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“EVERY MAN BEARS THE WHOLE STAMP OF THE HUMAN CONDITION”:
HOW DOES HEALTH INFORMATION PRIVACY LAW RESPOND TO THE SHARED NATURE OF GENETIC INFORMATION?

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A thesis submitted for the degree of
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at the
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ABSTRACT

This thesis examines the tensions that arise between the rights and interests of individuals and their genetic relatives as a result of the familial nature of genetic information.

The first tension exists between an individual’s interest in maintaining privacy and confidentiality in relation to his or her genetic information, and a relative’s interests in being informed of his or her potential risk of developing a condition that he or she was otherwise unaware of (that is, the right to know). The second tension exits between an individual’s interest in sharing his or her genetic information with relatives, and his or her relatives’ interest in remaining ignorant as to their genetic status (that is, the right not to know).

In examining these tensions, this thesis examines whether the rights and interests of both individuals and their genetic relatives are adequately recognised and protected under New Zealand’s existing health information privacy law. In doing so, it explores the scientific nature of genetic information, potential legal and ethical approaches to such information, and how existing law “fits” the familial nature of genetic information. It then examines approaches taken overseas in relation to the competing interests at stake and, against that backdrop, assesses the Privacy Commissioner’s proposal for reform. Finally it recommends a course of action for amending New Zealand’s health information privacy law, proposing to dispel the tensions identified above.
ACKNOWLEDGEMENTS

Writing a thesis involves a lot of focus, motivation, time and energy. For me, this would not have been possible without:

(a) The support of Ryan Duff and my family.

(b) The enthusiasm and encouragement of my supervisor Mark Henaghan, and the additional help and guidance provided by Paul Roth.

(c) The wonderful company of the “Wellington core” (you know who you are), who kept me entertained during my final months of writing.

Thank you all.
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LIST OF ABBREVIATIONS

AHEC  Australian Health Ethics Committee
ALRC  Australian Law Reform Commission
AMA Code of Ethics  Australian Medical Association Code of Ethics
BMA  British Medical Association
Code of Ethics  The New Zealand Medical Association Code of Ethics
Code of Practice  Confidentiality: NHS Code of Practice (United Kingdom)
Convention on Human Rights and Biomedicine and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No.164) (Council of Europe)
Data Protection Convention  Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1981
Data Protection Directive  Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
Director  Director of Human Rights Proceedings
Draft Protocol  Draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (Council of Europe Steering Committee on Bioethics)
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<tr>
<th>Term</th>
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<tr>
<td>Draft Explanatory Report</td>
<td>Draft Explanatory Report to the draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (Council of Europe Steering Committee on Bioethics)</td>
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<td>DOE</td>
<td>US Department of Energy</td>
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<td>DH</td>
<td>Department of Health (United Kingdom)</td>
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<td>ELSI</td>
<td>Ethical, Legal, and Social Implications of Human Genome Research</td>
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<td>ELSI Working Group</td>
<td>NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research</td>
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<td>EU</td>
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<td>EU Commission</td>
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<td>EU Council</td>
<td>Council of the European Union</td>
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<td>EU Parliament</td>
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<td>EU Treaty</td>
<td>Draft Reform Treaty (a Treaty intended to consolidate the existing European treaties in a single text) (European Union)</td>
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<td>FAP</td>
<td>Familial Adenomatous Polyposis</td>
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<td>GMC</td>
<td>General Medical Council (United Kingdom)</td>
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<td>HD</td>
<td>Huntington’s Disease</td>
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<td>HDSCR Code</td>
<td>Code of Health and Disability Services Consumers’ Rights</td>
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<td>HGC</td>
<td>Human Genetics Commission (United Kingdom)</td>
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<td>HGP</td>
<td>Human Genome Project</td>
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<td>HIPC</td>
<td>Health Information Privacy Code 1994</td>
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<td>HIPC Amendment</td>
<td>Proposed Amendment No 6 to the Health Information Privacy Code 1994</td>
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<td>HUGO</td>
<td>The Human Genome Organization</td>
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<td>ICO Guideline</td>
<td>The Information Commissioner’s Office guidance on the application of the Data Protection Act 1998 in relation to the use and disclosure of health information (United Kingdom)</td>
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<td>IPPs</td>
<td>Information Privacy Principles set out in the Privacy Act 1988 (Cth) (Australia)</td>
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<td>IPRC Act</td>
<td>Injury Prevention and Rehabilitation and Compensation Act 2001</td>
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<td>mRNA</td>
<td>Messenger RNA</td>
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<td>NHGRI</td>
<td>National Human Genome Research Institute</td>
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<td>NIH</td>
<td>National Institute of Health</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council (Australia)</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NPPs</td>
<td>National Privacy Principles set out in the Privacy Act 1988 (Cth) (Australia)</td>
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<td>NZMA</td>
<td>New Zealand Medical Association</td>
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<td>NZORD</td>
<td>New Zealand Organisation for Rare Disorders</td>
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<td>OECD</td>
<td>Organisation of Economic Co-operation and Development</td>
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OECD Molecular Genetic Testing Recommendation

The Recommendation of the Council on Quality Assurance in Molecular Genetic Testing

OECD Privacy Recommendation

The Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data (OECD)

OIA

Official Information Act 1982

Opinion


Recommendation on Genetic Testing

Recommendation No. R (92) 3 on Genetic Testing and Screening for Health Care Purposes (Council of Europe)

Royal College

Royal New Zealand College of General Practitioners

Steering Committee

Council of Europe Steering Committee on Bioethics

Tribunal

New Zealand Medical Practitioners Disciplinary Tribunal (now the Health Practitioners Disciplinary Tribunal)

UNESCO

United Nations Education, Scientific and Cultural Organisation

WHO

World Health Organization

WHO Report

Genomics and World Health – Report of the Advisory Committee on Health Research (WHO)

Working Document

The Working Document on Genetic Data (European Union: Working Party on Data Protection)
CHAPTER 1
INTRODUCTION

A Melbourne newspaper reports that a man in his early 20s faces a 50:50 prospect of survival after developing a hereditary form of cancer. His parents knew of the family’s history of the disease but did not tell their son. His cancer could have been prevented or cured if the genetic condition which caused the cancer was diagnosed early enough.¹

This story highlights a significant issue for New Zealand’s health information privacy law, and in particular how it responds to the developments in genetic science that enable doctors to collect medical information that has implications not only for the patient but also for that patient’s relatives.

The familial nature of genetic information creates tensions between the rights and interests of individuals and their genetic relatives. The first tension exists between an individual’s interest in maintaining privacy and confidentiality in relation to his or her genetic information, and a relative’s interests in being informed of his or her potential risk of developing a condition that he or she was otherwise unaware of (ie the right to know). The second tension exists between an individual’s interest in sharing his or her genetic information with relatives, and his or her relatives’ interest in remaining ignorant as to their genetic status (ie the right not to know).

These tensions in turn translate into potential conflicts between a health practitioner’s duty to respect a patient’s privacy and confidentiality, and his or her potential duty to recognise the patient’s relatives’ right to know (or right not to know) genetic information.

This thesis examines whether the rights and interests of both individuals and their genetic relatives are adequately recognised and protected under New Zealand’s existing health information privacy law. In doing so, it explores the scientific nature of genetic information, potential legal and ethical approaches to such information, and how existing law “fits” the familial nature of genetic information. It goes on to examine approaches taken overseas in relation to the competing interests at stake and, against that backdrop, assesses the Privacy Commissioner’s proposal for reform. Finally it recommends a course of action for amending
New Zealand’s health information privacy law, proposing to iron out the tensions identified above. A brief summary of each chapter is set out below.

Chapter two provides a brief overview of the development of, and a basic primer on, genetic science. It also discusses the Ethical Legal and Social Issues Programme that was established as part of the Human Genome Project. The purpose of chapter two is to provide a contextual background for the legal issues that arise as a result of the familial nature of genetic information.

Chapter three explores the nature of genetic information, and in particular how DNA contributes to disease, what causes genetic disease, how genes are shared within a family, and the informational impact that genetic information has for individuals and their genetic relatives. This provides a basis for understanding why competing interests in relation to genetic information arise between individuals and family members.

Chapter four discusses how genetic information should be treated from a legal and ethical perspective. In particular, it:

(a) Explores whether genetic information is so fundamentally different from other health information that it requires special (or at least separate) legal protection.

(b) Explores why competing interests in genetic information pose a challenge under existing health information privacy law.

(c) Examines four ethical models for dealing with the competing interests in genetic information, which are placed on a continuum which ranges from being overly individualistic (ie never allowing a health practitioner to disclose a patient’s genetic information to that patient’s genetic relatives) to overly paternalistic (ie always requiring a health practitioner to disclose a patient’s genetic information to all potentially affected family members, regardless of the informational impact of that genetic information).

The purpose of chapter four is to establish an appropriate framework in relation to dealing with the competing interests at stake, against which to compare New Zealand’s existing health information privacy law.

1 Noble, T. “Let us warn patients of cancer mutation, say doctors” The Age. (Melbourne, 6 August 2002), Health.
Having identified the relevant tensions that the familial nature of genetic information creates in chapter three, and discussing the cause of those tensions and considering different ethical and legal approaches to dealing with genetic information in chapter four, chapter five goes on to:

(a) Examine the concepts of privacy and confidentiality, and the ethical principles underlying each.

(b) Examine: (i) how New Zealand’s existing health information privacy law applies to personal genetic information, especially in relation to the competing interests between individuals and relatives; and (ii) whether or not it achieves an appropriate balance between the two.

(c) Demonstrate the individualistic nature of New Zealand’s health information privacy law by applying it to four hypothetical clinical scenarios.

(d) Conclude that New Zealand’s health information privacy law requires reform on the basis that it fails: (i) achieve an appropriate balance between an individual’s right to privacy and his or her genetic relatives’ interest in knowing such information; and (ii) acknowledge the genetic relatives’ right not to know (though it does indirectly uphold that right by default, in light of the issue raised in (i)).

In order to assess potential options for reform, chapter six examines the legal approaches taken in Australia, England, Europe (at an inter-governmental level) and other intergovernmental organisations, in dealing with the familial nature of genetic information.

Finally, chapter seven examines the Privacy Commissioner’s proposal to amend the Health Information Privacy Code 1994 in light of the changing nature of medical treatment brought about by the familial nature of genetic information. Chapter seven also discusses the submissions made to the Privacy Commissioner by relevant New Zealand stakeholders in relation to the proposed amendments.

Building on the analysis in chapters four and five, and drawing on the approaches to taken overseas to dealing with genetic information, chapter seven goes on to propose amendments to New Zealand’s health information privacy regime in general, so that it:

(a) acknowledges the issues that genetic information (and some traditional health information) creates for health information privacy protection;
(b) adequately recognises the interests of both individuals and their genetic relatives;

(b) can easily be developed to accommodate advancements in genetic science and the medical treatment of genetic disease.
CHAPTER 2

THE DEVELOPMENT OF GENETIC SCIENCE.

1. INTRODUCTION

Unravelling the mysteries of the biological dimension of human life and obtaining the knowledge and power to control and fine-tune human existence brings with it an awesome responsibility. With the recent completion of the Human Genome Project, acknowledging this responsibility has never been more important.

In this chapter I provide:

(a) An overview of the development of genetic science, providing a contextual background to the legal and ethical issues raised by the "new genetics". The Human Genome Project is represented as the major phase of development in the development of genetic science, and is discussed accordingly.

(b) A basic primer on genetics alongside each stage of development, systematically describing the advances in genetic science as they arose.

(c) A preliminary overview of the medical consequences of the completed Human Genome Project in order to identify the basis of genetic disease (and in particular inheritance patterns) that raise issues from a legal and ethical perspective (in particular, in relation to the confidentiality and privacy of genetic information).²

(d) A discussion about the "Ethical, Legal, and Social Issues Program" that was established as part of the Human Genome Project, focusing specifically on issues identified under that programme that have relevance to an individual’s interest in not disclosing his or her genetic information, and genetic relatives’ interests in knowing such information.

² Note, the medical consequences of the Human Genome Project relevant to this thesis are discussed extensively in Chapter 3.
2. **IN THE BEGINNING: THE DEVELOPMENT OF MODERN GENETICS**

2.1. **Mendel’s pea plants and the genetic basis of heredity**

Gregor Mendel, a Monk in and Augustinian monastery in the city of Brunn (in what is today the Czech Republic), seems an unlikely contender to have laid the foundations for modern genetics. However, it was he who spent eight years experimenting with tens of thousands of pea plants and in 1866 arrived at a set of principles explaining how inherited traits are transmitted during sexual reproduction. Mendel discovered that visible inherited traits are manifestations of discrete, though invisible, units of heredity. The significance of Mendel's laws of heredity was not recognized until they were rediscovered early in the 20th century, when they triggered the scientific pursuit to understand the nature and content of genetic information. A Danish botanist, Wilhelm Johannsen, named these units of heredity *genes*, and the entire complement of genes in an organism *genome*.

2.2. **Establishing the cellular and molecular basis of heredity**

Scientific progress in the first quarter of the 20th century saw the discovery of the cellular basis of heredity, that is, the chromosomes. With this discovery, the following features of genetic science were established:

(a) In human beings chromosomes are arranged into 23 pairs.

(b) One chromosome in each pair is derived from the mother, and the other from the father.

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4 Above, n3.


7 Above, n5.

8 A set of 23 chromosomes contains 22 numbered chromosomes (1-22) (known as autosomes) plus either an X or Y sex-determining chromosome. Females receive an X chromosome from each parent, while males receive an X and a Y chromosome (from the mother and father respectively): see Australian Law Reform Commission and Australian Health Ethics Committee. *Essentially Yours: The Protection of Human Genetic Information in Australia - Report 96* (Australian Law Reform Commission, Sydney, 2003), 111.
(c) The genome (the full complement of our genes) is distributed among the chromosomes, and the genes are arranged from end to end, with each gene having a particular location.9

(d) Every gene consists of the inherited material known as DNA (deoxyribonucleic acid) which contains instructions for the production of one or more specific proteins.

(e) Proteins are critical components of all cells determining colour, shape and function. When genes are activated within a cell, the protein coded for by the DNA in that particular gene is produced. Thus, different proteins are produced which have different structures, appearances and functions depending on which genes are activated in various cells, giving particular cell types their unique character (for example, brain cells, nerve cells, blood cells, bone cells etc).10

(f) Every human cell contains the same DNA. DNA occurs in long chains composed of repeating nucleotides. Nucleotides are often referred to as the 'building blocks' of DNA.11 A nucleotide consists of a simple sugar (deoxyribose), a phosphate group, and one of four nitrogenous bases (adenine (A), thymine (T), guanine (G) and cytosine (C)). A DNA molecule is composed of two nucleotide chains that are twisted together into an entwined spiral (the famous double helix), held together by weak bonds between complementary bases: adenine (A) in one strand to thymine (T) in the other, and cytosine (C) in one strand to guanine (G) in the other. Each of these linkages constitutes a base pair. (Note, the human genome is made up of approximately 3 billion base pairs.12) It is the unique sequence of these bases within each gene that represents the 'genetic code', which varies slightly from person to person (with the exception of identical twins).13

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9 Above, n8: 112.
10 Above, n8: 113.
11 Above, n8: 111.
13 Any two human beings are 99.9% identical. This explains both the similarities and differences among all people. This feature of the genetic make-up of human beings is especially relevant when examining the causes of genetic disease (which will be discussed in depth in Chapter 3). Above, n8: 115.
Armed with this information, Francis Crick and James Watson published a landmark paper in 1953 describing DNA as a double helix. In doing so, they defined the molecular basis of heredity.

2.3. The informational basis of heredity

Advancement in the understanding of genetics continued throughout the century. The informational basis of heredity was established with:

(a) The discovery of the biological mechanism by which cells 'read' the information contained in genes. Cells read the information contained in genes by the following process:

(i) First, the information from a gene is copied, base-by-base, from DNA into new strands of messenger RNA (mRNA). This process is called "transcription".

(ii) Secondly, the mRNA travels out of the nucleus, into the cytoplasm of the cell, and directs the assembly of amino acids in the particular order coded for by the mRNA. This process is called "translation".

(iii) Finally, when the whole message has been translated, the long chain of amino acids folds into a completed protein molecule.

(b) The invention of the recombinant DNA technologies of cloning and sequencing. Recombinant DNA technology is the procedure used to join together segments of DNA in an environment outside of a cell or organism. Under appropriate conditions, a recombinant DNA molecule (a combination of DNA molecules of different origin that are joined using recombinant DNA technologies) can enter a cell and replicate.

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14 Above, n3: 137.

15 Above, n5.


These developments meant that scientists too could “read” the information contained in genes. That is, it became possible for scientists to take pieces of DNA, clone them in large quantities, map, and locate different genes using DNA variations as markers on the human genome. Once a gene was identified and located, the gene could be sequenced, leading to an understanding of the nature of the protein that it codes for, and the ability to identify any disease related mutations.

In the last quarter of the 20th century there was a persistent drive to decipher first genes, and then complete genomes. These developments brought about the goal of sequencing the entire human genome.

3. THE HUMAN GENOME PROJECT

3.1. What is the Human Genome Project?

The Human Genome Project (“HGP”) was completed in April 2003. It has been described as "biology's mega project" and a project of "unparalleled scientific achievement", and compared with the accomplishment of landing human beings on the moon. The wealth of knowledge gained from the HGP (especially for biology and medicine) is manifold, profound and of immense proportion. Scientists propose that the application of such knowledge will, in time, materially benefit almost everyone in the world.

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18 Above, n5.


20 Above, n5.


The ultimate goal of the HGP was to generate a high-quality reference DNA sequence for the human genome's 3 billion base pairs, and to identify all human genes.

DNA underlies almost every aspect of human health, both in function and dysfunction. Thus, obtaining a DNA sequence provides the information needed to locate defective genes as well as predispositions to a number of pathologies. Such knowledge has had, and will continue to have, a profound impact on the way disorders are diagnosed, treated, and prevented, and promises to bring about revolutionary changes in clinical and public health practice. Scientists proposed that the information generated by the HGP will be the reference work of biomedical science for the 21st century.

3.2. How the Human Genome Project came about

The idea of sequencing the entire human genome was first put forward in 1985 during discussions at scientific meetings organised by the US Department of Energy ("DOE.")

Note: DNA sequencing is the process of determining the exact order of the 3 billion chemical building blocks (called bases and abbreviated A, T, C, and G) that make up the DNA of the 24 different human chromosomes in order to reveal the estimated 30,000 to 35,000 human genes within our DNA. The draft sequence (which was released in June 2000) involved determining the order of the base pairs in each chromosomal area at least 4 to 5 times to ensure data accuracy. The high-quality reference sequence (completed in April, 2003) involved additional sequencing with an estimated 8 to 9 times coverage of each chromosome area in order to close gaps, reduce ambiguities, and to virtually eradicate all errors (the standard for the HGP allowed for only a single error every 10000 bases). Obtaining the high-quality reference sequence is very important to understand, for example, the genetic basis for disorders such as heart disease, cancer and diabetes. See Human Genome Project Information: Facts about Genome Sequencing. Online. Accessed 5 May 2004. Available from Oak Ridge National Laboratory website (managed by UT Battelle for the U.S. Department of Energy). http://www.ornl.gov/sci/techresources/Human_Genome/faq/seqfacts.shtml#whatis.


It is important to note that both environmental and genetic factors have roles in the development of any disease. Genetic disorders may arise from changes or mutations that occur in the DNA sequence of one gene (single gene disorders), a combination of environmental factors and mutations in multiple genes (multifactorial disorders) (most common), abnormalities in chromosome structure as missing or extra copies or gross breaks and joinings (translocations) in the chromosome, or mutations in the nonchromosomal DNA of mitochondria (rare). See Human Genome Project Information: Genetic Disease Information. Online. Accessed 10 May 2004. Available from Oak Ridge National Laboratory website (managed by UT Battelle for the U.S. Department of Energy). http://www.ornl.gov/sci/techresources/Human_Genome/medicine/assist.shtml.

Above, n26.


Above n5: 862.
Initially the idea was met with much scepticism due to the enormous size of the human genome (about 3 billion base pairs in 24 types of chromosomes) and the huge anticipated cost. However, in 1986 the human genome initiative was approved and pilot projects were implemented.

In 1988, a committee appointed by the United States National Research Council endorsed the concept of the human genome initiative, but recommended an increase in the breadth of the program so that it included:

(a) the creation of genetic, physical and sequence maps of the human genome;

(b) parallel efforts in key model organisms (for example, bacteria, yeast, worms, fruit flies and mice); the development of technology to support such objectives; and (most importantly in the context of this thesis)

(c) research into the ethical, legal, and social issues raised by the human genome research.32

In 1989 the National Institute of Health (NIH)33 and the DOE agreed to collaborate on what became known as the HGP. Later that year, a memorandum was signed on how the NIH and DOE would cooperate on genome research,35 and in 1990, they presented Congress with a 5-year plan as the first phase of their 15-year project. 1 October 1990 was named as the official starting date of the HGP.37

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31 Above, n3: 137. Note, it was initially estimated that it would cost $1 for every nucleotide base that was sequenced. This cost eventually reduced to below $0.50 per nucleotide base with the development of new technology. The human genome contains approximately 3 billion chemical nucleotide bases. Above, n26.

