisions.[248] The HIPC does not impose a duty to contact the relatives at risk and disclose the information. The decision is discretionary and should be on the basis of whether it is a "matter of good practice for the health professional to first communicate his or her intention to do so to the patient" giving due consideration to the law and ethics involved.[249]

B Comparative Approaches

There are various approaches comparative approaches including enacting legislation, allowing the law to develop on a case by case basis as issues come before the courts or regulating by an express or implied contractual provision to the effect that the patient agrees to share genetic information with family members.[250]

A communitarian or medical model of genetic information was proposed by Guidelines in a Report of the Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria, endorsed by the Australia National Health and Medical Research Council in 1999. This proposes that genetic information needs to be treated separately from other kinds of medical information for the purpose of confidentiality because it is inherently familial in nature, setting aside the traditional presumption that the confidential status of that information be respected.[251] The Report notes a shift

[243] Richman Wee, above n 231, at 238, 239.
[244] At 239.
[245] At 239.
[246] Medical Council of New Zealand *Good Medical Practice* (2013) at [22].
[247] Richman Wee, above n 231, at 239.
[248] At 239.
[249] At 239.
[250] Bell and Bennett, above n 222, at 139.
[251] At 132, 133.

towards institutions looking after genetic information as the wider community representatives.[252] The Guidelines would allow non-consensual disclosure, although this should only occur following attempts to persuade the patient to voluntarily disclose information to their relatives.[253] This approach envisages a proactive role for doctors. The implications of this model would be that people would not have a right to control their genetic information or the use of tissue taken for genetic profiling and that health professionals would be expected to impart information contrary to the traditional obligation of maintaining patient confidentiality; a model based on community and familial obligations.[254]

Although a duty to warn has not been recognised by Australian courts to date, the 1999 case of *BT v Oei* in the NSW Australia Supreme Court held that a duty of care could be owed to a third party where they were at risk of contracting HIV.[255] However the duty could be discharged through the provision of appropriate advice to the patient (not to the third party directly) to get tested for HIV.[256] The Australian Law Reform Commission in 2003 recommended the amendment of the Privacy Act "to permit a health professional to disclose genetic information about his or her patient to a genetic relative of that patient where the disclosure is necessary to lessen or prevent a serious threat to an individual's life, health or safety, even where the threat is not imminent". This recommendation was put into effect in 2006, with amendments passed to make it discretionary, not obligatory, for health professionals to disclose genetic information to "genetic relatives". A genetic relative has been defined as "an individual who is related to the first individual by blood including, but not limited to, a sibling, a parent or a descendant of the first individual". The amendments provided for the National Health and Medical Research Council to develop guidelines to address circumstances where disclosure to genetic relatives is ethically justified or required, and the need for patients to be counselled about the disclosure of information. The guidelines came into effect from 15 December 2009, following approval by the Privacy Commissioner.

In Australia, the "Essentially Yours" Report recommended that s 6 of the Privacy Act 1988 (Cth) be amended to extend privacy protection to genetic samples as well as genetic information. However, the Report also found that the familial dimension of genetic information requires acknowledgment in the Privacy Act, as in the example that a doctor be authorised to disclose personal genetic information to a relative in

[252] At 135.
[253] At 135, 136.
[254] At 138, 139.
[255] *BT v Oei* [1999] NSWSC 1082.
[256] Bell and Bennett, above n 222, at 152, 153.

circumstances where disclosure is necessary to lessen or prevent a serious threat to an individual's life, health, or safety.[257]

In the United Kingdom, the Data Protection Act 1988 enables individuals to control or be aware of the use and content of personal data. This introduced the idea of "sensitive data" into United Kingdom law as data encompassing information pertaining to an individual's physical or medical health or condition and in sch 3, sets out the relevant conditions, including a requirement of explicit consent. However s 29 enables the Secretary of State to make an order to exempt and modify provisions in relation to personal data concerning physical or mental health and the disclosure of genetic information may fall within these exceptions.[258] The Nuffield Council on Bioethics in the United Kingdom found that the Data Protection Act 1998 which provides that holders of data have a positive obligation to inform the individuals concerned, required further clarification, possibly in the form of secondary legislation to ensure that the Act was not extended in this way.[259]

A legal model based on the patient's right to privacy and non discrimination is the opposite approach, which has been adopted in the United States in 2008 with GINA and was also present in the 1998 Genetic Privacy Non-Discrimination Bill which subsequently lapsed. This approach is based on autonomy and self-determination and would require the authorisation of the individual before families could be notified.[260]