32 Above, n5: 862.

33 Note, the National Human Genome Research Institute began as the National Centre for Human Genome Research, which was established in 1989 to carry out the role of the NIH in the HGP. In 1997 the United States Department of Health and Human Services renamed the National Centre for Human Genome Research the National Human Genome Research Institute, officially elevating it to the status of research institute - one of 27 institutes and centres that make up the NIH. See The National Human Genome Research Institute: a Brief History and Timeline, National Human Online. Accessed 5 May 2004. Available from the Genome Research Institute website. http://www.genome.gov/10001763.

34 Above, n3: 138.


36 Above, n3: 138.

37 Above, n3: 138.
3.3. International participation in the Human Genome Project

International participation in the HGP began early on, with a number of organizations in other countries supporting the project. In particular:

(a) the United Kingdom Medical Research Council and the Wellcome Trust supported Genomic Research in Britain;

(b) the Centre d'Etude du Polymorphisme Humain and the French Muscular Dystrophy Association initiated genome mapping efforts in France;

(c) the Science and Technology Agency, and the Ministry of Education, Science, Sports and Culture (among other Government agencies) supported genomic research efforts in Japan;

(d) the European Community helped to launch a number of international efforts supporting the project; and

(e) Germany and China eventually joined the international quest to sequence the genome.38

“Genome Centres” were created in the countries involved in the project, and The Human Genome Organization (HUGO) was founded in 1988 to coordinate international efforts.39 Accordingly, the HGP became an international consortium, involving more than 1000 scientists worldwide.

3.4. Phases of the HGP

The HGP was divided into two phases—the mapping phase and the sequencing phase.

Establishing a map covering the entire human genome was necessary both as a tool for medical purposes to facilitate identification of genes involved in genetic diseases and to set up the infrastructure for the sequencing phase.40 This was the first phase of the project.

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38 Above, n5: 862.
39 Above, n3: 139.
40 Above, 23: 1.
The sequencing phase was launched at a pilot level in 1995. Pilot projects were launched to demonstrate the feasibility of cost-effective large-scale sequencing. These projects were successful, and the human genome sequencing effort increased in pace in March 1999.

In 1998, Celera Genomics (a private company) announced their intention to use a new technique to sequence the entire human genome in 3 years. As a consequence, in September 1998, The DOE and NIH announced new goals. They proposed that the HGP would have a "working draft" ready by 2001, followed by the finished genome in 2003. The DOE and NIH project was, in effect, forced to keep pace and stay competitive in the 'race' to complete the genome in fear of how private corporations might control the use and release of the genome information.

3.5. Completion of the HGP

On 26 June 2000, leaders of the HGP and Celera Genomics made a joint announcement that the working drafts of the human genome sequence were complete.

The analyses of the draft sequences were published in the February 15, 2001 issue of Nature and the February 16, 2001 issue of Science respectively.

The HGP made a commitment to fill all the gaps and resolve the ambiguities in the sequence with 99.99% accuracy by 2003. This high-quality reference sequence was completed in April 2003, marking the end of the Human Genome Project - 2 years ahead of the original

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41 Above, n23: 2.
42 Above, n3: 863.
43 Michael Angelo Palladino. Understanding the Human Genome Project. (Benjamin Cummings, Monmouth, 2002), 7.
44 Above, n3: 139.
45 Above n5: 7.
schedule produced in 1990. Coincidentally, this was also the 50th anniversary of Watson and Crick's publication of DNA structure that launched the era of molecular biology.

3.6. What now?

Although sequencing the entire human genome is complete, and the "book of life" is now accessible, there is still a remarkable amount of work to be done to gain an understanding of the information now at hand. For example:

(a) Rosenthal and Vakalopoulou noted that:

The consequences for science, especially for biology and medicine, but also for our society in general, are manifold, profound, and at the moment hardly understood.

(b) The International Human Genome Sequencing Consortium concluded in their publication of the draft sequence of the human genome:

[The more we learn about the human genome, the more there is to explore.]

What we do know about the outcome of the completion of the human genome sequence is that the advances it has brought about and will bring about in medicine will have profound long-term consequences.

4. MEDICAL CONSEQUENCES OF THE COMPLETED HGP:

The completion of the HGP has already resulted, and will continue to result, in a greater ability to identify, screen, diagnose, treat, and (in some cases) prevent genetic diseases. This is possible through the development of:

(a) Genetic testing.

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48 Above, n26.

49 Above, n23.

50 Above, n5: 914.

51 Above, n26.
Genetic tests are DNA-based tests and were one of the first commercial medical applications of advances in human genetics. They can be used to diagnose diseases, confirm diagnoses, provide predictive information about the course of a disease, confirm the existence of a disease in individuals who bear no symptoms, and, in some cases, predict the risk of future disease in healthy individuals or their children. The nature of the information that results from genetic tests is central to this thesis, and is discussed further in the next chapter.

(b) Pharmacogenetics.

Pharmacogenetics is a discipline that blends pharmacology with genetics. It involves correlating DNA variants in the genes involved in drug metabolism with individual responses to medical treatments, identifying particular sub-groups of patients, and thereby developing drugs customized for those populations. Such developments are estimated to occur within the next decade and could drastically reduce the level of adverse responses to medications.

(c) Gene therapy or enhancement.

At present, gene therapy is a largely experimental field. It has the potential to treat or even cure genetic and acquired diseases such as cancers and AIDS by using normal genes to supplement or replace defective genes or strengthen normal functioning such as immunity.

This paper focuses on the ethical and legal issues, and in particular, issues in relation to the privacy and confidentiality of genetic information that is obtained during genetic testing.

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52 Above, n26.
53 Above, n26.
54 Above, n26.
5. ETHICAL, SOCIAL, AND LEGAL ISSUES IN THE HUMAN GENOME PROJECT

5.1. ESLI Programmes

As stated by the International Human Genome Sequencing Consortium: "[s]erious attention must be paid to the many ethical, legal and social implications raised by the accelerated pace of genetic discovery".\(^{55}\)

In recognition of this need, the Human Genome Project committed significant resources to examine such issues.\(^{56}\) The DOE and the NIH devoted 3% to 5% of their annual HGP budgets toward studying the ethical, legal, and social issues (ELSI) surrounding availability of genetic information.\(^{57}\)

In 1990, the NIH and DOE established the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) to coordinate ELSI policy and research between the two agencies.

In response to the ELSI Working Group's report, also in 1990, the National Human Genome Research Institute (NHGRI)\(^ {58}\) established the ELSI Branch (later renamed the ELSI Research Program) in its Division of Extramural Research, and the DOE established a separate ELSI Program in the Office of Energy Research.

Since their establishment, these two programs have collaborated closely, as evident from the:

(a) the joint support of the ELSI Working Group;

(b) the development of complementary research priority areas; and

(c) the co-funding of ELSI activities of mutual interest.\(^ {59}\)

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\(^{55}\) Above, n5: 914.

\(^{56}\) Above, n3: 27.

\(^{57}\) Above, n26.

\(^{58}\) As noted above (see n33), the NHGRJ was established to carry out the role of the NIH in the HGP.

The DOE and NIH ELSI programs focus on ethical, legal, cultural, social, and psychological consequences that could affect policy development and service delivery in relation to genetic technologies. Both programmes emphasise the importance of the privacy of genetic information, its safe and effective introduction into the clinical setting, fairness in its use, and professional and public education.

5.2. Two relevant issues explored under the ELSI Programmes: privacy and clinical integration

Two of the topics examined under the ELSI programmes are central to this thesis, ie the examination of:

(a) privacy and fairness in the use and interpretation of genetic information; and
(b) the clinical integration of new genetic technologies.

5.2.1. Privacy

Exploring privacy issues in relation to the use of genetic information involves the consideration of:

(a) assessing the impact genetic information may have on individuals and family members;
(b) deciding whether genetic information should attract additional legal protection, over and above traditional health information;
(c) determining who has access to, and ownership and control of, genetic information; and
(d) establishing what constitutes appropriate use and disclosure of genetic information.


62 These issues are discussed in chapters 3, 4 and 5 respectively.
5.2.2. Clinical integration

Examining issues surrounding the clinical integration of genetic technology involves assessing the impact of genetic testing and counselling on individuals, families, and society. This assessment involves an investigation of, among other matters:

(a) privacy and confidentiality policies regarding individual and family genetic information;\(^{63}\)

(b) issues in the delivery of individual and family genetic counselling and testing;

(c) elements of informed consent;

(d) consequences of testing for disorders for which there is no therapeutic intervention available;

(e) consequences of testing for disorders where genetics and environmental factors both play a role;\(^{64}\)

(f) cultural differences in attitude towards information sharing; and

(g) whether health professionals have adequate knowledge about genetics, genetic technologies and the ethical, legal and social implications surrounding their use in order to optimally provide genetic services to their patients.\(^{65}\)

These issues in relation to the clinical integration of new genetic technologies are discussed throughout this thesis when determining how best to deal with the informational consequences (and in particular, information sharing among families) of such technologies.

5.3. Relevance of the work ELSI programmes to this thesis

As illustrated, the scope of the issues covered under each area of the ELSI program is broad, and an extensive examination of each research project, report or conference funded by the program is beyond the scope of this paper.

\(^{63}\) Privacy and confidentiality laws and policies in New Zealand are discussed in chapter 5. Privacy and confidentiality laws and policies in other jurisdictions are discussed in chapter 6.

\(^{64}\) These issues are discussed in chapter 3.

\(^{65}\) Above, n61.
It is, however, important to note that a major focus of the ELSI programs has involved educating people about the issues regarding the advances in genetic science, so as to develop an extensive discourse surrounding such issues. As David Smith (founder and former director of the DOE Human Genome Project) noted, "now it's time for others to come and translate ELSI efforts into policy".

As such, the work of the ELSI program in introducing the issues has facilitated the development of a number of instruments concerning genetic data protection, including conventions, legislation, declarations, recommendations, guidelines and directives at international, regional, and national levels.

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66 This is achieved by holding conferences, educational programs, and producing reports relating to the Ethical, Legal and Social issues that arise as a consequence of the advances in genetic science. For example, at the end of the financial year in 1999, the DOE ELSI program had funded 14 research projects and 11 conferences, and the NHGRI ELSI program had funded 40 research projects and 8 conferences examining privacy issues surrounding genetic information alone. See National Human Genome Research Institute: Research: A Review and Analysis of the ELSI Research Programs at the National Institutes of Health and the Department of Energy (ERPEG Final Report). Online. Accessed 15 May 2004. Available from the Genome Research Institute website. http://www.genome.gov/10001727.


68 Bodies or organisations responsible for the development of policies in relation to the ethical, legal, and social issues that have arisen as a result of advances in genetic science at the international level include: the United Nations Educational Scientific and Cultural Organisation (and in particular, the UNESCO International Bioethics Committee), World Health Organisation, Human Genome Organisation, the World Medical Association, International Federation of Human Genetics Societies, International Huntington Association, and International Society of Bioethics. This list is not exhaustive, but is confined to those organisations that have produced policies that may have bearing on the protection and use of genetic information. See GenConnect: List of Organisations. Online. Accessed 12 May 2004. Available from the HumGen website. http://www.humgen.umontreal.ca/en/GenConnect.cfm. Policies developed by a selection of these organisations are discussed in Chapter 6.

69 Bodies or organisations responsible for policy statements at the regional level include, but are not confined to: the Council of Europe, the European Commission, the European Society of Human Genetics, the European Alliance of Patient and Parent Organisations for Genetic Services and Innovation in Medicine, the European Forum on Good Clinical Practice, the European Group on Ethics in Science and New Technologies, the Nordic Committee on Bioethics, the Ethical Legal and Social Aspects of the Life Sciences and Technologies (Belgium), the Centre for Ethics and Law (Denmark), the American Society of Human Genetics of North America, and the Human Genetics Society of Australasia. Above, n68. Policies developed by a selection of these organisations are discussed in Chapter 6.

70 Hundreds of governmental and non-governmental bodies and organizations have produced policies regarding the ethical, legal, and social implications of the human genome project within a number of different countries. Bodies and Organisations common to many jurisdictions include: Government Organisations such as Privacy / Data Protection Commissioners, Departments of Health; and Non-Governmental Organisations such as Medical Associations, Medical Research Councils, and Societies of Human Genetics. Further examples of national organizations or bodies who have produced policies regarding the ethical, legal, and social issues arising from the HGP include the Australian Health Ethics Committee and the Australian Law Reform Committee (Australia); the Human Genetics Commission, the Nuffield Council on Bioethics, the Wellcome Trust and the Public Health Genetics Unit (United Kingdom); the Genome Canada and the Canadian Genetic Diseases Network (Canada); and Toi te Taioio: the Biotechis Council (New Zealand). Above, n68. Policies developed by
Some of these instruments address the issue of sharing of genetic information within families, and will be discussed in Chapter 5 (to the extent they are New Zealand based policies) and Chapter 6 (to the extent they are policies developed in other jurisdictions) of this thesis.

Before embarking on an examination of the policies and laws in relation to the protection of genetic data protection (both nationally and internationally), however, it is important to clarify the extent and nature of the information that is available from DNA, and to consider an appropriate legal approach towards the protection of such information. These issues are considered in the following two chapters.

6. **CONCLUSION**

From studying pea plants to sequencing entire genomes, the development of genetic science has been astounding and has brought with it profound consequences.

This chapter provided a background to the development of the science of genetics in order to provide context to the current legal and ethical issues that arise in relation to genetic science in general, and for the purpose of this thesis in particular, the issues that arise in relation to privacy, confidentiality and information sharing within the family.

Before examining such issues, however, in the next chapter I build on the background provided in this chapter, and explain how genetic information is obtained, the nature of genetic information, and its relevance for family members.
Every man bears the whole stamp of the human condition. 71

1. INTRODUCTION

If human beings are 99.9 percent identical at the DNA level, then:

(a) Why are we all so different?

(b) Why may it be important for an individual to know their genetic make-up when everybody shares virtually the same genes?

(c) Why do traits and diseases “run in families”, rather than throughout the entire population?

In this chapter, in order to provide context for discussing the legal and ethical obligations of health practitioners and individuals in communicating diagnostic and predictive genetic information to the individual’s genetic relatives, I explore:

(a) The significance of the small percentage of genetic differences that occur between individuals and how DNA contributes to disease.

(b) How genetic mistakes occur (ie how diseases are inherited or acquired).

(c) How genetic mutations are discovered (ie genetic testing).

(d) Patterns of inheritance of genetic disease.

(e) The significance of genetic information for individuals and their genetic relatives.

(f) The benefits, limitations and risks associated with genetic testing.

71 Michel de Montaigne, French Writer and Philosopher, 1533 – 1592.
2. **HOW DOES DNA CONTRIBUTE TO DISEASE**

2.1. Gene mutations

Most DNA variations among individuals have no effect, but harmful variations in the base sequence of DNA (called mutations) can cause or contribute towards the development of many different diseases and conditions.\(^2\) When a mutation exists in a gene, the protein encoded by that gene will be abnormal. An abnormal protein either functions at a less-than-normal level or is completely non-functional. Some protein changes are insignificant, while others are disabling.\(^3\)

2.2. Types of genetic disorders

Genetic disorders can be classified as single-gene, polygenic, multifactorial; chromosomal, or somatic cell disorders.\(^4\) Briefly:

(a) A *single-gene* disorder, as the name suggests, arises from a single mutation in the DNA sequence of one or both members of a gene pair and causes such a severe effect on the function of its product that its presence usually results in disease. Examples include Cystic Fibrosis, Sickle Cell Anaemia, \(\beta\)-Thalassaemia, Tay Sachs Disease, Haemophilia, and Huntington's Disease.\(^5\)

Single gene disorders allow particularly accurate inferences to be drawn about an individual's future health from their current genetic status, in comparison to the majority of genetic disorders, where many complexities exist in the relationship between genetic status and genetic disease.\(^6\) Thus, the informational impact of being diagnosed with a single gene disorder is potentially high for both individuals and their genetic relatives.

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\(^5\) Above, n72: 8.

(b) *Polygenic* disorders arise where mutations exist in two or more genes, which interact to cause disease, increase the risk of developing disease, or modify the severity of an existing disease. Examples include many of the common birth defects, such as cleft lip and palate, and congenital heart malformations. 77

(c) *Multifactorial* disorders occur when an individual inherits one or more gene mutations, causing increased susceptibility or a predisposition to a certain condition. The condition will not be expressed, however, unless other factors, such as a certain diet or exposure to certain environmental factors are present. 78 The interaction of genes and environment may result in disease, increase the risk of developing disease, or modify disease severity. Examples include congenital malformations, diabetes, cancer and psychiatric disorders. 79 The informational impact for multifactorial disorders is therefore complex, as it is difficult to determine the cause of such disorders. In relation to the indeterminate nature of multifactorial disorders, Ridely aptly states:

> You had better get used to such indeterminacy. The more we delve into the genome the less fatalistic it will seem. Grey indeterminacy, variable causality and vague predisposition are the hallmarks of the system ... because simplicity piled upon simplicity creates complexity. The genome is as complicated and indeterminate as ordinary life, because it is ordinary life. This should come as a relief. Simple determinism, whether of the genetic or environmental kind, is a depressing prospect for those with a fondness for free will. 80

(d) *Chromosomal* disorders arise where there are extra or missing chromosomes, a translocation has occurred, or where cell line mixtures exist. 81 For example, Down Syndrome (or trisomy 21) is a common disorder that occurs when a person has three copies of chromosome 21.

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77 Above, n72: 8.

78 Above, n76: 121.

79 Above, n72: 9.


81 Above, n74: 70.
(e) A somatic cell disorder occurs where defects in DNA are found in specific somatic cells (that is, any cell in an organism which is not a germ cell). Somatic cell disorders are not inherited or passed on through generations, and therefore do not have any informational impact for an individual's genetic relatives.

3. **HOW DO GENE MISTAKES OCCUR?**

Gene mutations can either be inherited from a parent or acquired.

A hereditary mutation (or gene line mutation) is an error present in the DNA of almost all body cells. These gene changes exist in the reproductive cells (germ cells). When reproductive cells containing mutations combine to produce offspring, the mutation will be present in all of the offspring's body cells. More than 4000 rare diseases are thought to arise from single mutations that are inherited from one's mother and/or father.

An acquired (or somatic) mutation is a change in DNA that develops throughout an individual's life. Acquired mutations are thought to occur as a result of errors that arise during cell division, or to be the by-products of environmental stresses such as radiation or toxins. These genetic errors are passed only to direct descendants of those cells, and cannot be passed from generation to generation.

This thesis focuses on the familial context of genetics; hence I discuss only hereditary mutations.

4. **GENETIC TESTING: DISCOVERING GENE MUTATIONS**

The rapid increase in information available about human genetics as a result of the completion of the HGP, and in turn the identification of genetic mutations associated with human diseases, has laid the foundation for clinical genetic testing.

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82 Above, n74: 224.
83 Above, n73.
84 Above, n73.
85 Above, n73.
Information in relation to gene mistakes that lead to genetic disorders is, in the most part, obtained by using tests that: (a) have been developed to diagnose the many single gene disorders; and/or (b) are rapidly being developed to detect susceptibility to more common genetic conditions, such as breast cancer and heart disease.\textsuperscript{86}

Several types of genetic tests are available to determine if a person has a genetic condition or disease, or is likely to develop a genetic disease in the future. These include diagnostic testing, predictive testing, carrier testing, prenatal testing, pre-implantation testing and newborn screening. Each type of test has the potential to reveal genetic information that has relevance both for the individual tested as well as their genetic relatives. I discuss each in turn below.

4.1. Diagnostic testing

Diagnostic testing is used to confirm or rule out a known or suspected genetic disorder in a symptomatic individual. For example, an infant who is born with respiratory and digestive difficulties may be suspected as having cystic fibrosis. A diagnostic genetic test in the relevant gene may detect a mutation, and confirm this clinical diagnosis. There are a multitude of other disorders, both rare and common, which can be confirmed in this way.\textsuperscript{87} Because diagnostic testing is performed on symptomatic individuals, there is a higher likelihood that relatives of the individual tested will know or become aware of the outcome of the genetic test than, for example, a presymptomatic predictive genetic test (discussed below). This does not, however, render the information about whether a particular disorder has a genetic cause any less significant than, for example, presymptomatic predictive genetic tests.

\textsuperscript{86} National Health Committee. Molecular Genetic Testing in New Zealand: A Report from the National Advisory Committee on Health and Disability (National Health Committee). (National Advisory Committee on Health and Disability (National Health Committee), Wellington, 2003), 8. Note, there are a number of different ways in which genetic information can be obtained, including for example taking an individual’s family medical history or a performing a clinical examination of an individual that reveals a genetic disorder. For the purpose of the present paper, however, reference to a “genetic test” will usually allude to a test involving the direct analysis of DNA or other gene products.

4.2. Predictive testing

Predictive testing is offered to asymptomatic individuals with a family history of a genetic disorder. Predictive testing can be divided into two categories (that is, presymptomatic and predispositional testing), depending on the type of disorder being tested for.88

4.2.1. Presymptomatic testing

The outcome of a presymptomatic test determines that eventual development of symptoms of a certain disorder is certain when the gene mutation is present. At present, several types of genetic disorders, such as Huntington's Disease and Familial Adenomatous Polyposis ("FAP"), can be tested for using presymptomatic testing.89 Because presymptomatic tests: (a) are relatively determinative; and (b) reveal information that is otherwise unknown or unsuspected by people (such as genetic relatives) other than the individual tested, presymptomatic tests are of particular relevance to the potential conflict between individual and familial rights to genetic information.

4.2.2. Predispositional / susceptibility testing

Susceptibility testing detects gene mutations that indicate someone may have an increased likelihood of developing a particular genetic disorder. In comparison to presymptomatic predictive testing, where an individual will almost certainly develop a genetic condition if they carry the associated genetic mutation, the outcome of a susceptibility test only indicates that an individual or family has an increased risk, or predisposition to that disorder when a genetic mutation is detected. Tests for breast and bowel cancer both fall within this category.

Important issues to consider in relation to predictive testing include:

(a) the availability of clinical intervention;90

(b) psychological ramifications of the finding that one will or will not develop or be likely to develop a genetic disorder in the future.91


89 Above, n87: 8.

90 This issue is discussed further at paragraph 6 below.
(c) the necessity of testing other genetic relatives to find the specific gene mutation;\textsuperscript{92} and
(d) the implications of a positive result of an individual for other genetic relatives who have not requested testing (for example, children).\textsuperscript{93}

Informed consent and genetic counselling are mandatory before such testing will proceed,\textsuperscript{94} and the predictive testing of asymptomatic children at risk for adult onset disorders is strongly discouraged when no medical intervention is available.\textsuperscript{95}

4.3. Carrier testing

Carrier testing is performed to identify individuals who have a gene mutation for a disorder inherited in an autosomal recessive or x-linked recessive fashion. Thus, a carrier test identifies people who are not affected by the gene mutation, but can pass the gene to an offspring.

Such tests are offered to individuals: (a) who have one or more genetic relatives with an identified genetic condition; and/or (b) of a particular racial or ethnic group known to have a higher carrier rate for a particular condition.\textsuperscript{96} An important consideration to make before performing a carrier test is the possible effect of the outcome on reproductive choices, and the potential requirement of testing other family members to determine the specific mutation present in the family.\textsuperscript{97}

\textsuperscript{91} This issue is discussed further at paragraph 7 below.

\textsuperscript{92} Above, n88.


\textsuperscript{94} Above, n88.


\textsuperscript{96} Above, n88.

\textsuperscript{97} Above, n88.
Individuals who undergo carrier testing can then find out whether they carry the recessive gene and are at risk of passing on the disorder to potential children. A common example of a recessive disorder for which carrier testing can be offered is Cystic Fibrosis.\(^98\)

### 4.4. Prenatal testing

Prenatal testing refers to a genetic test that is performed during pregnancy to test a foetus at risk of a chromosomal or genetic disorder.\(^99\) Such tests are offered when there is an increased risk of having a child with a genetic condition due to maternal age, family history, ethnicity, or as suggested by ultrasound examination.\(^100\) Prenatal tests are usually diagnostic or presymptomatic, and are performed to allow parents to make informed choices about a pregnancy.\(^101\)

### 4.5. Preimplantation testing

Preimplantation testing is performed on early embryos (in the laboratory) resulting from in vitro fertilization. The results of this testing allow couples to decide whether or not to transfer affected embryo’s to the mother.\(^102\) This procedure is not yet available in New Zealand. The Minister of Health, however, has recently authorised the use of preimplantation genetic diagnosis in principle, and has asked the National Ethics Committed on Human Reproduction to develop guidelines for appropriate use and treatment.\(^103\)

### 4.6. Newborn screening.

Newborn screening is offered to identify newborns who are affected by certain diseases before symptoms appear, so that treatment can begin immediately. For example, screening newborns for phenylketonuria (PKU) and hypothyroidism, and providing treatment to affected babies prevents brain damage that would otherwise begin soon after birth. These

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\(^{98}\) Above, n87: 8.

\(^{99}\) Above, 87: 8.

\(^{100}\) Above, 87: 8.

\(^{101}\) Above, 87: 8.

\(^{102}\) Above, 87: 8.

\(^{103}\) Above, n86: 11.
tests are often referred to as "Guthrie Heel Prick Tests". Seven tests are offered to test for genetic metabolic disorders in New Zealand, including PKU, hypothyroidism, and Cystic Fibrosis (among others). Such tests are voluntary, although it is thought that almost 100% of babies born in NZ are tested in the newborn screening programme.  

4.7. Summary of types of genetic tests

There are a number of methods that can be used to obtain genetic information. Each genetic test has a slightly different function. Common to each type of genetic test, however, is the fact that a genetic test will always reveal a degree of information about both the individual tested and his or her genetic relatives. The impact of the information for individuals and their genetic relatives that results from a genetic test will vary depending on: (a) the inheritance pattern of the genetic disorder tested for; (b) the type of test conducted (eg predictive or diagnostic), and therefore how definitive the information that is obtained from the test is; and in turn (c) the significance of the information. These factors discussed below.

5. PATTERNS OF INHERITANCE: HOW ARE GENETIC MUTATIONS INHERITED?

Understanding the patterns of inheritance of different genes helps to determine: (a) who will be, or will likely be, affected by a hereditary genetic mutation; and therefore (b) which individuals within a family may benefit from knowing the genetic information of a family member who has had a genetic test.

5.1. Inheritance patterns: background

Just as each parent contributes one chromosome to each pair of chromosomes, so each parent contributes one gene to each pair.

As noted in chapter two, genes contain a code for producing various proteins, and proteins are the critical component of cells which determine the expression of different traits (depending on the protein produced). Usually one gene has a stronger influence on the trait than the other gene. The stronger gene is called the dominant gene, while the weaker gene is

104 Privacy Commissioner. *Guthrie Tests.* (Office of the Privacy Commissioner, Wellington, 2003.)

105 Chapter two, paragraph 2.2(d)-(e).
called the recessive gene. Only one copy of a dominant gene is needed to control a trait, while two copies of a recessive gene are needed to express a trait. Therefore, a dominant disorder involves a mutation on only gene, whereas a recessive disorder results if both genes have mutations.\(^{106}\)

Many genes also come in a number of different forms. These variant forms are referred to as alleles.\(^{107}\) An individual is said to be *homozygous* if both alleles are identical and *heterozygous* if the alleles are different.

The following inheritance patterns illustrate how different types of disorders are passed on through generations.

### 5.2. Autosomal dominant inheritance

*Autosomal* inheritance involves traits that are encoded for by the 22 pairs of human autosomes (that is, chromosomes which do not determine sex).\(^{108}\)

An autosomal dominant disorder occurs where an individual with only one copy of a mutated allele (inherited from either parent) manifests that trait. Autosomal dominant disorders follow a vertical mode of transmission, that is the disease will be passed down through generations.

Children of individuals with a dominant mutated allele will have a 50 percent chance of inheriting that allele and trait.\(^{109}\) This risk is independent of: (a) sex; or (b) whether the disease is fully developed or preclinical.\(^{110}\) The risk to children and more distant descendants of unaffected family members is not increased over the general population risk.\(^{111}\)

Figure 1.1 below depicts a family pedigree showing the autosomal dominant inheritance of a genetic disorder over three generations. Examples of disorders that follows autosomal

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\(^{106}\) Above, n76: 116.

\(^{107}\) Above, n72: 8.

\(^{108}\) Above, n74: 37.

\(^{109}\) Above, n76: 116.


\(^{111}\) Above, n110.
dominant inheritance include Huntington’s Disease, familial adenomatous polyposis, early onset familial Alzheimer’s disease, and familial breast cancer.

As illustrated in Figure 1.1, individuals who undergo genetic testing for an autosomal dominant genetic disorder may reveal information about the risk of their parents (where symptoms are not yet manifest), children, or siblings for developing the same disease. For a hypothetical clinical scenario involving an autosomal dominant disorder, see scenario four at Appendix One to this thesis.

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113 Above, n76: 124 - 127.

114 Note, such information is revealed regardless of whether the test shows the presence or absence of the disease causing genetic mutation. Where the gene is absent, the risk for the individual’s children developing the disease is not greater than the population risk, however the risk for siblings or parents is still present when the disease is known to exist in the family.
Figure 1.1: Autosomal Dominant Inheritance over three generations.\textsuperscript{114}

5.3. **Autosomal recessive inheritance**

Most individuals with autosomal recessive disorders are born to two healthy (that is, unaffected), but heterozygous individuals (with one of their genes carrying a mutation). For each child born to such parents, there is a one in four chance that they will be homozygous-normal or homozygous-affected for that trait or mutation. There is a 50 percent chance that each child will him/herself be a carrier (heterozygotes) for the trait or mutation. Males and females are affected with equal probability.

The mode of transmission for an autosomal recessive disorder follows a horizontal rather than a vertical pattern. This is because affected individuals tend to be limited to a single sibship\(^\textsuperscript{115}\) and the disease is not usually found in multiple generations.\(^\textsuperscript{116}\) It is difficult to establish that a disorder actually follows this mode of inheritance, as the inheritance pattern described is not always apparent, especially in communities where the number of offspring is not high.\(^\textsuperscript{117}\) The occurrence of the genetic trait or mutation may *appear* to be sporadic in such instances.\(^\textsuperscript{118}\)

Cystic Fibrosis is the most common autosomal recessive disorder in Caucasians, affecting approximately 1 in 2000 births, with a carrier rate in Northern Europeans of five percent.\(^\textsuperscript{119}\) Tay Sachs disease is 10 times more common in Central and Eastern European Jewish communities than in non-Jewish or Middle Eastern Jewish communities.

Figure 1.2 below depicts a family pedigree showing the inheritance of a genetic disorder with an autosomal recessive inheritance pattern over three generations. Like Figure 1.1, it shows that an individual's genetic information in relation to an autosomal recessive genetic condition has potential implications for parents, children, or siblings. For example, such information may disclose carrier status, or the potential status of future offspring where both partners are aware of their genetic status regarding the disease in question. For a hypothetical clinical scenario involving an autosomal recessive disorder, see scenario three at Appendix One to this thesis.

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\(^{115}\) A sibship refers to a group of individuals (siblings) who have the same parents.

\(^{116}\) Above, n74: 41.

\(^{117}\) Above, n110: 28.

\(^{118}\) Above, n74: 41.

\(^{119}\) Above, n74: 42.
Figure 1.2. Autosomal Recessive Inheritance over three generations.\textsuperscript{120}
5.4. X-linked inheritance

*X-linked* traits are determined by genes found on the X-chromosome,\(^\text{121}\) that is, the sex determining chromosome.\(^\text{122}\) X-linked disorders result when the gene function associated with the X-chromosome is abnormal.\(^\text{123}\)

Since males have only one X-chromosome, they can only ever have one copy of each of the genes found on the X-chromosome and will always express these genes.\(^\text{124}\) Females, on the other hand have two X-chromosomes. Therefore, if the mutated allele is recessive, the trait may not be expressed because of the presence of a normal allele on the other X-chromosome.\(^\text{125}\) A female who has one mutated allele on the X-chromosome will be a carrier of the defect in the majority of cases.\(^\text{126}\)

X-linked disorders usually occur when a heterozygous female carrier and a normal male reproduce. Each son has a 50 percent risk of being affected by inheriting the mutant allele from his mother. Similarly, each daughter has a 50 percent chance of inheriting the abnormal allele from her mother, but she will remain unaffected due to the fact that she has her father’s normal X-chromosome. However, females may be symptomatic carriers or develop X-chromosome related disorders if they inherit a frequently occurring X-related gene from both parents.\(^\text{127}\) An example of a disorder that follows an X-linked pattern of inheritance is Haemophilia – a bleeding disorder.

Figure 1.3 (below) depicts a family pedigree showing the inheritance of a genetic disorder with an X-linked inheritance pattern over three generations. It illustrates that interested parties to information about genetic status for disorders of X-linked recessive inheritance include: (a) the affected or potentially affected male offspring; (b) potential female carriers


\(^{123}\) Above, n74: 50.

\(^{124}\) Above, n121.

\(^{125}\) Above, n121.

\(^{126}\) Above, n74: 50.

\(^{127}\) Above, n74: 51.
who are planning on having children (including the mother, daughter, aunt, sister etc); and (c) possibly, the partner of a female carrier due to the effect such information may have on reproductive planning.
Figure 1.3. X-Linked Recessive Inheritance over three generations. \(^{128}\)

\(^{128}\) Above, n114.
6. ASSESSING THE SIGNIFICANCE OF PERSONAL GENETIC INFORMATION FOR INDIVIDUALS AND THEIR GENETIC RELATIVES

6.1. Introduction

Just as there are a number of ways to obtain information, there are a number of different categories of genetic information, that is genotype, phenotype and family information. These categories, along with the nature of the disease revealed by the information, have an impact on the significance of genetic information for individuals and their genetic relatives.

6.2. Types of personal genetic information

The “genetic information” that results from a genetic test includes not only the information about an individual’s genetic material, but also the inferences that can be drawn from knowledge of this sequence information. For example, genetic information includes: (a) knowledge of the presence in an individual of an abnormal DNA sequence associated with breast cancer; and (b) the fact that individuals with this genetic abnormality have an increased susceptibility for developing breast cancer.

Genetic information can be divided into three categories, ie information about genotype, phenotype, or family information.

6.2.1. Genotype

Genotype information refers to the information that is only evident at the DNA or protein level. An individual's genotype provides details of precise variations inherited from both parents. It is generally obtained by direct analysis of DNA or by analysis of proteins or other body chemicals (such as ABO blood group substances). Genotype information

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129 This includes information: (a) about the DNA sequences, chromosomes, RNA, proteins, and substances present in the blood or tissue; and/or (b) derived from medical imaging techniques, clinical examination, and the study of an individual's family tree.

130 Above, n72: 9.

131 Above, n72: 9.


133 Above, n132.
includes both DNA sequence information as revealed by a genetic test and the inferences that can be made from knowledge of the sequence.\textsuperscript{134}

6.2.2. \textbf{Phenotype.}

A simple glance at an individual reveals information about them. A person's gender, race, height, weight and eye colour are all related, in whole or in part, to that person's genetic inheritance.\textsuperscript{135} These observable characteristics, along with physiological characteristics such as blood pressure and cholesterol level, make up an individual's phenotype. Phenotype information is often a product of the interaction between genotype and environmental factors. It can be gathered in a number of different ways, such as by chemical laboratory testing of tissue or body fluid samples, or by physical studies including X-rays, visual examination or measurements.\textsuperscript{136} Phenotype information allows assumptions to be made about one's DNA sequence.

6.2.3. \textbf{Family information}

Inheritance patterns of different phenotypic characteristics or disease among relatives provide another form of genetic information. This is known as family information, and can be gathered by taking a family medical history. Family histories reflect the consequences of genetic susceptibility, shared environment, and common behaviours. Family information can therefore provide information on the likelihood that a person may have a disease causing gene based on familial inheritance, although this form of genetic information varies in reliability according to the condition in question and accuracy of diagnosis.\textsuperscript{137} Thus, like information about one's phenotype, family information allows inferences to be drawn about the sequence of an individual's DNA.

\textsuperscript{134} Above, n121: 86.

\textsuperscript{135} Above, n76: 129.

\textsuperscript{136} Above, n132.

\textsuperscript{137} Note, family information often only raises the \textit{possibility} that a person has a particular genetic variation rather than confirming or excluding the existence of it.
6.3. Sensitivity of genetic information

Not all types of genetic information are equally sensitive, ie different types of genetic information have different levels of significance for the individual tested or for his or her genetic relatives. The level of informational impact of a genetic test result has a bearing on whether or not an individual's genetic relatives may have an interest in knowing (or not knowing) the resulting genetic information.

Genetic information that has low "informational impact" or significance for an individual’s genetic relatives include data which reveal limited information about inheritance, or which indicate somatic gene mutations. Such information is unlikely to result in any significant benefit or burden to an individual’s genetic relatives, whether or not it is disclosed to them.

Genetic information that has potentially high "informational impact" or significance for an individual's genetic relatives include genetic test results that reveal information about the inheritance of a condition, where that condition has (or might have in the future) a major impact on the health of the individual tested, and therefore possibly also his or her genetic relatives. Examples of such genetic test results include information about the potential inheritance of a late onset genetic disorder such as Huntington's Disease, or about foetal abnormalities. Such information has the potential to provide significant benefits or burdens to the individual tested and his or her genetic relatives. Thus, the analyses in this thesis focus on genetic information with a high informational impact.

6.4. Factors which influence the sensitivity of genetic information

The penetrance of, and the availability of any intervention for, genetic disorders are two of the key features of any genetic information that reveals the presence of a disease causing genetic mutation in an individual. These features will influence its impact for (and thus whether or not it should be disclosed to) his or her genetic relatives.

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138 Above, n132: 51.

139 Above, n132: 51.

140 Above, n132: 51.
6.4.1. Penetrance of a genetic disorder

The expression of a genetic condition is not straightforward. The relationship between genetic status and genetic disease is complex. Not all individuals who have a disease causing gene mutation will develop the associated genetic condition. For example, only around 60 percent of individuals who carry a mutated BRCA1 gene will develop breast cancer.\textsuperscript{141} The degree of likelihood that an individual who carries a particular genetic trait that could cause a disorder will actually develop it is known as “penetrance”. Penetrance can be either low or high, and is referred to as a percentage value. For example, Huntington's Disease (HD) has a very high penetrance of nearly 100 percent. This means that those individuals who have the HD mutation will almost certainly develop the disease.\textsuperscript{143} The same is true for Classical FAP.\textsuperscript{144}

The level of penetrance of a genetic disease therefore has bearing on its informational impact for individuals and their genetic relatives. If an individual’s genetic information reveals they have a genetic condition that has relatively high penetrance, it becomes more significant for potentially affected genetic relatives: if they in fact carry the affected gene, there is a higher chance that they will develop the condition and/or pass it onto to future offspring.

6.4.2. Availability of intervention

The availability of an effective intervention for a genetic disease may result in: (a) prevention of the onset of disease;\textsuperscript{145} (b) reduction in the risk of developing disease;\textsuperscript{146} and (c) the choice of having extensive monitoring to provide early detection and treatment.\textsuperscript{147}

\textsuperscript{141} A mutation in the BRCA1 or BRCA 2 genes is associated with familial breast cancer.

\textsuperscript{142} Above, n76: 125.

\textsuperscript{143} Above, n76: 117.

\textsuperscript{144} Above, n76: 125.

\textsuperscript{145} For example, prophylactic surgery may be used in cases of susceptibility to breast or colon cancer to prevent onset of the disease. Additionally, Phenylketonuria (PKU) (tested for in newborn screening programs) is disorder in which immediate intervention prevents the onset of symptoms associated with the disorder. With careful dietary supervision, children born with PKU can lead normal lives, and mothers who have the disease can produce healthy children. Genes and Disease. Online book. Accessed 12 September 2003. Available on the National Centre for Biotechnology Information website. http://www.ncbi.nlm.nih.gov/books/boookres.fcgi/gnd/gnd.pdf.

\textsuperscript{146} For example, an individual who is aware of his or her susceptibility to heart disease can make life-style changes, such as changing their diet and increasing their level of fitness, in order to reduce the risk.
The availability of effective intervention for a particular genetic condition is a crucial consideration when considering whether or not the genetic relatives of an individual who has been diagnosed with a genetic disorder, or is found to have an increased susceptibility for a genetic disorder, should be informed of their risk. However, for many genetic tests there are no available interventions, and disclosing an individual's genetic information to his or her at risk genetic relatives in these circumstances has the potential to cause more harm than good.

With this in mind, I explore the potential risks, benefits and limitations involved in genetic testing.

7. GENETIC TESTING: BENEFITS, LIMITATIONS AND RISKS

7.1. What are the benefits of genetic testing?

Genetic testing, although a new technology, has already dramatically improved lives. Some of the benefits associated with genetic testing are as follows:

(a) A genetic test may identify people at high risk of developing conditions that are preventable, or diagnose people with conditions for which interventions are available to reduce the risk.\(^\text{148}\)

For example, aggressive monitoring and removal of colon growths in individuals who have inherited the genetic mutation for FAP has saved many lives. Also, a person with a genetic susceptibility to heart disease may be able to make lifestyle changes in light of his or her increased risk, for example by modifying his or her diet, or avoiding workplace stress.