C Recommendations for New Zealand

Health professionals in New Zealand can disclose a patient's genetic information to family members at any time providing that the patient has given consent. If the patient does not consent, the HIPC enables health professionals to make disclosures in limited circumstances. Consistent with *Tarasoff v Regents of the University of California*, the HIPC allows exceptions to the usually strong policy against disclosure in the case of a "serious and imminent threat" to the public or to a third party where the health professional is able to avoid that harm. It is unclear in New Zealand whether the threat of predispositions would fall under this exception. Future case law will help define the limits of the HIPC and the circumstances in which there will be a duty to warn patients and relatives of the risks associated with unfavourable genetic profile results.

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[257] Australian Law Commission and the National Health and Medical Research Council, above n 63, at [21.89].
[258] Gannon and Villiers, above n 80, at 50.
[259] Henaghan and others, above n 62, at 425.
[260] Bell and Bennett, above n 222, at 137, 138.

It is recommended that the HIPC be amended to specifically address genetic information including the clarification of circumstances in which genetic information should be disclosed to other family members. When balancing the public interest in disclosure against the public interest in maintaining confidentiality, considerations include the existence of a cure or treatment for the condition, the likelihood of harm to relatives and the degree of severity.[261] The courts in the United States decisions did not address a number of the factors which will likely be critical in the future, such as the accuracy of the test performed and the ability of the doctor to interpret the results. A balancing approach is advocated, incorporating into the proposed amendments to the HIPC in New Zealand. This includes balancing the severity of the disease, the availability of treatment, the reliability of the test, the ability of the health professional to interpret the issues relevant to the test and the protections provided against discrimination.[262] The Advisory Body could have a role in the development of policy, to assist the Privacy Commissioner in providing guidelines for health practitioners as to their duty in this complex area, with further review as the technology develops and the uses of genetic profiling expand.

VII Pharmacogenetics

Pharmacogenetic testing is the subset of genetic profiling that analyses drug response. It has arisen through the study of individual DNA variation, identifying variants at multiple gene loci affecting drug response. Developments in technologies, such as the Polymerase Chain Reaction to amplify DNA and the advances in whole genome sequencing techniques that led to the sequencing of the entire human genome in 2001 have been catalysts in the progress that has occurred in this area of genetic profiling.[263] It is envisaged that the potential benefits of pharmacogenetic testing are likely to lead to personalised medicine becoming a central component of health care.

Adverse reactions to medication are a significant health issue as evidenced by statistics from the United States suggesting over two million hospitalised patients from adverse drug reactions in one year.[264] The use of pharmacogenetics to reduce adverse reactions to drugs would be a positive step towards increased drug efficacy by enabling drug therapy to be based on personal genotype. This in turn is likely to reduce the time and cost of developing new drugs and also enable the New Zealand Pharmaceutical Management Agency (PHARMAC) to more efficiently subsidise

[261] At 155.
[262] At 156.
[263] Henaghan and others, above n 62, at 396.
[264] At 396.

drugs on the basis of their likelihood of working for that individual.[265] Given the advantages of pharmacogenetic testing and the likely increased role, it is very relevant, within the context of this paper, to consider the ethical, social, legal and policy implications that arise.

Although many of the considerations are similar to those for other uses made of genetic profiling, there is debate about whether similar safeguards should also apply to pharmacogenetics.[266] It is argued that unlike testing for the inheritance of disease associated genes, pharmacogenetic tests do not predict risk of disease and should therefore not be subject to the regulatory requirements that apply to genetic profiling for mutations associated with diseases as such standards could hinder the integration of pharmacogenetics into clinical practice.[267]

Alternatively, pharmacogenetic testing may affect a patient's outlook on life and as the information has the potential to be misused, there is a need to define professional protocols for informing the patient of the risks and benefits, obtain prior consent and provide assurance to the patient that adequate measures have been taken to ensure the privacy of the test results.[268] Failure to take these steps may affect acceptance and integration of pharmacogenetic testing into health practice.[269]

Where a pharmaceutical company is sponsoring a clinical drug trial, it is routine for the DNA samples to be retained, with an assurance that samples will be destroyed at the request of the participants.[270] The complex arrangements with third party corporate bio-banks and the fact that pharmaceutical company genetic databases are not subject to the same regulatory mechanisms as public genetic databases mean that there is no guarantee that samples are actually destroyed.[271] Another question arises as to whether voluntary consent to retaining samples is realistic, where non-consenting may restrict access to a new medicine.[272] The result is that the patient's autonomy to decide what happens with their tissue samples is compromised as they may be coerced in order to receive a potentially beneficial drug.[273] Privacy issues in relation to research data also arise but there are various levels of protection, including coding

[265] At 396.
[266] At 419.
[267] At 419.
[268] At 419, 420.
[269] At 419, 420.
[270] At 423.
[271] At 423.
[272] At 424.
[273] At 423.

and anonymised samples that could be legislated for, to ensure privacy of the participating individuals.[274]

Pharmaceutical tests have less relevance to family members as they predict responses to medicines as opposed to disease susceptibility, as stated earlier. The emerging issue of ancillary information recovered by these tests may challenge this view and raise similar issues with disclosure.[275] The likelihood that pharmacogenetic information would reveal serious or imminent health consequences for family members, although small compared to other types of genetic information, is still possible as ancillary health information in the future and that means there may be cases where the Advisory Body is invoked in relation to pharmacogenetic testing.[276]

Issues around stigmitisation are also relevant, including the labelling of responders and non-responders, with financial consequences and the potential to result in insurance and employment discrimination.[277] There are concerns that stratification of the population according to disease and drug response genotypes will lead to inequities in drug development efforts and resource allocation.[278]

It is unclear whether pharmacogenetics will increase or decrease the cost for medicines. Although it may enable medicines to be developed more quickly at less cost and regulatory approval could be granted sooner, fragmentation of the market may lead to reduced profits for pharmaceutical companies, driving up the costs of medicines.[279] Another issue is that pharmacogenetic data may influence the resource allocation of PHARMAC in New Zealand, in that cost effectiveness analysis may favour treatment for a group with a higher chance of responding to a medicine.[280]

A number of statutory and non-statutory mechanisms have been identified by which genetic profiling in general can be regulated, including changes to the HRA, the role of the Insurance and Saving Ombudsman and the development of policies to assist employers and health practitioners in making decisions. These considerations are equally relevant in the context of pharmacogenetic testing and it is recommended that the proposed Advisory Body be involved.

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[274] At 424.
[275] At 425.
[276] At 425.
[277] At 426.
[278] At 432.
[279] At 433.
[280] At 433.

VIII Embracing the Challenges

New Zealand currently relies on an assortment of related legislation, regulations, ethical guidelines and policies to govern genetic profiling, with a number of aspects lacking in clarity. Analysis of the current legislation results in the conclusion that it is not illegal to discriminate on the basis of genetic information. This is seen as inadequate, suggesting that the law is lagging behind the rapid advances associated with genetic profiling technology. The potential benefits for new technologies to support significant improvements to public health may be limited by public confidence in the safeguards provided by the current regulatory framework. There are many ambiguities for individuals accessing genetic profiling technology, such as through employment, insurance or other privacy implications, that may lead to undesirable implications for people.

In seeking an appropriate legal response to advances in genetic profiling technology, it is essential that laws are informed by ethical debate and reflect as largely as possible common New Zealand societal values.[281] The major challenge is to find an approach that meets the dual requirement of encouraging innovative research in the field of genetics along with practice that best meets public needs and creating a legal framework that supports an environment of trust and confidence within acceptable ethical boundaries, for the use of all technologies.

The development of an Advisory Body to oversee the implications of the use of genetic profiling, as discussed throughout this paper, is seen an alternative to implementing an overarching piece of legislation governing all of these areas. This would enhance public confidence by increasing the awareness of all stakeholders (including patients, employers, employees, the insurance industry and researchers) with regard to the legal and ethical obligations.

Other changes have been recommended to deal with specific gaps that have been identified by this paper. A range of safeguards and improved policies are recommended for the use of genetic information by the insurance industry. This should be aimed at ensuring that genetic information is used in a scientifically reliable and acceptable manner. The ISO, with the assistance of the Advisory Body, should be responsible for ensuring procedures are fair and justified, supported by an appropriate and accessible system for complaints, along with undertaking a role of providing education and training to the industry.

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[281] Laurie, above n 223, at 2.