(b) A genetic test can offer relief from uncertainty (whether the test result is positive or negative) for individuals who face a high-risk for developing a genetic disorder. For example: (i) a negative test result (meaning the person does not carry a genetic mutation associated with developing a particular disorder) may bring about a sense of relief; or (ii) a positive test result, revealing that the person carries a genetic mutation associated


\(^{148}\) Above, n72: 17.
with developing a particular disorder, gives the individual the ability to make informed
decisions about their future (for example, by making lifestyle and/or reproductive
decisions).\footnote{149}

Given the shared nature of genetic information, this thesis examines whether the genetic
relatives of the individual tested should be entitled to the resultant genetic information that
gives rise to such benefits.

### 7.2. What are the limitations associated with genetic testing?

The limitations of genetic testing of relevance to the issues discussed in this thesis are as
follows.

First, one of the most serious limitations of genetic testing is the lack of certainty that the
results bring. While a positive test result for a predispositional genetic test indicates that the
person tested carries a disease-associated mutation, they may in fact never develop the
disease.\footnote{150} Similarly, a negative test result cannot completely rule out the presence of a
disease-associated mutation in cases of mutation variability (that is, where numerous
mutations can cause the same disease). In such cases only the most common mutations are
tested for.\footnote{151} For example, Cystic Fibrosis can display more than 700 different mutations, yet
only 70 of the most common mutations are tested for.\footnote{152}

Secondly, interpretive problems in gene testing also arise due to differences in gene
expressivity.\footnote{153} For example, the severity of Cystic Fibrosis ranges from mild bronchial
symptoms and male sterility to severe lung, pancreatic and intestinal difficulties, yet few
specific mutations have been correlated with the severity of their expression in an
individual.\footnote{154}

Thirdly, when testing for multifactorial disorders (such as inherited breast or colon cancer, or
late onset Alzheimer's Disease) current gene tests cannot always provide conclusive results

\footnote{149}{Above, n87: 9.}
\footnote{150}{Above, n147.}
\footnote{151}{Above, n72: 19.}
\footnote{152}{Above, n147.}
\footnote{153}{Gene expressivity refers to the range of disease severity for a certain disease or mutation. Above, n147.}
\footnote{154}{Above, n147.}
about the cause of the disease. In some families, multiple cases may reflect shared environmental exposures rather than inherited susceptibility.155

Finally, despite rapid developments in genetic technology, there are few treatments or preventive measures available for genetic conditions. The number of diseases that can be diagnosed or predicted by genetic tests are not matched by state-of-the-art diagnostics and therapies.156 In many cases this limitation will outweigh any benefits of testing.

Such limitations mean that it is not certain that knowing genetic information will always benefit the individual or his or her genetic relative. This raises issues in determining when such information should be disclosed or not.

These limitations are accompanied by risks inherent in gene testing.

7.3. What are the risks of gene testing?

The information revealed by a genetic test has the potential to have a significant impact on both the life of the individual tested and his or her genetic relatives. Sometimes that impact will not be positive. The risks inherent in genetic testing are discussed below.

7.3.1. Negative psychological impact

A positive test result (revealing that the individual tested carries a genetic mutation associated with a genetic disease) may carry with it a negative psychological impact, especially where penetrance of the disease is high, development of the disease is certain, and there is no available intervention. In addition to the burden of disease itself, an individual who receives a positive test result may face anxiety long before symptoms develop.157 Further, a negative test result may arouse emotions of survivor guilt where other genetic relatives test positively.158

155 Above, n72: 19.
156 Above, n87: 10.
157 Above, n87: 10.
158 Above, n72: 20.
7.3.2. Medical choices

A positive test result may prompt an individual to undergo dangerous preventive or therapeutic measures that may be unnecessary. For example, someone who tests positively for a cancer susceptibility gene may choose to undergo breast or ovary removal, despite potential dangers and uncertainty of the test result.\(^{159}\)

7.3.3. Family relations

The effect of a genetic test on the family of the individual tested is central to the issues examined in this thesis. Because of the familial nature of genetic information, all of the risks associated with genetic testing extend to the individual's genetic family. The decision to have a gene test, as well as the test results, can have serious consequences for a number of people. For example, if a baby tests positive for a certain genetic disease, it indicates that one of his or her parents is a carrier, and that his or her sisters may also carry the associated genetic mutation.

7.3.4. Privacy issues

Genetic information, as a component of health information, is very sensitive, and having a genetic test that reveals genetic information necessarily creates a need to protect it. Adverse consequences associated with the protection of genetic information may arise in the context of employment, insurance and/or the family.

This thesis focuses primarily on the privacy issues associated with genetic information that arise in the family context. Examples of these issues are as include the following:

(a) An over zealous attempt to protect an individual's genetic information may place family members at unnecessary risk. Failing to inform genetic relatives of the existence of a disease causing genetic mutation within the family may place them at an increased risk of developing a disease where intervention is available.

(b) On the flipside, flippantly disclosing genetic information to one's genetic relatives who were otherwise unaware of their risk of developing a genetic condition, and did not want to know of that risk, may interfere with their right not to know.

\(^{159}\) Above, n72: 20.
Like limitations discussed above, these risks mean that it is not certain that knowing genetic information will always benefit the individual or his or her genetic relative, and again raises issues in determining when such information should be disclosed or not.

7.4. Relevance

At first glance, the benefits, risks and limitations discussed above do not all appear to be directly associated with the familial conflicts that may arise in the context of genetics. However, the familial nature of genetic information means that every benefit, risk, or limitation associated with genetic testing has the potential to extend to both individuals and his or her genetic relatives, regardless of whether or not those genetic relatives chose to undergo testing.

8. CONCLUSION: TO DISCLOSE OR NOT TO DISCLOSE?

Understanding: (a) the significance of genetic information to individuals and genetic relatives; and (b) the benefits, risks and limitations associated with genetic testing (and therefore knowing genetic information) that apply to both individuals and genetic relatives, assists in developing an appreciation of the importance of disclosing (or not disclosing) an individual’s genetic information to his or her genetic relatives in certain circumstances.

From the preceding analysis, and as a preliminary observation only (before examining ethical and legal rules in relation to the use and disclosure of genetic information), it seems that when the following conditions are present it is appropriate for an individual to disclose his or her genetic information to his or her genetic relatives:

(a) The genetic condition in question is hereditary in nature, rather than somatic.

(b) The inheritance pattern of the particular genetic condition leads to an inference that a genetic relative may be at-risk of developing it or passing it on (that is, he or she might be affected with, or be a carrier of, the genetic disease).

(c) The genetic condition in question has relatively high penetrance (that is, when the genetic information derived from the genetic test is more definitive than not of the future health of an individual and potentially his or her genetic relatives).

(d) There are clinical interventions available in relation to the particular genetic condition.
On the flipside, if there is no clear benefit to a genetic relative in knowing genetic information, that is there is nothing he or she could do to prevent the development of the genetic disease or lessen its impact, it is not appropriate for an individual to disclose his or her genetic information to his or her genetic relatives.

9. **CONCLUSION**

Understanding how genes contribute to disease, how genetic mutations occur, how they are revealed and how they are passed on through generations provides a basis for understanding:

(a) the significance of genetic information for individuals and their genetic relatives;

(b) why and when it might be important for an individual to disclose (or not to disclose) genetic information to genetic relatives; and therefore

(b) the potential tensions that exist between the rights and interests of individuals and genetic relatives in relation genetic information.

Before examining how these potential tensions are dealt with under New Zealand’s health information privacy law (see chapter five), in the next chapter I examine whether, in light of its familial nature, genetic information requires special legal protection. I also explore four ethical frameworks in relation to the disclosure of genetic information, so as to provide a reference point for the analysis of current legal mechanisms governing the disclosure of genetic information in New Zealand.
CHAPTER 4

LEGAL AND ETHICAL APPROACHES TO GENETIC INFORMATION

As lawyers we are by no means uniquely qualified, or perhaps even adequately qualified, to address the complex science involved, nor the profound moral issues modern science is thrusting upon us. Nevertheless, as lawyers, we are certain to be involved in the resolution of those issues.160

1. INTRODUCTION

As technology progresses, and as our knowledge in relation to the use of genetic testing expands, the need to address the legal and ethical issues associated with such developments becomes increasingly important. However, complexities surrounding the nature of genetic information and genetic disease raise questions regarding how such information should be treated from both a legal and ethical perspective.

The purpose of this chapter is to:

(a) Determine whether or not genetic information is fundamentally different from health information, and whether it requires special legal protection. In particular, I examine arguments in support of and against “genetic exceptionalism” and assess which position is most appropriate for New Zealand’s legal environment.

(b) Discuss the potentially competing interests involved in relation to the collection, use and disclosure of genetic information.

(c) Examine ethical approaches to resolving the potentially competing interests between: (i) an individual’s right to privacy and his or her genetic relatives’ right to know relevant genetic information; and/or (ii) an individual’s desire to share his or her genetic information, and his or her genetic relatives’ right not to know. Specifically, I consider four ethical frameworks governing the disclosure of genetic information in order to

provide a point of reference for the analysis of current legal mechanisms governing the disclosure of genetic information in New Zealand.

2. GENETIC INFORMATION AS A SUB-SET OF HEALTH INFORMATION

Given the multitude of sources and types of genetic information, difficulties arise when attempting to define it. The type of genetic data relevant to this thesis is that which reveals information about the health or well-being of an individual and his or her genetic relatives. Therefore, this type of genetic information falls squarely within the definition of “health information” in section 22B of the Health Act 1956 and Rule 4(1)(a) of the Health Information Privacy Code 1994. Only certain genetic characteristics which do not convey information about the health of an individual, such as eye or hair colour, are excluded. Accordingly, most genetic information, as a sub-set of health information, attracts privacy protection under New Zealand law.

The nature of genetic information in comparison to other forms of personal health information, however, raise questions as to whether genetic information is so fundamentally different that it requires special legal protection in relation to its collection, use and disclosure.

161 See chapter 3, paragraph 6, for a discussion on varieties and sources of genetic information.

162 These difficulties are discussed in detail below. See paragraph 3.3.5, p57.

163 It is important to note that until DNA has been processed in a way that conveys meaning, it remains “genetic data” as opposed to “genetic information” - see Paul Roth, "What is "Personal Information"?" (2000) 20 NZULR, 40, 51. Simply linking a DNA sample to the individual from whom it was taken may be sufficient to convey meaning. Once this is done, the DNA becomes identifiable; it becomes information about someone's genetic makeup, as opposed to mere 'context-less' data.

164 Both of these provisions define “health information” as including information about the health of an identifiable individual, including his or her medical history.

165 See chapter 3 for an overview of the nature of genetic information, genetic disease and genetic testing.
3. **DOES GENETIC INFORMATION REQUIRE SPECIAL LEGAL PROTECTION?**

There are two polarised schools of thought in relation to whether genetic information is unique and therefore whether it should be treated differently from other forms of personal health information. The concept of "genetic exceptionalism" is central to this debate.

3.1. Genetic exceptionalism

"Genetic exceptionalism" is "the claim that genetic information is sufficiently different from other kinds of information that it deserves special (legal) protection". Arguments supporting and opposing genetic exceptionalism pervade contemporary policy debates about whether genetic information requires special legal protection.

3.2. Arguments in support of special legal protection

Responses to threats of privacy invasion (both anticipated and actual) as a result of the rapid advance of genetic technology have already resulted in the enactment of a number of genetic-specific statutes in the United States. A number of arguments have been put forward justifying the need for such legislation, and thus supporting genetic exceptionalism.

Proponents of genetic exceptionalism argue that genetic information is uniquely powerful, uniquely personal, and that it presents special threats to privacy, therefore justifying increased legal protection. Specifically, Annas, Glantz and Roche postulate that genetic information

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166 Thomas H. Murray "Genetic Exceptionalism and 'Future Diaries': Is Genetic Information Different from Other Medical Information" in Mark A. Rothstein (ed) Genetic Secrets: Protection Privacy and Confidentiality in the Genetic Era (Yale University Press, New Haven (USA) 1997) 60, 61. Note, under a more reductionist approach, 'genetic exceptionalism' is described as the notion that genes determine who we are in every important respect. In such cases, genetic exceptionalism becomes more akin to genetic essentialism or genetic determinism: Douglas H. Ginsburg "Genetics and Privacy" (1999) 4 Tex Rev L & Pols 17, 18. For the purpose of establishing appropriate legal safeguards to genetic information, the approach defined above is more relevant.

can be considered uniquely private or personal information for at least three reasons. That is, genetic information:

(a) cannot be altered, can predict an individual’s likely medical future for a variety of conditions and can be obtained from merely one drop of blood, one strand of hair or from any other cell in the human body;

(b) reveals personal information about one’s parents, siblings, and children (and other genetic relatives); and

(c) has been used historically to stigmatise and victimise individuals.\(^{168}\)

Annas notes that while describing DNA as the “book of life” goes too far, DNA “does contain an enormous amount of information about you and your probable medical future”.\(^{169}\) He proposes that new statutory protection is needed for genetic information, rather than treating it like other especially sensitive health information.\(^{170}\) Additionally, Gostin's early justifications for protecting the privacy of genetic information revolve around the breadth of discoverable information surrounding genetics. That is:

(a) genetic information provides the potential to unlock secrets about an individual;

(b) genetic information allows certain identification of an individual; and, of particular relevance to this paper; and

(c) it is possible to generalise genetic information across families and ethnic groups.\(^{171}\)

These arguments offer a prima facie justification for providing special legal protection in relation to genetic information. However, a number of counter arguments exist which identify the weaknesses in each argument above, and do not support the concept of treating genetic

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170 Above, 169: 9.

information as sufficiently different from other kinds of health-related information to deserve special protection.

3.3. Arguments against special legal protection

Opponents to genetic exceptionalism argue that genetic information is just one of a number of sources of personal health information, and that there is no need for any increased or special protection. The following arguments propose reasons why arguments in favour of genetic exceptionalism (outlined above) fail, and therefore why genetic information should not be considered as unique or “exceptional”.

3.3.1. Does the predictive nature of genetic information render it unique?

Opponents to genetic exceptionalism reject the idea that genetic information is unique due to the fact that it provides us with information about our future health. While genetic data may provide a more complete profile of current and future health with a greater degree of scientific accuracy than other health data, opponents to genetic exceptionalism propose that this does not necessarily render genetic information unique.\textsuperscript{172} Murray, for example, notes that traditional health information (such as the existence of asymptomatic hepatitis B infection, early HIV infection, and cholesterol levels) may provide us with the same degree of insight into our future health as genetic information.\textsuperscript{173} Further, Ginsburg asserts that:

\begin{quote}
the difference between a state-of-the-art DNA test and simple medical history form is merely one of degree. Obviously, because a genetic test provides a nearly definitive answer about whether a person has a particular gene, it may also provide a clearer indication of the probability that a person will develop a particular disease than does that person's family medical history. Nonetheless, both are informative about that person's higher-than-average probability of developing that disease.\textsuperscript{174}
\end{quote}


\textsuperscript{173} Above, n166: 64.

\textsuperscript{174} Douglas H. Ginsburg "Genetics and Privacy" (1999) 4 Tex Rev L & Pols 17, 19.
Further still, Murray argues that the "future diary" metaphor of genetic information offered by Annas promotes genetic determinism. The concept of genetic determinism ignores the uncertainty of contributing factors to disease that are not genetic in nature, and assumes that genetic information provides us with enough information to estimate the likelihood that an asymptomatic individual will suffer from a condition in the future. In fact, in complex disorders with many contributing factors, genetic information tends to offer only an uncertain range of probabilities, which Murray asserts to be "something that falls short of a probabilistic future".¹⁷⁵

Thus, while an individual's genetic information provides, at times, definitive information about one's future, this predictive feature of the information is neither unique nor special.

3.3.2. Does the familial nature of genetic information render it unique?

Likewise, opponents to genetic exceptionalism propose that one cannot claim that genetic information is unique on the basis that it provides information of concern to an individual, his or her genetic relatives, and perhaps even the larger ethnic community.

Murray contends that non-genetic information may have equal bearing on an individual's family or community.¹⁷⁶ For example, he explains that:

(a) if one family member suffers from Tuberculosis, this would certainly be relevant to the rest of the family as well as everyone who has contact with the infected individual;

(b) if an individual has a sexually transmitted disease, such information has bearing on his or her partner; and

(c) signs of early heart disease that may lead to disability or death will have a profound effect on other family members in terms of life choices.¹⁷⁷

¹⁷⁵ Above, n166: 67.

¹⁷⁶ Above, n166: 65.

¹⁷⁷ Above, n166: 65.
In addition, Ross points out that certain areas of medicine such as transplantation and public health also have implications beyond the individual, and take into account the fact that individuals are members of families and communities.\textsuperscript{178}

Thus, while genetic information may be highly sensitive due to its relevance to other family members, Murray argues that this feature alone does not make it unique. Just as information that an individual carries the \textit{BRCA1} gene reveals information about his or her parent's, sibling's, or child's susceptibility to breast cancer, so too does information that an individual suffers from Tuberculosis, in that it reveals information about the risk of developing the disease for individuals (often family members) who were in contact with the infected individual. The fundamental difference is that the implications for family members in the breast cancer scenario arise due to the shared nature of genetic information, however the implications for family members in the Tuberculosis scenario occur due to a shared environment. Nevertheless, opponents to genetic exceptionalism argue that the fact that genetic information reveals information about family members, and possibly individuals in the wider ethnic community, does not render it unique.

3.3.3. \textbf{Does the risk of stigmatisation, victimisation, or discrimination regarding an individual's genetic status render it unique?}

Opponents to genetic exceptionalism note that a variety of different types of information have been used to discriminate, stigmatise and/or victimise people, and therefore genetic information is not unique in this respect. A specific example of health information being used to discriminate is the use of evidence of current and future disease (such as HIV/AIDS) by insurers to decide who is entitled to receive insurance protection. Whilst not endorsing such discrimination, opponents to genetic exceptionalism say that this example makes it difficult to justify special protection of genetic information because to do so would suggest that it is fair to discriminate on non-genetic factors, but unfair to discriminate on genetic ones.\textsuperscript{179} Ross

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\textsuperscript{179} Above, n166: 65.
aptly notes that discrimination and stigmatisation exist as long as differences exist between people, whether or not those differences have a genetic basis.\textsuperscript{180}

3.3.4. \textbf{Does the fact that genetic information is predominantly immutable justify special treatment?}

Ross points out that while genetic information is nearly immutable (in that it cannot be altered), mutations do occur throughout an individual’s life, and our knowledge of the human genome is far from complete in terms of these possible genetic variations.\textsuperscript{181}

Thus, the immutability of genetic information is not so significant as to isolate genetic information from other medical information.\textsuperscript{182}

3.3.5. \textbf{Further arguments against treating genetic information as distinct from health information.}

Further to the arguments above, opponents to genetic exceptionalism also propose that genetic information does not deserve special legal protection for the following reasons.

First, according to Rothstein, genetic specific legislation seems illogical.\textsuperscript{183} Genetic specific legislation emphasises differences between genetic information and other health information when, as emphasised in the arguments above, a demarcation between these two sets of data may not be appropriate or justified. In particular, medical research indicates that genetic information should be placed on a continuum of medical information, and that genetic predispositions to disease are simply risk factors alongside behavioural and environmental components to disease.\textsuperscript{184}

\textsuperscript{180} Above, n178.

\textsuperscript{181} Above, n178.

\textsuperscript{182} Above, 178.

\textsuperscript{183} Mark A. Rothstein. “Why Treating Genetic Information Separately is a Bad Idea” (1999) 4 Tex Rev L & Pols 33, 34.

\textsuperscript{184} Above, n172: 32.
Rothstein discusses the differences between genetic and non-genetic medical information and notes "everything that we discover in the future is going to make the distinction even more difficult". Thus, genetic-specific legislation that provides greater legal protection for genetic information but denies it for other health information in situations where no clear boundary between genetic disorders and other disorders necessarily exists, is inappropriate.

A condition such as breast cancer illustrates the difficulty in drawing the distinction between genetic information and traditional health information. Opponents to genetic exceptionalism argue that there appears to be no logical reason for drawing a distinction in the level of privacy protection offered to an individual who suffers from breast cancer of genetic origin, compared with that offered to an individual who suffers from breast cancer of a non-genetic origin. Why should one woman not be afforded the level of privacy protection offered to a woman who is known to have one of the BRCA genes simply because she suffers from breast cancer of a non-genetic origin? Enacting genetic specific legislation that treats genetic information as different from other types of health information for the purpose of protecting privacy effectively offers special protection from disclosure of medical information to approximately five percent of breast cancer patients where, arguably, no clear reason to do so exists. On the other hand, reasons exist which could justify the disclosure of the fact that an individual has breast cancer with a genetic origin, which do not exist where an individual has breast cancer of a non-genetic origin. Those reasons are based on the fact that the presence of one of the BRCA genes means that "at-risk" family members have a much higher chance of developing breast cancer in comparison to the general population. Being aware of that risk would empower an individual to seek regular screening, which would increase the likelihood of early detection and, in turn, survival. Genetic relatives of an individual who suffers breast cancer of a non-genetic origin, however, face no greater risk of developing breast cancer than the general population.

Secondly, treating genetic information differently from other health information fails to recognise that other equally sensitive, personally identifiable health information is in need of

185 Above, 183.

186 Above, n172: 23 and n183: 35.

187 Above, n183: 35.

188 Above, n183: 35.
an equivalent level of protection. Such information may include, for example, information about an individual’s mental health, HIV status, the existence of an STD, or other stigmatising conditions.\textsuperscript{189}

Finally, Rothstein argues that treating genetic information separately from other health information for privacy/disclosure purposes is “...infeasible, if not totally impossible”.\textsuperscript{190} Rothstein identifies the logistical nightmare that would necessarily follow if health practitioners were required to make distinctions between genetic and non-genetic information in an individual’s medical record if both forms of information were subject to different disclosure provisions. The impossibility of such a practice becomes apparent when considering conditions that have both genetic and non-genetic origins, where it is impossible to disclose information about one set of information and not the other. As stated above, genetic information and traditional medical information are part of a continuum and cannot always be easily distinguished.\textsuperscript{191}

This problem is emphasised when one attempts to develop an effective working definition of "genetic information" for the purpose of regulating and protecting such information separately from other medical information. That is:

(a) “Genetic information” can be defined narrowly, for example, as:

any information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or makers, and which has been obtained:

(i) from an analysis of the individual’s DNA; or

(ii) from the analysis of the DNA of a person to whom the individual is related.\textsuperscript{192}

\textsuperscript{189} Above, n172: 23.

\textsuperscript{190} Above, n183.

\textsuperscript{191} Above, n172: 32.

\textsuperscript{192} Definition of “genetic information” in the proposed Genetic Privacy Act in the United States: Above, n168: 362.
This definition does not cover a vast amount of genetic information that is not derived specifically from a genetic test (the analysis of an individual’s DNA). A narrow definition of genetic information would therefore create inconsistencies in the protection of information that is essentially the same as that obtained from a DNA analysis. Rothstein uses the example of information that indicates a risk for Huntington’s Disease to illustrate these inconsistencies.\(^{193}\) He notes that where an individual’s medical record contains a notation that his or her father died of Huntington’s disease, this indicates that the he or she has a fifty-percent chance of developing the invariably fatal disorder. Despite being genetic information per se, it would not fall within the narrow definition of “genetic information” outlined above. These inherent problems in adopting a narrow definition of genetic information are illustrated if one considers the effect of granting absolute privacy protection over genetic information but not over traditional health information,\(^{194}\) that is:

(i) If an individual tests positive for Huntington’s Disease, under the above scenario, no circumstance would give rise to that information being lawfully disclosed to, for example, that individual’s genetic relatives.

(ii) If, on the other hand, an individual’s mother or father dies of Huntington’s Disease, and that information is on his or her medical record, under the above scenario, such information would not be genetic information because the information was not obtained from DNA analysis. Accordingly, circumstances may exist where the fact that that individual is at risk of developing Huntington’s Disease might be disclosed to his or her genetic relatives, employers or insurers (ie where an exception under health information privacy legislation allows disclosure of health information but not genetic information).

(b) Alternatively, “genetic information” could be defined broadly as including, for example:

any information about an identifiable individual, or about a person to whom that individual is related, which enables inferences to be drawn about the presence, absence, alteration or mutation of a gene or genes.\(^{195}\)

\(^{193}\) Above, n183: 33.

\(^{194}\) Note, this example is used for illustrative purposes only, and does not reflect the law in New Zealand.

\(^{195}\) Definition drafted for illustrative purposes.
This broad definition would also raise difficulties if the hypothetical scenario in paragraph (a) above is applied, ie granting absolute privacy protection over "genetic information" but not over traditional health information. This is because genetic components are continually being discovered in the many diseases, including, among others, common multi-factorial disorders such as heart disease, cancer, or osteoporosis.196

A broad definition of genetic information would include information about predispositions to any disease known to have a genetic component, thus eventually giving most medical information a level of absolute privacy protection, even where justifications exist for limiting privacy in relation to health information. Rothstein aptly states "if we ever could separate genetic from non-genetic medical information, that day has long since passed".197

Rothstein concludes that these examples illustrate that regulating and protecting genetic information separately from other medical information is not viable for the practical reason that it is impossible to develop a working definition for "genetic information".198

3.3.6. Lessons to Be Learned From HIV

Analysing the differential treatment of human immunodeficiency virus (HIV) in comparison to other infectious diseases provides an example of a non-genetic medical condition that produces the same concerns that are now at the centre of the debate regarding whether or not genetic information should be afforded special legal status. An examination of the concept of "HIV exceptionalism", and the move away from treating HIV/AIDS differently to other infectious diseases provides potential insight into the way genetic information ought to be treated.

HIV exceptionalism was a phrase used "to distinguish the policies that had emerged in the face of the AIDS epidemic from more conventional approaches to public health issues".199 In

196 Above, n183.

197 Above, n183.

198 Above, n183: 33.
the beginning of the HIV/AIDS epidemic, issues such as: (a) fear about discrimination against those identified as having HIV; (b) the psychological burden of diagnosis without therapy; and (c) the violation of privacy rights involved in compulsory identification or disclosure of HIV positive results, led to the decision in the United States to approach HIV/AIDS differently from other major infectious diseases.200

The distinctive treatment of HIV was reflected in the methods used for the medical management of the virus. Practices such as pre- and post- HIV test counselling, the development of specific consent forms for HIV testing, and stringent requirements for confidentiality of HIV test results, illustrate the unique approach taken in dealing with the disease.201

The distinctive treatment of HIV/AIDS from other infectious diseases, however, did not last. A change in approach (that is, away from HIV exceptionalism) took place as therapeutic advances were made that raised possibilities of managing HIV-related opportunistic infections and slowing the course of HIV progression.202 These therapies heightened the importance attached to early identification of those infected with HIV, as well as a willingness to consider traditional public health approaches to screening, reporting and partner notification.203

Eventually, HIV and AIDS treatments were integrated into mainstream medical practice, and the rules surrounding clinical practice in testing for and treating the disease were no longer afforded “exceptional” legal protection or status. For example:

(a) The initial consensus that HIV testing should only be performed with an individual's informed, voluntary and specific consent was eventually replaced with the view that HIV antibody tests should be treated like other blood tests, where consent of the

199 Ronald Bayer. "Clinical Progress and the Future of HIV Exceptionalism" (1999) 159 Archives of Internal Medicine, 1042, 1042.

200 Above, n199.

201 Above, n178: 141.

202 Above, n199.

203 Above, n199.
individual is presumed, after the medical significance of identifying those with early HIV disease became apparent.\textsuperscript{204} 

(b) Therapeutic advances also saw a change in attitude regarding the appropriateness of naming those individuals infected with HIV. In the early days of the epidemic, people saw a need for increased patient confidentiality and privacy in AIDS cases because of legitimate concerns about the public reaction to the disease, and the need to ensure people were not reluctant to seek clinical care. The practice of reporting AIDS cases to confidential state public health registries (as is the practice in respect of other infectious diseases) was, nevertheless, generally accepted when people began to accept that HIV reporting would ensure effective treatment, reduce the transmission of the virus, and bring about an effective and necessary partner notification program.\textsuperscript{205} 

Thus, the development of effective therapeutics was a major force behind a change in policy that led to a move away from HIV exceptionalism.\textsuperscript{206} 

Whilst the “HIV/AIDS epidemic” and the “genetic era” are at different stages of development, and will not necessarily evolve in the same way, a lesson can be learned from the move away from HIV exceptionalism. That is, it is possible to manage new medical/scientific issues under existing frameworks, provided that any new legal or practical issues that arise in respect of the new medical or scientific phenomenon are considered and appropriately integrated into the existing framework. This is as opposed to either: 

(a) forcing new issues to be dealt with under a framework that does not “fit”; or 

(b) creating a whole new framework to govern the new issues that may lead to inconsistent treatment with other health information that is potentially inappropriate. 

3.4. Conclusion: an integrated approach

From my analysis of: (a) the arguments postulated by proponents of and opponents to genetic exceptionalism; and (b) the move away from treating HIV/AIDS differently to other
infectious diseases, I conclude that an integrated approach to the legal treatment of genetic information is most appropriate. That is:

(a) there is no clear distinction between health information and genetic information that justifies the special legal treatment of genetic information, so genetic information should be dealt with as a component of health information under existing health information privacy law; but

(b) some features of genetic information (such as its familial nature) are not likely to be adequately recognised under existing health information privacy law (which, as illustrated in chapter five, is very individualistically focussed), and give rise to potential conflicts in relation to access to and use of genetic information.

Accordingly, these conflicts should be examined in the context of existing health information privacy law, and a determination made as to whether health information privacy law needs to be amended to resolve these conflicts (as they apply to health information generally, rather than developing genetic specific legislation).

The next section of this chapter examines the nature of the potential conflicts that arise due to the familial nature of genetic information.

4. COMPETING INTERESTS IN GENETIC INFORMATION

The key reason that genetic information raises new issues in relation to health information privacy is that it relates not only to the individual from whom it was obtained, but also his or her genetic relatives.

207 This approach is consistent with the approach taken by the Australian Law Reform Commission in its report regarding the protection of human genetic information: Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia - Report 96* (ALRC, Sydney, 2003), 140-142.

208 The Australian Law Reform Commission aptly states that "potential privacy conflicts that arise in the clinical use of genetic information usually have to do with the familial nature of the disorder or information as opposed to the genetic nature." Above, n207: 238.
The new issues that arise in relation to health information privacy as a result of increased knowledge and use of genetic testing (and resulting genetic information) and that I focus on in this thesis are the potential conflicts between an individual’s:

(a) rights to privacy in relation to genetic information and his or her genetic relatives’ interest in knowing such information; and

(b) desire to share his or her genetic information with genetic relatives, and their wish to remain ignorant.

In this section I briefly: (a) outline why these potentially competing interests pose a challenge under existing health information privacy laws; and (b) examine the nature of each interest, so as to provide a foundation for assessing how the respective interests of individuals and genetic relatives are protected under existing health information privacy law.

4.1. Challenging the basis of privacy protection

The familial nature of genetic information challenges the Western liberal tradition of both law and ethics of focussing on the rights of the individual with minimal interference by others.

The fact that genetic information:

(a) reveals information about an individual and his or her genetic relatives; and

(b) where known to an individual and his or her genetic relatives, can in certain circumstances either:

(i) enable that group of people to seek regular screening for the presence of genetic diseases; and/or

(ii) lead to the early detection and, where available, treatment of disease,

means that sharing genetic information within the genetic family can be extremely important.

While most individuals who have a genetic test will consent to the disclosure of information obtained from that test to at-risk genetic relatives, there may be circumstances where an individual refuses to disclose or consent to the disclosure of his or her genetic relatives, for example where: (a) the relationship between the individual and his or genetic relatives is dysfunctional; or (b) where an individual does not want, for one reason or another, his or her
genetic relatives to know he or she is suffering from a genetic disease. In these circumstances, however, both the individual tested and his or her genetic relatives may have equally valid claims to such information. This is not necessarily reflected in individualistically framed laws.

4.2. The nature of the competing interests

Understanding the competing interests to genetic information is essential in order to examine whether existing health information privacy law protects:

(a) an individual’s interest in genetic privacy and confidentiality;
(b) the comparably important interest his or her genetic relatives may have in knowing this information; and
(c) genetic relatives’ rights “not to know” their genetic information.

My analysis of the nature of these competing interests is set out below.

4.2.1. Privacy vs knowledge

As a starting point for examining the nature of competing interests in genetic information, Laurie draws on the common language definition of “interest”, in particular:

a claim that a benefit can come to the party in question by recognising that she or he has a significant, or potentially significant, relationship with the subject of our attention, which in this case is genetic information.209

Further to that definition, Laurie explains that the perspectives which might form the basis of one’s relationship with genetic information could be personal, societal, economic and/or paternalistic.210 The personal basis of one’s relationship with genetic information (ie that the information is about the person and/or might affect him or her in his or her personal capacity) is of particular relevance to the competing interests discussed in this thesis,


210 Above, n209.
Using Laurie's approach, the above definition of interest, and in particular the notions of 'benefit' from knowing, and 'relationship' with, genetic information, as a starting point, I discuss below when and whether an individual and/or his or her genetic relatives might have an interest in genetic information.

It is clear that an individual who undergoes genetic testing has a significant interest in knowing the resulting information. That is because such information was obtained from, and directly relates to, him or her and can have a significant impact on his or her life and/or health. As Laurie notes, "[b]ecause of their status as moral agents, respect is due to them, their wishes, and their interests concerning such inherently personal material".211

Genetic relatives may be able to claim an interest in such genetic information for the same reasons, ie that the results of an individual's genetic test might also reveal information about his or her genetic relatives, which may have an impact on the life and/or health of those genetic relatives.

The fundamental difference between the two interests lies in the conscious decision of the individual who has been tested to acquire the information.212 But should this difference prevent an individual's genetic relatives from knowing information about them where that information may be of considerable benefit (as discussed above), but where the individual who underwent the testing refuses to disclose that information?

While the genetic relatives of an individual who has had a genetic test certainly appear to have a valid claim to the resulting genetic information, the strength of this claim may vary according to the circumstances of the case, ie how much benefit will result through knowing the genetic information in question, and how this benefit compares to the potential harm caused as a result of the privacy intrusion which will necessarily result from the disclosure of that information.

For example, a genetic relative of the individual tested may benefit from learning of an impending genetic disorder where he or she is able to undergo screening or effective preventative treatment. On the flipside, an intrusion into the privacy of the individual tested may result in negative psychological implications for that individual. Further, where no

211 Above, n209: 115.

212 Above, n209: 116.
treatment is available, a genetic relative of the individual tested may suffer more harm than good from learning about his or her risk of developing an impending, untreatable disease. On the other hand, an individual may benefit where his or her wishes and values are supported, for example, his or her desire to maintain privacy in his or her genetic information.\textsuperscript{213} The American Society of Human Genetics provides further examples of harm that may arise from either disclosure or non-disclosure of genetic information. In particular, it notes that:

(a) Harm from disclosure may include:

(i) psychological, social and financial harm;

(ii) the possibility of stigmatization, discrimination and labeling; and

(iii) the potential to either lose or encounter difficulty in obtaining employment or insurance.

(b) Harm from non-disclosure may involve:

(i) limited opportunities for treatment or prevention of the genetic condition; or

(ii) in terms of reproductive choices, children who would otherwise have been spared the effects of a genetic condition will have to bear them, and couples who would otherwise choose not to conceive would be deprived of the option.\textsuperscript{214}

If disclosing an individual's genetic information to a genetic relative would enable that relative to take action to avoid a serious risk to their life or health, it is possible for that relative to assert a strong moral right to such information. This situation satisfies each component of establishing an 'interest' in the genetic information. In particular, that genetic relative would benefit from knowing the information, has a significant relationship with the information, and the harm caused by an intrusion into individual privacy is likely to be outweighed by any such benefits (provided the disclosure is strictly limited to the genetic relative and his or her health practitioner).


Alternatively, if the benefit received from knowledge of the information does not outweigh the harm caused by intrusion into privacy, or where no clear benefit exists from knowing the information, genetic relatives are unlikely to have a valid claim to the information.

Where the interests of two individuals conflict, a decision must be made as to how to avoid the greater threat of harm.

4.2.2. The Right Not to Know.

Balancing the competing interests of individuals and their genetic relatives' in genetic information is complicated. Not only is it important to assess whether disclosing genetic information results in the greatest benefit or avoidance of harm when fulfilling an individual's (or his or her genetic relatives') "right to know", but it is also necessary to consider whether an individual may in fact have a legitimate "right not to know" their genetic information, and how best to realise this interest.

The Australian Law Reform Commission defines the "right not to know" as:

the right people should have to be protected from information that their own bodies can yield, based on the principle of respect for autonomy.

The issue of the right not to know arises where knowing one's genetic information cannot be used to prevent or screen for a genetic disease for which treatments are available. For example, where a genetic test reveals that an individual and (potentially) his or her genetic relatives are carriers of a genetic mutation associated with a terminal disease, they might not want to know their disposition because: (a) nothing can be done to avert the potential harm; (b) knowing the information deprives them of the ignorance of when and how they will die; and (c) they may live in constant fear of its onset.

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215 Note, where no benefit exists from knowing genetic information, and where knowledge of genetic information may in fact cause harm (for example, psychological harm), genetic relatives may be able to assert their right not to know.

216 Above, n213: 15.

217 Above, n207: 240.

4.2.2.1. Problems inherent in recognising a "right not to know"

The problem inherent in recognising one's right not to know, is the inability to know whether or not an individual wants to exercise their right, without inadvertently disclosing a degree of (potentially unwanted) information. There are three ways that this problem could be minimised.

First, the Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria noted that there should be a strong presumption that relatives will be grateful for being warned in relation to genetic conditions where virtually all who carry the gene mutation develop the disorder, and in which the disorder can be prevented. Genetic disorders of this variety, however, are rare. As such, this presumption, whilst useful in certain scenarios, cannot be broadly applied.

Secondly, in situations where the presumption explained above cannot apply, the Australian Office of the Federal Privacy Commissioner suggested that "in some families the person best qualified to make a particular decision regarding disclosure to a relative is another member of the family or even a friend of the family". In this scenario, it is also important that the family member responsible for the disclosure is appropriately supported (that is, by a genetic counsellor) in making the decision regarding whether or not to disclose the information to others. The above scenario would not apply in circumstances where the individual who underwent testing refuses to consent to the disclosure, of his or her genetic information.

Thirdly, in situations where the first and second scenarios cannot or do not apply, it would be up to the health practitioner to assess whether or not to inform at-risk relatives. This would require the health practitioner to: (a) identify of any at-risk relatives; (b) consider the amount and nature of information the at-risk relative may be willing to accept, and whether he or she would want to exercise his or her right not to know (which may be impossible where relatives do not attend the same health practitioner); and (c) assess whether disclosure would amount to a justified exception to their duty of confidentiality.

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219 For example, FAP. See above, n207: 551.

220 Above, n207: 551.

221 Above, n207: 551.
The Australian Law Reform Commission points out that, in order to recognise an individual's right not to know his or her genetic information, it is important that any disclosure provisions are framed in a way that does not encourage information to be inappropriately disclosed in an overzealous attempt to comply with the requirements of the legislation.\textsuperscript{222}

Thus, it is important that any common law or statutory exceptions to privacy:

(a) Allow the disclosure of genetic information in certain, defined circumstances, for example:

(i) where such disclosure can prevent or lessen serious harm to the recipient; and

(ii) the benefit to the recipient outweighs any harm resulting from interfering with another individual's privacy.\textsuperscript{223}

(b) Does not compel disclosure of genetic information in all circumstances.

(c) Require the relevant party to consider genetic relatives' right not to know genetic information.

Whether this is reflected under New Zealand health information privacy law is discussed in chapter five.

5. \textbf{FOUR MODELS OF DISCLOSURE}

Having examined the nature of the potentially competing interests in genetic information (that is, between individuals and their genetic relatives), it is now necessary to determine the best way to achieve an appropriate balance between those claims to genetic information. The following examination and critique of four possible ethical frameworks in relation to the disclosure of genetic information:\textsuperscript{224}

(a) illustrates where the balance of rights lies under each; and

\textsuperscript{222} Above, n207: 240.

\textsuperscript{223} Note, the circumstances in which the law should allow the disclosure of genetic information are discussed in more detail in chapter seven.

\textsuperscript{224} Above, n214: 477.
(b) outlines some of the benefits and disadvantages of each in terms of the protection of individual and familial interests.

This exercise provides a backdrop against which to assess the effectiveness of the current law in terms of protecting both familial and individual interests.

Each position is considered below, and is examined in terms of its effectiveness in protecting both individual and familial interests to genetic information.

5.1. Model One: Confidentiality is absolute

In the first ethical model, confidentiality is absolute. Health practitioners would be obliged to inform patients who are undergoing gene testing about the potential impact their genetic information may have on relatives. They would, however, be prohibited from disclosing such information to their patients' genetic relatives. No exceptions would exist under this model. Any disclosure of genetic information would be considered unethical.225

This model is in direct contrast to the purpose of this thesis, which is to find an appropriate balance between individual and familial claims to genetic information in a way that protects individual privacy without denying the interests of genetic relatives in knowing such information.