Employers should only gather and use genetic information in exceptional circumstances, for example, where this is necessary to protect the health and safety of workers or a third party, and the action should comply with the stringent standards developed by the proposed Advisory Body. This paper has recommended changes to legislation in order to close the current gaps, including an amendment to the disability definition in relation to discrimination in employment and insurance, and also an amendment to the HIPC to address the particular challenges of human genetic information. This should include acknowledgment of the familial nature of genetic information, as in the example of a health professional being authorised to disclose personal genetic information to a genetic relative in circumstances where disclosure is necessary to lessen or prevent a serious threat to an individual's life, health, or safety. In order to assist an effective nation-wide approach to sharing DNA information, it is recommended that the New Zealand Government develop a registration system with respect to the collection, use, storage and destruction of DNA (including the genetic profiles created from the DNA).

The main recommendation of this paper is the establishment of an independent body similar to the Human Genetics Commission of Australia, in order to provide advice to the Government as the use of genetic profiling technologies increases in New Zealand and to help develop policies which would assist relevant industries such as those involved in employment, insurance and research. Such an Advisory Body could also have an educative role to promote community awareness in response to emerging issues.

IX Conclusion

The increased use and availability is likely to impact on the range and complexity of the issues surrounding genetic profiling. This paper has identified areas where concerns are likely to arise and has attempted to address those with a number of key recommendations. The emphasis is on the need to support access and encourage the use of genetic profiling technologies to help improve public health in New Zealand and to promote ongoing research and advancement of such technologies. This can only be made possible by ensuring that the public can have confidence that safeguards will adequately protect from the unwanted consequences of possible misinterpretation or misuse of genetic information.

The paper concludes that the option of a comprehensive piece of legislation combining the issues that arise from genetic profiling such as discrimination in insurance, implications for employment, unacceptable use of genetic databases and the duty to disclose information to relatives, under the same umbrella, cannot be

justified at this time. The introduction of an Advisory Body is proposed to monitor the positions being taken by other jurisdictions and to consider the appropriateness in a New Zealand context.

The current moratorium in the insurance industry may be seen to provide sufficient safeguards against the risks of stigmatisation but could result in a disincentive as it may prevent people taking advantage of the technology available, due to such possibilities as higher premiums or ineligibility for insurance. Allowing insurance companies to request genetic profiling under current human rights legislation (by including genetic discrimination as a prohibited ground), expanding the role of the ISO and the introduction of the Advisory Body to monitor discrimination, may resolve some of the complex and controversial issues.

The ambiguities of the law safeguarding discrimination in employment have been discussed, with recommendations made to clarify the position of the HRA with respect to genetic information, including an Advisory Body role in the development of policies. Employers should continue to be required to alter work place practice in order to provide a safer environment, where possible. The policies should emphasise employee autonomy and the familial implications of genetic profiling as far as possible, while allowing for restrictions where third parties, such as other employees, are affected. Employers should also be responsible for providing relevant genetic counselling for an employee.

Genetic databases should be subject to a registration regime that is under the authority of the Advisory Body, to enable comprehensive information to be gathered. Under this proposal, the Advisory Body would be responsible for using this information to monitor and ensure that all legal and ethical standards are maintained, as well as having a role in informing the public about procedures being followed in current research. This would be a useful way of encouraging increased use of genetic profiling technology and further research, as it would safeguard against possible public fears surrounding the misuse of genetic information.

The duty of health professionals to inform the relatives of a patient of an unfavourable genetic profile is unclear in New Zealand. Although the HIPC enables disclosure in cases of serious and imminent threat to a third party, the nature of genetic information means that the risk factor will often be unclear. It is therefore recommended that the HIPC be amended to clarify the appropriate circumstances for revealing genetic information to relatives, weighing the seriousness of the disease and the availability of treatment against conflicting issues, such as the protection against discrimination and the public expectation that health professionals maintain confidential relationships.

The proposed Advisory Body could assist the Privacy Commissioner in both developing and reviewing policy, as the uses of genetic profiling technology become more wide ranging.

Genetic profiling and pharmacogenetic testing are significant recent advances that have the potential to change the nature of health care in New Zealand. It is important that the public are engaged and aware of implications for individuals and their relatives that may arise from the use of this technology in the context of insurance, employment and research, along with other issues not yet considered. The introduction of an Advisory Body is one way of monitoring compliance with the law. The Advisory Body could have a role in developing policies to assist with the complex issues, thus providing adequate assurance for individuals that they will not be disadvantaged when using genetic profiling technology.

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