5.2. Model Two: Disclosure is permitted in some circumstances

Under the second ethical model, disclosure of genetic information is permissible in certain circumstances. A number of overseas organisations have adopted the position whereby, if a patient refuses to inform at-risk family members, disclosure by a health professional is allowed when (a) reasonable efforts to encourage voluntary consent to disclosure have been unsuccessful; (b) it is highly likely that harm will occur if the information is not disclosed, and that the information that is divulged will be used to avert harm; (c) the harm to identifiable individuals that is likely to result from non-disclosure would be serious; and (d)

225 Above, n214: 477.
reasonable precautions are taken to ensure that only the genetic information needed for
diagnosis and/or treatment of the disease in question is disclosed.226

This paradigm requires health practitioners to undertake an extensive analysis in weighing up
the necessity of disclosing information so as to ensure that disclosures are only made where it
is considered essential to protect at-risk family members of the individual tested. While this
places some limitations on the protection of individual privacy, it only does so to the extent
necessary to recognise the interests of genetic relatives in knowing the information. On this
basis, a permissive approach to disclosure provides an effective balance between familial and
individual claims to genetic information.

5.3. Model three: Disclosure is inevitable in some circumstances

The third ethical model involves warning the patient, before testing takes place, about
situations where disclosure of genetic information to relatives will occur.227 In this situation,
the exceptions to confidentiality would be outlined in advance, and if the patient was not
willing to consent to such disclosure, they would have the option of not proceeding with the
genetic test. This position suggests that the health practitioner would actually disclose the
information to relatives where the disease in question is serious and either treatable or
preventable. That is, it goes beyond merely encouraging the patient to make the disclosure
him or herself.

Warning a patient in advance about circumstances that may result in disclosure of genetic
information to other family members: (a) provides the patient with a degree of control over
his or her genetic information, in that he or she can refuse to undergo the test if unhappy about
the proposed disclosures; but (b) still permits for disclosure to genetic relatives in certain
situations, such as where it is necessary to prevent or lessen harm.

The consequences of adopting this model of disclosure are as follows:

226 Organisations who have adopted this position (or similar positions) include the Institute of Medicine
Committee on Assessing Genetic Risks (America), the Science Council of Canada, the Medical Research

227 Above, n214: 478.
(a) Genetic relatives of the individual tested will always be informed of important genetic information that arises as a result of any genetic test, subject to certain considerations (such as the severity of the genetic disease in question, the availability of preventive measures, and the likelihood of the genetic relatives experiencing, and the extent of, any anxiety, if informed).

(b) Individuals may be deterred from undergoing genetic testing, even though such testing might be of significant benefit to him or her, or to his or her genetic relatives.

Despite (b) above, provided the individual who proposes to undergo genetic testing is informed prior to the testing that his or her information will be disclosed where certain criteria are met, model three could offer a satisfactory balance between individual and familial interests. This is because:

(a) The individual who proposes to undergo genetic testing retains control over whether or not his or her genetic information is disclosed by choosing to proceed with having the test or not (provided also that he or she has been adequately informed of the benefit that could result from having the genetic test, or harm that could result from not having it). Accordingly, the individual’s (no-absolute) right to privacy is recognised.

(b) Genetic relatives of that individual will always be informed of important genetic information, but only where there is a clear benefit, which objectively outweighs the potential harm, in doing so. Accordingly, the genetic relatives’ interest in knowing genetic information is recognised, and their interest in not knowing the genetic information is recognised, to the extent possible.228

5.4. Model Four: Disclosure is mandatory

The final paradigm would oblige rather than permit health practitioners to warn genetic relatives of harm in the situations outlined in the second ethical position.

228 Refer to paragraph 4.2.2.1 above for an explanation of the problems inherent in recognising one’s “right not to know”.
Imposing a *duty* to warn at-risk genetic relatives of potential harm in the situations described in the second ethical position, goes against current policy considerations in New Zealand,\footnote{229} and ignores the existence of one's "right not to know" genetic information. Such countervailing policy issues are likely to prevent such an obligation from becoming an ethical or legal standard in New Zealand.\footnote{230} Moreover, it does not appear to offer an appropriate balance between individual and familial interests in genetic information, because such a duty may interfere with an individual's privacy and autonomy to a greater extent than is necessary to achieve adequate protection of the interests of family members in knowing relevant genetic information, because health practitioners are not given the discretion to disclose in situations where disclosure may not be necessary. Further, it fails to recognise the rights of genetic relatives to remain ignorant about their genetic status.

5.5. **Conclusion: disclosure at the discretion of the health practitioner**

An examination of these four possible ethical models indicates that giving health practitioners the *discretion* to warn at-risk genetic relatives in certain circumstances (that is where disclosure can prevent or lessen serious harm to a genetic relative of the individual tested, and the benefit to the genetic relative outweighs any harm caused to the individual by disclosure) offers an appropriate balance between the competing interests in genetic information. Such a discretion would prevent information being inappropriately disclosed to genetic relatives in an "over zealous" attempt to comply with the requirements of a duty.\footnote{231} That is, if a health practitioner is given the discretion to disclose genetic information in certain situations, they may have a greater opportunity to assess whether or not genetic relatives might want to know that information, rather than being forced to comply with a legal duty, where disclosure is obligatory. For example, the Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria notes that a strong presumption can be made that relatives who are at-risk of

\footnote{229} See *Maulolo v Hutt Valley Health Corporation* [2002] NZAT 375, 383 where Wild J decided that the imposition of a duty to warn would place "an intolerable burden on [the clinicians], diverting them away from the patient's best interests and resulting in an overly cautious attitude". Also, the imposition of a duty to warn may have a negative impact on patients' willingness to seek genetic testing in the first place and has an overly paternalistic essence to it.

\footnote{230} The American Society of Human Genetics notes that an ethical duty can become a professional norm of practice even where no corresponding legal duty exists. Above, n214: 478.

\footnote{231} Above, n207: 240.
developing a condition like FAP, in which virtually all who carry a gene mutation develop cancer, and in which the cancer may be prevented, will be grateful for being warned.\textsuperscript{232} Hence, if the circumstances in which disclosure is permitted are limited to situations where it is necessary to lessen or prevent a serious risk, and where clinical interventions are available for lessening or preventing serious risk, it is reasonable to assume that in most circumstances an individual would want to be informed of the risk and the treatment options. A health practitioner who has experience in dealing with such disclosures may, in some instances, have the opportunity to make more informed presumptions, rather than having his or her behavior dictated by a stringent duty.

Thus, giving health practitioners the discretion to disclosure genetic information to at-risk genetic relatives provides them with an opportunity to weigh up whether potential harm from disclosure is outweighed by potential harm from non-disclosure, and to make a decision depending on where the balance lies. Moreover, it does not deny familial interests in genetic information by making individual privacy absolute. Hence, for the reasons discussed at paragraphs 5.2 and 5.3 above, a combination of the second and third ethical models, under which disclosure is permissible in certain circumstances, but where no duty to warn is imposed, and the patient is made aware of those potential disclosures before testing occurs, seems to provide an answer as to how best to achieve (from an ethical perspective) an appropriate balance between individual and familial interests in genetic information.

6. **SUMMARY AND CONCLUSION**

Genetic information is complex. This is reflected in the multitude of necessary legal and ethical considerations alluded to in this chapter when considering the most appropriate way to treat genetic information.

From the above analysis, it seems that an integrated approach to the protection of genetic information is most appropriate, that is recognising that genetic information is not so different to other sensitive medical data so as to justify special/increased legal protection, but that some features of genetic information nevertheless raise important issues in relation to protecting health information which require recognition.

The familial nature of genetic information is one of the features of genetic information which raises such issues. It gives rise to potentially competing interests between:

(a) An individual's rights to privacy and his or her genetic relatives' rights to know their genetic information where such knowledge would potentially enable them to avoid harm and suffering.

(b) An individual’s desire to share information with his or her genetic relatives and the genetic relatives’ interest in not knowing it.

When determining how best to deal with these competing interests, it is necessary to assess the benefit and harm that may be experienced if an individual’s genetic information is disclosed (or not). In making such an assessment, the primary consideration should be which course of action gives rise to avoidance of the greater threat of harm.

Examining ethical models in relation to the disclosure of genetic information provides a useful starting point for assessing whether existing health information privacy laws achieve an effective balance between the protection of both individual and familial interests. Out of the four ethical frameworks examined, two recognise: (a) both an individual's interest in maintaining privacy in his or her personal genetic information, and the interests his or her genetic relatives may have in knowing relevant genetic information; and (b) the existence of a genetic relative’s right to remain ignorant about his or her genetic status. The common feature of these two frameworks is the discretion conferred on the health practitioner to disclose genetic information to genetic relatives in certain circumstances.

Having: (a) identified the nature of genetic information and the potentially competing interest involved; and (b) determined that a combination of the second and third ethical models (which involves warning the patient, before genetic testing takes place, about situations where disclosure of genetic information to his or her genetic relatives will occur, therefore enabling the patient to proceed with the genetic test on that basis or not) offer the most appropriate balance between the competing interests involved, I now have a useful foundation upon which to examine existing health information privacy laws, and to assess their effectiveness in providing an appropriate balance between individual and family interests in genetic information.

The following chapter provides a comprehensive analysis of New Zealand’s existing health information privacy law, its application to genetic information, and the extent to which it
addresses the competing interests that necessarily arise between an individual and his or her genetic relatives in relation to the collection, use and disclosure of genetic information.
CHAPTER 5

EXISTING LAW IN NEW ZEALAND IN RELATION TO THE DISCLOSURE (OR NOT) OF PERSONAL GENETIC INFORMATION

Over himself, over his own body and mind, the individual is sovereign.\textsuperscript{233}

1. INTRODUCTION

Genetic information, as a component of health information, is protected by the long-standing tradition of privacy and confidentiality within the physician-patient relationship.\textsuperscript{234} As discussed, however, the familial nature of genetic information (as compared to non-genetic health information) allows inferences to be drawn about persons other than the individual from whom the information was obtained, i.e., that individual's genetic relatives. Thus, two possible conflicts arise when dealing with genetic information. First, there is a tension between an individual's privacy interest in his or her genetic information, and a genetic relative's interest in knowing or accessing such information where it can be used to avert harm. (This tension is referred to throughout this thesis as "the right to know"). Secondly, there is a tension between an individual's desire to share his or her genetic information, and his or her genetic relatives' interest in not knowing it. (This tension is referred to throughout as "the right not to know").

Examining these potential conflicts from a legal perspective raises questions as to: (a) when an individual can claim a legitimate interest in or right to privacy and/or confidentiality; (b) whether that interest or right is absolute; and (c) how to protect a "right not to now".

In Part A of this chapter I explore the concepts of privacy and confidentiality, and the ethical principles that underlie both concepts.

In Part B of this chapter I go on to:

(a) examine how the existing laws in New Zealand governing health information privacy and confidentiality apply to personal genetic information, looking specifically at the potential conflicts outlined above; and

(b) discuss whether or not an appropriate balance is achieved between an individual’s and his or her genetic relatives’ competing interests under the current legal regime in New Zealand.

Finally, in Part C, I demonstrate that New Zealand’s health information privacy law is individualistically framed by applying it to the hypothetical clinical scenarios set out at Appendix One, and in Part D I conclude that New Zealand’s health information privacy law requires amendment.

234 Note, most health information is inherently private because of its intimate and often sensitive nature.
PART A

2. THE RIGHT TO PRIVACY

2.1. The development of privacy as a distinct legal right

Before the end of the 19th Century, privacy as a distinct legal right did not exist in British Common Law, nor was it a right under the U.S. Constitution.

Modern legal interest in the protection of privacy in America had its roots in the famous Warren and Brandeis article of 1890, which proposed that a right to privacy existed that was separate from rights of property, contract and trust, and sought to protect the individual's right to be let alone. The proposed injury from breach of such a right was regarded as the consequent mental anguish that would result from an intrusion into one's private life. The right of privacy was eventually adopted in American common law through the introduction of several torts dealing with the invasion of privacy. It also received Constitutional protection.

English privacy law, on the other hand, developed later in the twentieth century as a response to the information age. In particular, a concern for personal privacy developed as part of the commitment to individual rights seen in the United Kingdom in the late 1960s and early 1970s. During this period, various privacy Bills were introduced into the United Kingdom Parliament. It was not until 1984, however, that the United Kingdom's first Data Protection Act was enacted.

Parallel developments took place in:

235 Note, however, that aspects of privacy attracted legal protection through other Common Law and equitable actions, such as breach of confidence, trespass, and passing off. Common Law and equitable actions in relation to breach of confidence are discussed further at paragraphs 5.1 and 5.2 below.


238 Note, personal privacy encountered some early resistance in evolving as common and legislated law, but eventually came to be recognised: see above, n 236: 48.

(a) New Zealand, with the enactment of the Privacy Commissioner Act in 1991, followed by the Privacy Act in 1993 (which repealed the Privacy Commissioner Act 1991). In particular, the Privacy Act 1993 proposes to "promote and protect individual privacy".

(b) Australia, with the enactment of the Privacy Act (Cth) 1988.

Development of privacy protection laws in New Zealand, England and Australia mirrored international developments, including, in particular:

(a) The recognition of the right to the protection of the law against arbitrary interference with one’s privacy, family, home or correspondence under the Article 12 of the Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948.

(b) The recognition of the right to private and family life as a fundamental right under Article 8 of the European Convention for the Protection of Rights and Fundamental Freedoms, adopted in 1950 by the Council of Europe.

(c) The adoption of an identical provision to Article 12 of the Universal Declaration of Human Rights in Article 17 of the International Covenant on Civil and Political Rights by the United Nations General Assembly in 1966.

(d) The adoption of guidelines governing the protection of privacy and transborder flows of personal data by the Organisation for Economic Co-operation and Development on 23 September 1980.

(e) The adoption of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data by the Council of Europe on 28 January 1981.

Thus, privacy is now recognised as a distinct legal right, with sensitive information being protected simply as an interest worthy of legal protection.

240 Privacy Act 1993, s 129(2) and Schedule 7.

241 Privacy Act 1993, Long-title. Note, under New Zealand common law, the existence of a right to privacy, enforceable by a cause of action in tort for invasion of privacy has recently been accepted. See paragraph 5.2.1 below for a brief discussion on why this tort is unlikely to apply in the context of the disclosure of an individual's genetic information, without his or her consent, to his or her genetic relatives.
2.2. Defining privacy

Whilst privacy is now recognised as a distinct legal right, defining privacy per se is not straightforward.

Privacy is an extremely broad concept and encompasses a number of values including autonomy, anonymity, solitude, security, reputation and confidentiality. Privacy can therefore take on a range of meanings or types, depending upon the context in which it is being examined. Those meanings/types include:

(a) A decision based privacy right. This type of privacy right relates, for example, to the decision about whether to undergo pre-birth genetic testing or the continuation or termination of a pregnancy.

(b) The right to be let alone (also referred to as a non-molestation right, autonomy, self determination and/or self actualisation). This type of privacy right encompasses the "right not to know" one’s genetic risk.

(c) An information based privacy right. This type of privacy right encompasses the protection of personal (and genetic) information about an individual, and is the type of privacy protected, for example, under the Health Information Privacy Code 1994 (discussed later in this chapter).

(d) A property based privacy right. This type of privacy right encompasses, for example, claims for intellectual property in genetic knowledge.

This thesis examines privacy as it applies to genetic information (ie information that relates to more than one family member). The relevant privacy types in this context are, therefore, informational privacy (applicable when examining the collection and disclosure of an individual’s genetic information) and the right to be let alone (applicable when examining the concept of the right not to know one’s genetic risk).

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2.3. An informational privacy interest in genetic information

Both Westin and Wacks propose definitions of 'privacy' which, when applied in the relevant context, provide a useful explanation of what constitutes an informational privacy interest in genetic information.

At the outset of his book, Westin describes privacy as "the claim of individuals, groups or institutions to determine for themselves when, how and to what extent information about them is communicated to others". 243

Consistently, Wacks suggests that: 244

Instead of pursuing the false god of 'privacy', attention should be paid to identifying what specific interests of the individual we think the law ought to protect. And it is submitted that at the core of the preoccupation with the 'right to privacy' is the protection against the misuse of personal, sensitive information.

If we applying these definitions in the context of genetic information, according to Westin, an informational privacy interest in one's genetic information would constitute an individual's interest in determining to whom, and to what extent, their genetic information is disclosed to third parties (for example, at-risk genetic relatives). That is, it identifies the specific interests of the individual that the law ought to protect (as per Wack's definition). 245

2.4. The right not to know as a form of privacy interest?

Related to but distinct from an individual's informational privacy interest in genetic information, is his or her genetic relatives' "right not to know".

Applying Westin's and Wack's notions of privacy respectively, an interest in remaining ignorant about one's genetic information:

(a) Can be framed as an individual's specific interest in determining not to receive relevant genetic information.


245 Whether or not an interest in determining to whom and to what extent one's genetic information is disclosed to third parties is an absolute right, and whether or not it should be an absolute right, is discussed later in this chapter.
(b) Is inherently linked to the "core of the preoccupation with the 'right to privacy'" being the protection against the misuse of personal, sensitive information.

(c) Encompasses autonomy.

Whilst an interest in not knowing one's genetic information does not fit neatly within the concept of a privacy interest in every respect (eg, how does one determine not to receive genetic information when he or she does not first know of its existence?), the discussion below in relation to the ethical justifications for the right to privacy illustrate that the right to privacy and the right not to know are nevertheless related.

2.5. Privacy interests versus a privacy rights

Finally, it is important when examining individual privacy rights to note the distinction between a 'privacy right' and a 'privacy interest'.

That distinction is explained concisely by Davis as follows: "when protected by law, interests become rights".\(^\text{246}\) Thus, one may have an 'interest' in privacy, but no corresponding right unless that interest is protected by law.\(^\text{247}\)

On that basis, the purpose of this chapter is to examine the extent to which (if at all) the interests of an individual and his or her genetic relatives in relation to genetic information are protected by law and therefore attract corresponding rights.

3. THE RIGHT TO CONFIDENTIALITY

3.1. When does the right to confidentiality arise?

A person has a right to confidentiality where he or she imparts personal information of a confidential nature in circumstances where the recipient of that information owes an obligation of confidence. That individual is entitled to the expectation that his or her

\(^{246}\) Frederick Davis. "What Do We Mean by 'Right to Privacy'?" (1959) 4 South Dakota L. R. 1, 6.

\(^{247}\) Relevantly, applying this rule in a New Zealand law context, the privacy interests found in the Information Privacy Principles in the Privacy Act 1993 and the Health Information Privacy Rules in the Health Information Privacy Code 1994 only become "rights" (ie are only protected by law) when interfering with those interests results in some degree of harm or loss to the individual in terms of section 66(1) of the Privacy Act 1993. Accordingly, the risk of harm to the individual from whom the genetic information was originally derived is the operative principle in respect of whether he or she has a right to privacy in relation to his or her genetic information. That is, what constitutes a privacy right, as opposed to a privacy interest, is not dependent upon the definition of a "privacy right" but rather the consequences of interfering with one's
confidential information will not be divulged without his or her consent to others in ways that are inconsistent with his or her understanding at the time of the original disclosure.

3.2. The origin of the right to confidentiality

That obligation of confidence exists either by reason of the particular relationship between the parties, or in an express or implied term of a contract between the parties.

Both sources of the obligation are relevant to the obligation of confidence owed by a health practitioner to his or her patient. That is, the obligation of confidence imposed on health practitioners arises by way of the special nature of the doctor-patient relationship, and also, at times, by way of a contractual relationship between health practitioner and patient (ie in private practice). The obligation to respect a patient’s confidence has its roots in the Hippocratic Oath.248 (ie an oath taken by doctors before beginning their practice in medicine, which dates back to the fifth Century BC).

3.3. The difference between privacy and confidentiality

From the discussion above, it is apparent that privacy and confidentiality are similar but distinct concepts. The basic difference between the two concepts is as follows:

(a) A breach of confidence, ie an unauthorised disclosure of personal information, can only be made by a person who receives such information in confidence.

(b) Whilst a breach of privacy also involves the unauthorised disclosure of personal information, it is not necessary that such information was initially given in confidence for a breach to occur.

This thesis examines when a health practitioner can justifiably disclose genetic information to third parties (and in particular, genetic relatives). Thus, both concepts apply.249

privacy interest. Refer to paragraph 5.4.6 below for a discussion on such consequences, ie a discussion on what constitutes loss or harm in terms of section 66(1) of the Privacy Act 1993.

248 Below, n286.

249 Note, throughout the remainder of this thesis, both concepts are discussed interchangeably.
3.4. The importance of privacy and confidentiality in the doctor-patient relationship

Corkill states that “the doctor-patient relationship is the core of clinical medicine” and considers the essential ingredients of a good doctor-patient relationship to be communication, respect, confidentiality, professional honesty and trust.\(^{250}\)

Confidentiality and trust are inextricably linked, and are pre-requisites to the provision of effective treatment, ie:

(a) maintaining the privacy/confidentiality of a patient’s health information is essential to preserve trust between doctor and patient; and

(b) without trust in the doctor-patient relationship, patients might refuse to disclose important health information (which, in the present context, would be by way of agreeing to have a genetic test) unless they are confident that the doctor will not disclose the resultant information without his or her consent, which would place serious limitations on the doctor’s ability to provide effective treatment.

4. ETHICAL JUSTIFICATIONS FOR RULES OF PRIVACY AND CONFIDENTIALITY

The field of ethics, also known as moral philosophy, involves examining concepts of right and wrong behaviour. In the medical profession, laws set out what a health practitioner may or may not do, and often reflect what is considered to be appropriate conduct.\(^{251}\) Medical ethics regularly influence the interpretation of laws in a given clinical situation. For example, ethical standards are often used by the courts as a guide to what can reasonably be expected of a competent medical practitioner.\(^{252}\) Thus, before embarking on an examination of health privacy and confidentiality law in New Zealand as it relates to genetic information, it is useful to look at the ethical principles that underlie privacy and confidentiality and justify the existence of such rights/interests, and any exceptions to them.


\(^{251}\) Alistair Campbell, Max Charlesworth, Grant Gillet, & Gareth Jones, Medical Ethics, (2 ed, Oxford University Press, Auckland, 1997), 197.

\(^{252}\) Furniss v Fitchett [1958] NZLR 396, at 396.
4.1. Autonomy (self rule) as a justification for privacy

The word *autonomy* derives from the Greek terms *autos* (self) and *nomos* (rule or law), and essentially means freedom to determine one's own life without interference from others. John Stuart Mill saw personal autonomy and personal liberty as being interconnected. That is, to the greatest extent possible, individuals should be free to live their lives as they so desire, provided their actions do not harm others.

Beauchamp and Childress discuss the concept of "respect for autonomy" and note that an autonomous action occurs in situations where an individual acts: (i) intentionally; (ii) with understanding; and (iii) in the absence of controlling influences that determine their action. The principle of respect for autonomy therefore:

(a) requires one to acknowledge an individual's right to make decisions based on personal values and beliefs (that is, to act autonomously); and

(b) encompasses an individual's right to control the dissemination of his or her personal health information.

Respect for autonomy is therefore the primary ethical justification for the right to privacy.

The obligation of respect for autonomy may be recognised before or after a patient's genetic information has been obtained by a health care professional. If a patient is aware that some of their information derived in the course of diagnosis or treatment may be disclosed to certain individuals in some situations before they undergo testing or treatment, they are acting autonomously in choosing to go ahead with treatment provided that they are fully informed, have an adequate understanding, and are not coerced into agreeing to proceed with it. Likewise, the patient acts autonomously in intentionally authorising or declining access to their information after the information has been obtained, provided they were not coerced into doing so by another person.

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254 Phillipa Malpas, "The right to remain in ignorance about genetic information – can such a right be defended in the name of autonomy?" (August 2005) 118 The New Zealand Medical Journal, 1220.

255 Tom L. Baeuchamp and James F. Childress, Principles of Biomedical Ethics, (5 ed, Oxford University Press, New York, 2001), 59.

256 Above, n255: 297.

257 Above, n255: 296.
4.2. Ethical justifications for the right to confidentiality

Beauchamp and Childress propose that rules to protect confidentiality are justified on three grounds:

(a) First, consequentialist arguments (ie the ends justify the means) suggest that maintaining/protecting confidentiality is appropriate on the basis that if patients cannot trust health professionals to maintain confidentiality in their health information, they would be reluctant to fully disclose the information necessary to make accurate diagnoses, prognoses, or to recommend the best course of treatment.258

(b) Secondly, arguments based on rights to privacy and respect for autonomy can be used to justify a right to confidentiality. Breaches of confidentiality are often seen as violations of privacy and personal autonomy, and the value of maintaining privacy and autonomy themselves (as opposed to appealing to the consequences of such violations) support the rules of confidentiality.259

(c) Finally, confidentiality is justified based on a physician’s general obligation of fidelity. The obligation of fidelity requires health professionals to live up to a patient's reasonable expectations of privacy and confidentiality. According to this principle, if a health professional does not expressly renounce the express or implied promise of confidentiality, the patient has a right to expect it. A failure of fidelity therefore significantly undermines the doctor-patient relationship. On this ground, the obligation of fidelity justifies the patient’s right to confidentiality.260

None of these three arguments, however, propose that rules of confidentiality should be treated as absolute. As pointed out by Beauchamp and Childress, "when rules of confidentiality are used as absolute shields, they can eventuate in outrageous and preventable injuries and losses".261

258 Above, n255: 307.
259 Above, n255: 308.
260 Above, n255: 308.
261 Above, n255: 308.
4.3. Ethical justifications for limiting privacy and confidentiality

4.3.1. The non-absolute nature of autonomy as a justification for the disclosure of confidential information.

Although the existence rights to/interests in privacy and confidentiality are justified on the basis of the principle of respect for autonomy, it does not follow that privacy and confidentiality are absolute concepts. This is because respect for autonomy is not an absolute value in itself, and is sometimes overridden by competing moral considerations, in particular, the value of beneficence.\textsuperscript{262} For example, if our choices are likely to harm others, our right to exercise personal autonomy can be justifiably limited.\textsuperscript{263} Accordingly, recognition of the interests of family members in an individual's genetic information could potentially override autonomy. If an individual chooses not to disclose genetic information to a relative who is at risk of developing a preventable or treatable genetic condition, his or her autonomy may be justifiably overridden where doing so could prevent harm to the individual's relative.

Because the value of autonomy is not absolute, and because autonomy is used as a justification for the existence of rules of privacy and confidentiality, it follows that the rights of privacy and confidentiality are subject to justified limitations in certain situations, as discussed at paragraph 4.3.2 below.

4.3.2. Beneficence as a justification for disclosure or non-disclosure of confidential information

4.3.2.1. An overview of the principle of beneficence

Beneficence requires a doctor to achieve the best possible outcome for an individual patient. However, the principle of beneficence also encompasses concern for: (a) the safety of other identifiable individuals; or (b) public welfare.\textsuperscript{254} On that basis, ethical justifications for limiting privacy and confidentiality are generally based on the principle of beneficence.

\textsuperscript{262} Above, n255: 65.

\textsuperscript{263} Above, n255: 65.

The context of this thesis requires an examination of whether concern for the safety of other identifiable individuals (i.e., relatives of an individual who has been diagnosed with an identifiable genetic condition) justifies limiting an individual's right to privacy and confidentiality in relation to his or her genetic information.

A closer look at the principle of beneficence provides insight into why, how, and when such justifications should be applied, and whether the principle of beneficence justifies the disclosure of confidential information to the relatives of an individual with a known genetic condition, when not disclosing that information places those relatives at high risk of serious harm.

4.3.2.2. A closer look at beneficence

The principle of beneficence is a moral obligation to act for the benefit of others. It involves taking positive steps to help others rather than merely refraining from harmful acts. Examples of the general rules of beneficence include:

(a) preventing harm from occurring to others;
(b) removing conditions that will cause harm to others; and
(c) rescuing persons in danger.\(^{265}\)

The principle of beneficence is not absolute, and significant limits are placed on the scope of the obligation. We are not morally required to benefit all individuals on all occasions, even when we are in a position to do so.\(^{266}\) According to Beauchamp and Childress, directing the principle of beneficence to all persons would be "overly romantic and impractical".\(^{267}\) Moreover, they suggest that such a position is also perilous "because [such a standard] may divert attention from our obligations to those to whom we are close and indebted".\(^{268}\)

The limited nature of the obligation of beneficence means that we are generally only required to help or benefit those individuals who we have special relationships with or special

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\(^{265}\) Above, n255: 167.
\(^{266}\) Above, n255: 167.
\(^{267}\) Above, n255: 169.
\(^{268}\) Above, n255: 169.
commitments to. The limited nature of the obligation does not, however, preclude the obligation to rescue a stranger under conditions of minimal risk.

Whether a doctor has a duty to act for the benefit of his or her patient's relatives who are outside the doctor-patient relationship will depend on: (i) whether a special relationship exists between a health practitioner and his or her patient's relatives; and/or (ii) whether or not the physician has an ethical duty to rescue his or her patient's relatives.

(i) Special relationship between health practitioner and relative?

A “special relationship” arises when some kind of dependence or reliance exists between two people. The physician-patient relationship has long been considered a special relationship in the eyes of the law and society.

Whether or not a health practitioner is said to have a "special relationship" with a genetic relative of a patient, however, is not clear cut. Strictly speaking, there is no direct dependency or reliance between the genetic relative and the health practitioner. Additionally, the health practitioner's actions will not always have a direct influence on the genetic relative. This is because:

(a) First, the health practitioner, through his or her actions, cannot change the genetic make-up of an individual. Even in circumstances where the disclosure of relevant genetic information to a genetic relative provides the possibility of preventing or reducing the potential harm caused by a genetic mutation through early detection or treatment, there remains a lack of direct dependence or reliance on the health practitioner by the genetic relative.

(b) Secondly, disclosure by the doctor to the at-risk genetic relative is not the only way in which the genetic relative can be informed of their potential risk.

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269 Above, n255: 168.
270 Above, n255: 168.
271 ie by way of the Hippocratic Oath.
272 For example, early detection of FAP allows at-risk individuals to undergo frequent surveillance, thereby providing the opportunity for early detection and treatment of the disease.
The genetic relative of an individual with an identifiable genetic condition is only dependent upon the health practitioner (and then, only indirectly dependent) where:

(a) an individual fails to act benevolently, and refuses to inform their genetic relative(s) of his or her potential risk (which, in itself, is a breach of his or her ethical duty); and

(b) a health practitioner is aware that the at-risk relative(s) has not been informed.

While limited, arguably (given the potential dependence of the genetic relative on the health practitioner) the circumstances in (a) and (b) above give rise to a "special relationship" between the health practitioner and the genetic relative. Thus, in limited circumstances, a health practitioner has an ethical obligation to act with beneficence towards genetic relatives.

(ii) Ethical Duty to Rescue?

The standard example used to illustrate one's obligation to rescue involves a passer-by who observes someone drowning, but has no special moral relationship to that person.\(^{273}\) The passer-by has an obligation to act beneficently and attempt to rescue the drowning individual if it does not put him or her at significant risk. While there is no moral relationship, there is a critical relationship of another kind between the passer-by and the victim. That is, the passer-by is well placed to help the victim, without putting him or herself at significant risk, and as such has an obligation of specific beneficence.\(^{274}\)

Beauchamp and Childress state that an ethical obligation to rescue exists when the following conditions are satisfied:

(a) \(Y\) (for example, an at-risk relative) is at risk of a significant loss of or damage to life or health or some major interest.

(b) \(X\)'s (for example, the health practitioner's) action is needed (singly or in concert with others) to prevent loss or damage.

(c) \(X\)'s action has a high probability of preventing or lessening the potential loss or damage to \(Y\).

(d) \(X\)'s action would not present significant risks, costs, or burdens to \(X\).

\(^{273}\) Above, n255: 170.

\(^{274}\) Above, n255: 170.
(e) The benefit that Y can be expected to gain outweighs any harm, costs, or burdens that X is likely to incur.\textsuperscript{275}

In the drowning example above, all of Beauchamp and Childress's conditions (Conditions) are satisfied. (There are, however, obvious circumstances where the Conditions would not be satisfied, such as where the passer-by cannot swim and would drown if he or she attempted to rescue the victim.)

It goes without saying that an individual owes his or her genetic relatives a duty to warn them of their risk of developing genetic diseases in certain situations (ie where disclosing relevant genetic information has a high probability of preventing or lessening the effect of any harm caused by the genetic disease).

Whether or not a health practitioner has an ethical duty to rescue the at-risk relative of a patient (ie where the health practitioner obtains genetic information from his or her patient and therefore knows important genetic information about or the genetic risk faced by that patient's genetic relative or relatives) depends on whether the Conditions are satisfied in the circumstances, which in turn depends upon the genetic condition in question.

For the purpose of illustrating when such a duty might arise in the context of a health practitioner, it is useful to assess whether the examples in hypothetical clinical scenarios one and four (set out in Annexure One to this thesis), ie the scenarios at either end of the continuum, satisfy the Conditions.

The example in scenario one satisfies the first three Conditions on the basis that:

(a) The genetic relative is at risk of a significant loss of or damage to life or health or some major interest. That is, if the relative also carries the relevant gene, he or she will eventually develop cancer, which if not treated early, is terminal.

(b) The health practitioner's action (ie informing the relative of her risk where the health practitioner's patient refuses to do so) is needed to prevent or lessen the loss or damage, ie by enabling the relative to either: (i) be screened regularly for cancer before it develops; (ii) choose to undergo preventative surgery; or (iii) treated for cancer.

\textsuperscript{275} Above, n255: 171.
(c) The health practitioner's action has a high probability of lessening the potential loss or damage to the relative. In particular, if the health practitioner informs the relative of his or her risk, and that information leads to the relative undergoing screening for, or early detection of, colon cancer, the likelihood of him or her dying from it is likely to be significantly reduced.

In relation to the fourth and fifth Conditions respectively:

(d) Whether or not disclosing a patient's genetic information to an at-risk relative would present a significant risk, cost, or burden to the health practitioner depends upon the consequences to the health practitioner of breaching patient confidentiality. (At worst, the health practitioner will likely face disciplinary action and/or a complaint being brought against him or her under the Health Information Privacy Code.)

(e) That being the case, it would be difficult to argue from an ethical perspective (assuming that the value of life is placed above all else) that the benefit to the at-risk relative (ie significantly reducing his or her risk of death) would not outweigh the likely cost/burden to the physician. On that basis, the fifth Condition is satisfied.

Accordingly, in relation to Scenario One, the physician has an ethical duty to rescue an at-risk relative.

The example in Scenario Five fails to satisfy the Conditions on the basis that while the genetic relative of a patient with Huntington's disease faces significant health risks, the health practitioner cannot lessen that risk in any way by informing that relative of his or her risk. (In fact, informing that relative might give rise to psychological harm.)

The examples therefore illustrate that, in some circumstances at least, a health practitioner will have an ethical duty to inform the genetic relative of a patient of his or her genetic risk, even if no special moral relationship exists between the health practitioner and the at-risk genetic relative. (Though, as stated above, arguably a health practitioner does have a special ethical relationship with a genetic relative in some circumstances.)
4.3.2.3. **Conclusion: beneficence justifies the disclosure of confidential information in some circumstances**

On the basis that in some circumstances: (a) a "special relationship" exists between the health practitioner and the at-risk genetic relative of the health practitioner’s patient (albeit an indirect one); and (b) a health practitioner has an ethical duty to rescue an at-risk genetic relative, it follows that, in some circumstances a health practitioner has an ethical obligation of specific beneficence towards the genetic relatives of his or her patients.

Those circumstances are likely to be limited to those where: (a) the at-risk relative faces a risk of suffering from a potentially serious, but treatable, genetic condition; and (b) disclosure of an individual’s genetic information is required in order to prevent, lessen or treat the at-risk relative, such as the circumstances outlined in Scenario One.

It follows that in those circumstances the ethical obligation to rescue may justify limiting confidentiality and privacy of an individual to the benefit of an at-risk genetic relative, ie by disclosing an individual’s genetic information to that at-risk genetic relative.

4.4. **Are the ethical justifications for disclosing confidential information reflected in the law?**

Having now established that:

(a) individuals have a right to privacy and confidentiality in relation to their genetic information; and

(b) there are ethical justifications for both the existence and limitation (in certain circumstances) of those rights,

in Part B of this chapter, I explore the extent of, and relevant limitations to, the rights to privacy and confidentiality under New Zealand law. In particular I examine, justified legal limitations to privacy and confidentiality rights, and whether or not the rights of at-risk family members to know the genetic information of the individual tested are recognised at law.
5. **NEW ZEALAND PRIVACY AND CONFIDENTIALITY LAW**

Genetic information that reveals information about the health, or potential health of an individual falls within the broader category of health information. Accordingly, existing health information privacy and confidentiality rules apply to most types of genetic information.

There are a variety of mechanisms under New Zealand law which protect against the unauthorised disclosure of health information. Professional medical ethics, common law duties and legislative instruments including the:

(a) New Zealand Medical Association Code of Ethics;
(b) duty of care owed by doctor to patient under the common law;
(c) Privacy Act 1993;
(d) Health Information Privacy Code 1994;
(e) Health Act 1956;
(f) Official Information Act 1982; and
(g) Code of Health and Disability Services Consumers' Rights 1996,

all provide constraints on the collection, use and disclosure of health information.

As discussed above (see paragraph 4.3) however, patient confidentiality and privacy are not absolute concepts. This non-absolute nature of confidentiality and privacy is reflected in the law by way of the exceptions that exist in certain situations where the law permits disclosure of health information.

The purpose of the present section is to provide a comprehensive analysis of the regulatory framework in New Zealand in relation to the privacy and confidentiality of genetic

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276 Health Information Privacy Code 1994, Rule 4(1)(a). See also Health Act 1956, s22B; and Privacy Act 1993, s46(7).
information. In particular, I proposed to examine the circumstances (if any) in which the law permits the disclosure of an individual’s genetic information to his or her genetic relatives when they have an interest in knowing such information.

5.1. Professional medical ethics: a foundation for the law relating to patient confidentiality and the privacy of health information.

5.1.1. Medical Ethics in New Zealand

Ethical codes have provided guidance to members of the medical profession, and protection to patients, for centuries. The first ethical codes date back to the School of Hippocrates in 5th Century BC when doctors would take the Hippocratic Oath before beginning their practice in medicine. Such codes have evolved through constant revision and development, and through the consideration of modern ethical dilemmas.277

The New Zealand Medical Association (NZMA) has been involved in medical ethics since its inception in 1886,278 providing a Code of Ethics outlining the standard of ethical behaviour expected of New Zealand Medical Practitioners. The New Zealand Medical Association Code of Ethics (Code of Ethics) is applicable to all doctors in New Zealand. It lays down principles of ethical behaviour and provides recommendations for professional medical practice. The Code of Ethics is regularly revised in order to keep pace with developments in medicine and the changing social environment in which doctors practice.279 The current Code of Ethics was approved by the NZMA on 27 March 2002. It is currently under review.280


280 On 1 October 2007, Dr John Adams, chairman of the NZMA Ethics Committee sent a letter to all NZMA members enclosing a draft revised Code of Ethics, seeking comments as part of the consultation process undertaken by the NZMA Ethics Committee when reviewing and revising the Code of Ethics. Comments are due on 16 November 2007. The primary changes to the draft revised Code of Ethics is the addition of two new sections on “Medical Responsibilities in Prioritising Care” and “Medicine and Industrial Action”. I note that none of the proposed revisions have any impact on the issues examined in this thesis. About the New Zealand Medical Association. Online. Accessed 5 October 2007. Available on the New Zealand Medical Association website. http://www.nzma.org.nz/about/ethics.html.

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5.1.2. Status of the Code of Ethics

While the NZMA does not propose to set out rigid or binding rules for the practice of medicine in the Code of Ethics, the standards outlined in the Code of Ethics may nevertheless be used as evidence of the legal standard of care required in some situations. In particular, in *Furniss v Fitchett*\(^ {281} \), Barrowclough J discussed the legal force of a Code of Ethics. He stated that:

> The standard of care required of a medical practitioner is the general professional standard to which a reasonably careful, skilled and informed practitioner would conform. The British Medical Association's Code of Ethics is evidence of that standard, but no more than evidence.\(^ {282} \)

Moreover, a breach of any of the principles in the Code of Ethics may have serious repercussions for the practitioner. In particular, patient complaints are directed to the Health and Disability Commissioner, or other appropriate agencies (such as the Privacy Commissioner), and may result in proceedings before the New Zealand Medical Practitioners Disciplinary Tribunal (now the Health Practitioners Disciplinary Tribunal) (Tribunal), where the practitioner might be charged and penalties imposed. For example, two cases regarding breaches of privacy and confidentiality have come before the Tribunal since its inception in 1996.\(^ {283} \) While neither case involved the disclosure of genetic information to at-risk relatives, an examination of the nature of the breach, and the penalties imposed in each decision, provides an indication as to the seriousness attached to maintaining privacy and confidentiality within the doctor-patient relationship.

First, in *Decision No. 98/36C*,\(^ {284} \) the Complaints Assessment Committee of the Tribunal imposed five charges on Dr White (the subject of the complaints). One of those charges concerned his failure to observe patient privacy and confidentiality in breach of the Code of Ethics. It was alleged that Dr White made statements about personal and medical matters in relation to his patients in the hearing of other patients and members of the public. Dr White

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\(^ {281} \) [1958] NZLR 396.

\(^ {282} \) Above, n281: 396. Note, the British Medical Association Code of Ethics was applicable in New Zealand at the time of the decision.

\(^ {283} \) Note, The Tribunal’s predecessor was the New Zealand Medical Council, which also heard a number of cases on breaches of confidentiality, including *Duncan v Medical Practitioner’s Disciplinary Committee* [1986] 1 NZLR 513, see paragraph 5.2.4 below.

\(^ {284} \) *CAC v Dr White* (30 April 1999) unreported, Medical Practitioners Disciplinary Tribunal, Decision No 98/36C.
was subsequently found guilty of "conduct unbecoming a medical practitioner which reflects adversely on his fitness to practice medicine" in respect of breach of privacy.

Secondly, and in comparison, in *Decision 01/78C* the Tribunal commented that a doctor, who was the subject of a complaint, would reasonably tell his or her spouse about the complaint, and may also discuss the identity of the complainant patient. The Tribunal held that the disclosures made by the doctor to his wife, which identified the patient, were limited, and did not cause the patient any particular prejudice or harm. Accordingly, the Tribunal found that the disclosure did not warrant a penalty.

5.1.3. Recognising the Importance of Patient Confidentiality

The Code of Ethics specifically recognises the importance of the principle of confidentiality. In particular, Principle 5 of the Code of Ethics provides that all medical practitioners are to:

> Protect the patients' private information throughout his/her lifetime and following death, unless there are overriding public interest considerations at stake, or a patient's own safety requires a breach of confidentiality.

The NZMA provides a set of recommendations alongside the Code of Ethics to give a general indication of what amounts to professional behaviour consistent with the principles set out in the Code of Ethics. The recommendation given in respect of Principle 5 states that:

> Doctors should keep in confidence information derived from a patient, or from a colleague regarding a patient, and divulge it only with the permission of the patient except when the law requires otherwise, or in those unusual circumstances when it is clearly in the patient's best interests or there is an overriding public good.

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285 *CAC v A medical practitioner* (10 December 2001) unreported, Medical Practitioners Disciplinary Tribunal, Decision No 181/01/78C.

286 The principle of confidentiality is recognised in one of the oldest binding documents in history – the Hippocratic Oath. The Oath provides that: “What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.” See Ludwig Edelstein. *The Hippocratic Oath: Text, Translation, and Interpretation.* (Johns Hopkins Press, Baltimore, 1943), 3. While the modern version of the oath has changed, the principle behind it has not. See *New Zealand Medical Association Code of Ethics* - March 2002, Principle 5. Online. Accessed 5 October 2007. Available on the New Zealand Medical Association website. [http://www.nzma.org.nz/about/ethics.html](http://www.nzma.org.nz/about/ethics.html).


5.1.4. Justifiable Disclosure under the Code of Ethics

The Code of Ethics issued by the New Zealand Medical Association provides constraints on the disclosure of health information by medical practitioners in most circumstances. It recognises, however, that consistent with the ethical justifications for limiting privacy/confidentiality, they are not absolute concepts, and circumstances exist which require a medical practitioner to disclose a patient’s health information.

Thus, where the patient consents, the law requires otherwise, or where an overriding public interest exists, disclosing genetic information to the genetic relatives of the patient may be justified. Addressing each in turn:

(a) Where the patient consents to the disclosure of his/her genetic information to his/her genetic relatives, ethical and legal rules in relation to privacy and confidentiality cease to apply (to the extent of the patient’s consent). (Note, this may raise issues in relation to the genetic relatives’ “right not to know”. The right not to know is discussed above at paragraph 2.4. Recommendations are made in relation to providing legal recognition of the right not to know in Chapter 7.)

(b) Circumstances where the law requires disclosure, ie where common law or statutory exceptions to patient confidentiality or privacy exist, are discussed in detail below.289

(c) What constitutes an 'overriding public interest' is unclear. Neither the Code of Ethics nor the Recommendations that accompany the principles listed in it outline the elements of such a justification for limiting patient confidentiality, but some guidance may be taken from the common law interpretations of 'public interest'. An analysis of what constitutes an exception to patient confidentiality on the basis of public interest is discussed at paragraph 5.2.4 below (‘Exceptions to the Duty of Confidentiality’). Based on that analysis, it seems unlikely that the potential aversion from harm that genetic relatives may experience if relevant genetic information is disclosed to them would be sufficient to constitute an overriding public interest.

289 See paragraph 5.2.4 below for common law exceptions to patient privacy/confidentiality; see paragraph 5.3 below for statutory rights and exceptions to patient privacy/confidentiality.
5.1.5. Summary of position under the Code of Ethics

At face value, the position under the Code of Ethics in relation to privacy and confidentiality is consistent with the ethical basis for such concepts. That is, the Code of Ethics recognises that privacy and confidentiality are not absolute concepts, and circumstances exist which require disclosure of health/genetic information to third parties.

A proper review of the position under the Code of Ethics, however, is not complete without a full analysis of the common law and statutory provisions surrounding patient confidentiality. Relevantly, Recommendation 17 of the Code of Ethics provides:

Doctors shall accept those obligations to patients which are imposed by statutory provisions and the codes of the Privacy Commissioner, the Human Rights Commissioner and the Health and Disability Commissioner, and the requirements of the Medical Council of New Zealand.290

5.2. The Common Law Duty of Confidentiality

While the Health Information Privacy Code 1994, Privacy Act 1993 and Code of Health and Disability Services Consumers' Rights (discussed further below at paragraph 5.4), and the dispute resolution procedures available there-under,291 have largely obviated the scope of tortuous, contractual and equitable civil causes of action, the duty of confidentiality upon health professionals towards their patients may still, in some circumstances, be recognised by way of civil proceedings based in tort, contract, or equity.292 Accordingly, a discussion of the basis of civil liability for breaching patient confidentiality is necessary for a complete discussion of the law relating to the privacy and confidentiality of health information.


291 Note, the dispute resolution procedures available under these legislative instruments were brought about predominantly for the purposes of increasing accessibility and decreasing the cost of bringing proceedings for breaches of the interests and rights protected under such instruments.

292 As stated in Coke's Institutes of the Laws of England (1917) cap 20, 200 (cited in Hobson v Harding (6 March 1995) unreported, High Court, Auckland Registry, CP 312/94, 18), "it is a maxim in the common law, that a statute made in the affirmative, without any negative expressed or implied, does not take away the common law". Additionally, in a study of the privacy regime in New Zealand, it was stated that "if there is a breach of confidentiality, then the individual may still seek a remedy through the courts. (This action is in no way reduced by the remedies available under the Privacy Act and the Health [Information Privacy] Code)" (see Elizabeth Longworth and Tim McBride The Privacy Act (GP Publications, Wellington, 1994) 161.) These statements reinforce the fact that common law obligations still exists independently of the Privacy Act 1993.
5.2.1. **Tortious Duty of Care.**

Under the common law, a doctor owes a duty of care to his or her patients not to disclose confidential information without first obtaining his or her patient's consent (Duty). This principle was accepted in New Zealand in *Furniss v Fitchett*. In particular, Barrowclough J held that:

> At common law, a doctor's duty of care to his patient includes a duty not to give a third party a certificate as to his patient's condition if he can reasonably foresee that the certificate might come to the patient's knowledge and that that would be likely to cause the patient physical harm.

Any loss or damage suffered by an individual as a consequence of a medical practitioner’s breach of Duty is likely to be mental injury. That is, the consequent mental suffering that would result from an interference with his or her private life. The most likely remedy to be awarded for an individual who has suffered such loss or damage is an award of damages.

Whilst compensation for personal injuries suffered by any New Zealand resident (whether suffered inside or outside New Zealand) is now dealt with under the Injury Prevention and Rehabilitation and Compensation Act 2001 (**IPRC Act**), tortious remedies for damages suffered by an individual as a result of a breach by his or her health practitioner of the Duty may still be available. This is because the likely loss or damage suffered by the individual as a result of the breach (ie mental injury) does not fall within the definition of “mental injury” under the IPRC Act. Mental injury is defined in the IPRC Act as “a clinically significant behavioural, cognitive, or psychological dysfunction”, and is only covered under the IPRC Act when it is caused by physical injuries and/or certain criminal acts.

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293 Above, n252.

294 Above, n252.


296 Injury Prevention, Rehabilitation and Compensation Act 2001, s27.

297 Above, n296: s67.
In addition, there has been recent discussion as to whether a general tort for breach of privacy exists in New Zealand. The Court of Appeal in Hosking v Runtini\(^{298}\) held that a tort of invasion of privacy exists in New Zealand, and two fundamental requirements must be satisfied for a successful claim for interference with privacy. That is: (i) the existence of facts in respect of which there was a reasonable expectation of privacy; and (ii) publicity given to those private facts that would be considered highly offensive to an objective reasonable person.\(^{299}\) The use of the term "publicity" in the second element implies that the information in question be disseminated to more than a few other persons, and to the public at large, as opposed to disclosure to a limited number of people in an intimate family setting. Thus, disclosure by a health practitioner of a patient's genetic information to that patient's at-risk genetic relatives is unlikely to result in a successful claim for interference with privacy under the new tort.

5.2.2. Contractual Duty of Confidentiality.

In circumstances where it is possible to identify a contractual relationship between a doctor and patient (such as in private practice), a duty not to disclose confidential information about the patient may be imposed by way of an implied term in that contract. The existence of a contractual duty of confidence was accepted in Parry–Jones v The Law Society\(^{300}\) where such a duty was held to exist between solicitor and client, banker and customer, doctor and patient, and accountant and client.\(^{301}\)

Despite this, actions in contract against doctors are rare due to the nature of the doctor-patient relationship. There are no New Zealand case law examples of a patient bringing a claim for breach of confidence against his or her medical practitioner on the basis of an implied term in the contract between them. This is most likely because, unlike bringing an action for breach of contract, bringing an action in negligence for breach of confidence does not require proof of the existence of an agreement between the doctor and patient, and an implied term in that

\(^{298}\) [2005] 1 NZLR 1.

\(^{299}\) Above, n298: 32.

\(^{300}\) [1968] 1 All ER 177.

\(^{301}\) Above, n300: 180.
agreement, though the remedy is likely to be the same. Thus, it is somewhat superfluous to bring an action in contract as well as an action in tort.\textsuperscript{302}

An indirect limitation on the disclosure by a health practitioner of an individual’s genetic information to his or her genetic relatives may also exist by way of a term of contract (either express or implied) between the health practitioner and his or her employer. While the individual has no remedy under such a contract against his or her medical practitioner for wrongful disclosure of his or her genetic information, the contractual duty may nevertheless deter the health practitioner from making any such disclosure.

5.2.3. Equity – Fiduciary Obligation.

Equity has developed a series of obligations (ie fiduciary obligations) on persons whose activities should be regulated on the basis of the nature of their relationship with others.\textsuperscript{303} Such obligations generally arise if the relationship is one in which one party places substantial trust or confidence in the other.\textsuperscript{304}

Whilst the doctor-patient relationship is one in which one party (the patient) places a substantial amount of trust in the other (the health practitioner), the House of Lords held that the doctor-patient relationship was not fiduciary in nature and therefore the patient would not be entitled to equitable relief in the event of a breach of duty by the health practitioner.\textsuperscript{305} This is because the health practitioner is constrained by ethical and other legal responsibilities as opposed to fiduciary duties alone.\textsuperscript{306} The House of Lords did, however, acknowledge that the doctor-patient relationship is a special one.

Despite there being no fiduciary relationship between health practitioner and patient per se, and because of the special nature of the relationship, there are still situations where a health practitioner owes his or her patient a fiduciary duty, one being the obligation not to disclose a

\textsuperscript{302} David B Collins, \textit{Medical Law in New Zealand} (Brooker and Friend Ltd, Wellington, 1992) 176.

\textsuperscript{303} Above, n302: 173.

\textsuperscript{304} Above, n302: 173, citing \textit{Day v Mead} [1987] 2 NZLR 443, 458 (a case relating to the solicitor-client relationship).

\textsuperscript{305} Above, n302: 173, citing \textit{Sidaway v Board of Governors of the Bethlam Royal Hospital} [1988] 1 All ER 643, 650-651.

\textsuperscript{306} \textit{Breen v Williams} (1996) 186 CLR 71; 138 ALR 259.
patient’s health information unless required to do so by law. This was recognised by the High Court in New Zealand in *Duncan v Medical Practitioner’s Disciplinary Committee* where Jeffries J held:

> The platform support of a description of medical confidence is to identify the doctor-patient relationship as a fiduciary one. Without trust, it would not function properly so as to allow freedom for the patient to disclose all manner of confidences and secrets in the practical certainty they would repose with the doctor. There rests with a doctor a strong ethical obligation to observe strict confidentiality by holding inviolate the confidences and secrets he receives in the course of his professional ministerings. If he adheres to that ethical principle then the full scope of his ability to administer medical assistance to his patient will develop.

Thus, if an individual can establish that: (a) his or her medical practitioner owed him or her a fiduciary obligation not to disclose his or her health/genetic information without his or her consent; and (b) the medical practitioner breached that duty, for example, by disclosing the individual’s genetic information to his or her at-risk genetic relatives, the individual will be entitled to a full range of remedies, including damages (both compensatory and exemplary).

### 5.2.4. Exceptions to the Duty of Confidentiality.

Despite the constraints under tort, contract and equity on the disclosure of an individual’s health/genetic information, the law recognises (consistent with the ethical justifications for privacy) that the protection of confidentiality is not absolute. Under the common law, in limited circumstances, health practitioners may be justified in disclosing confidential health information.

While limited case law exists in New Zealand regarding potential exceptions to the duty of confidentiality, both *Duncan v Medical Practitioners’ Disciplinary Committee* and *Furniss v Fitchett* raise the subject of medical confidence and discuss the potential exceptions, including

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308 *Duncan v Medical Practitioner’s Disciplinary Committee* [1986] 1 NZLR 513: 520-521.

309 Note, damages were awarded for breach of a purely equitable obligation of confidence in *Seager v Copydex Ltd* [1967] 2 All ER 415 (CA) and in *New Zealand Development Company Ltd v Porter* [1992] 2 NZLR 462. In this context, however, equity and common law are mingled (see *Aquaculture Corporation v New Zealand Green Mussel Company Ltd* [1990] 3 NZLR 299 (CA)), and a full range of remedies is available, regardless of whether the duty originated in common law, equity or statute. See, for example, *Day v Mead* [1987] 2 NZLR 443 (CA) at 450-451, 460-462, 467 and 469.
(a) where an overriding public interest exists; and (b) where the medical practitioner has a duty to warn third parties of potential harm. I discuss each in turn:

5.2.4.1. Overriding Public Interest

The existence of an overriding public interest has been considered in New Zealand (and in other Commonwealth countries) to constitute an exception to the duty of confidentiality.\(^{310}\) This limiting principle to the Duty requires a court to carry out the complex process of considering the strength and value of the interest in preserving confidentiality and the damage which may be caused by breaking it, and weighing this up against a potential countervailing public interest favouring disclosure.

An example of the damage which may be caused by breaking confidentiality is the deterrence of potential HIV/AIDS sufferers seeking treatment for fear of discovery, and considered in \(X v Y\).\(^{311}\) In particular, the Court held that the public interest in maintaining confidentiality of hospital records identifying actual or potential AIDS sufferers prevailed over the public interest in the freedom of press to publish such information, because victims of the disease ought not to be deterred, by fear of discovery, from going to hospital for treatment.\(^{312}\) In particular, Rose J stated that:

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\text{In the long run, preservation of confidentiality is the only way of securing public health; otherwise doctors will be discredited as a source of education, for future patients will not come forward if doctors are going to squeal on them. Consequently, confidentiality is vital to secure public as well as private health.}^{313}\]

On the contrary, the public interest favours disclosure of confidential information where it eliminates risk to public safety. For example, in \(W v Edgell\)\(^{314}\) the Court of Appeal held that disclosing confidential information about the mental state of a potentially violent inmate applying for release into a low security prison or into the community would be justified. Bingham J noted that the public interest exception must only be invoked where there is a “real

\(^{310}\) Above, n308: 521 and n252: 406.

\(^{311}\) [1988] 2 All ER 648

\(^{312}\) Above, n311: 661.

\(^{313}\) Above, n311: 653.
risk of consequent danger to the public. Further, section 74 of the Health Act 1956 requires disclosure of confidential health information where an individual's medical condition presents an infection risk to others.

This balancing exercise was applied in both *Duncan* and in *Furniss v Fitchett*. The Court did not find that a public interest that justified the disclosure of confidential information existed in either case. In *Duncan*, the Court of Appeal held that disclosure by a medical practitioner of information regarding a patient's heart condition to a potential passenger on his patient's bus, and later, to the national news media, did not constitute an instance where an interest in reducing the risk to public safety was sufficient to override patient confidentiality. Jeffries J confirmed that instances where disclosures of confidential information are justified must be restricted to "exceptional circumstances, and then only if the public interest is paramount", and should only be made to 'the responsible authority'. Jeffries J gives some guidance in determining what situations constitute 'exceptional circumstances' in an obiter statement to the effect that a doctor may be justified in disclosing information about a patient when the doctor discovers that another's life is in immediate danger, and urgent action is required to eliminate this risk. Specifically, Jeffries J states that in such a situation, if a doctor reasonably believes that such a danger exists based on their professional judgement, then they "must act unhesitatingly to prevent injury or loss of life even if there is to be a breach of confidentiality".

Similarly, in *Furniss v Fitchett*, where Dr Fitchett gave a letter about a patient to her husband, stating that she exhibited signs of paranoia, and where the lawyer of the patient’s husband then produced it in open Court during separation proceedings, the Court found that the public interest in disclosing confidential information did not override the public interest in maintaining confidentiality in the circumstances. In discussing when the public interest justified disclosure of confidential information, Barrowclaugh CJ stated (obiter) that, where a doctor discovers that his patient is 'liable to cause death or grievous bodily harm' to another at any moment, the public interest requires the doctor to report the finding to someone.

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314 [1990] 1 All ER 835.
315 *W v Edgell* [1990] 1 All ER 835 at 853.
316 Above, n308: 521.
317 Above, n308: 521.
318 Above, n252: 405.
Thus, the overriding public interest exception is subject to limitations, and disclosure must be confined to exceptional circumstances where: (a) another's life is in immediate danger; (b) urgent action is required; (c) there is a real risk of consequent danger to the public; and/or (d) where a patient is liable to cause death or grievous bodily harm. Further, only disclosure that is reasonably necessary to minimise the risk to public safety and that is to a responsible authority is condoned.

The uncertain and (in most situations) non-imminent nature of genetic risk means that it is unlikely to invoke a public interest justifying the disclosure of confidential information under the common law.

Further, an essential difference exists between the nature of the potential risk to the third party when comparing genetic risk and risk of, for example, violence or contagious disease. That is:

(a) in the case of threat of violence, the patient's actions are likely to harm others, and in the case of the risks involved with a contagious disease, the exposure of the infected patient to others is likely to (in most cases) significantly increase their chances of contracting the disease; whereas

(b) in the case of genetic conditions, the patient does not put relatives at risk simply by carrying the gene mutation. The relatives already either carry or do not carry the mutation. In addition, because the disclosure will have to be made to the family member who is at risk, rather than to a responsible authority, the public interest exception does not 'fit' the scenario in which the disclosure of genetic information may arise.

Thus, even though the threat of developing a genetic condition may be very real, and the resulting harm significant, the common law public interest exception to the duty of confidentiality does not provide a justification for disclosing an individual's genetic information to his or her at-risk relatives where he or she does not consent.

5.2.4.2. A Duty to Warn?

The imposition of a 'duty to warn' third parties of their potential risk is also a potential exception to the common law duty of confidentiality.

In comparison to the United States, and Australia, the New Zealand judiciary has, to date, not imposed a positive duty on a health practitioner to ensure that a third party is warned of potential harm. In the New Zealand High Court, Wild J decided that the imposition of a duty to warn goes against current policy considerations, as it would place an:

intolerable burden on [the clinicians], diverting them away from the patient's best interests and resulting in an overly cautious attitude.  

Despite the lack of a ‘duty to warn’ under New Zealand common law, principles of good clinical practice in New Zealand suggest it is appropriate for doctors (or genetic counsellors) to inform patients of the familial nature of genetic information, and hence, encourage them to disclose such information to at-risk relatives. This principle is also reflected in a number of recommendations and guidelines that have been established overseas regarding genetic information. Thus, it is likely that if a common law duty to warn is ever imposed in New Zealand, it will be limited to a duty to warn the patient of the risk to genetic relatives, as opposed to a duty to warn the family members directly.

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320 The imposition of a duty on a doctor to warn an at-risk individual has been established in America. The duty developed following the decision in Tarasoff v Regents of the University of California (1976) 17 Cal. 3d 425, where it was held that health professionals could have a duty to warn identifiable third parties of a foreseeable risk to their safety. Following Tarasoff, two cases in the United States have considered the existence of a duty to warn in the context of information about genetic risk within a family. In Pate v Threlkel (1995) 661 So 2d 278, the Supreme Court held that a doctor owes a duty of care to the children of the patient. However, the duty was limited to the provision of a warning to the patient as opposed to the at-risk genetic relative. The Court states that "...the patient ordinarily can be expected to pass on the warning" and "to require the physician to seek out and warn various members of the patient's family would place too heavy a burden upon the physician", p282.

A different approach was taken in Safer v Pack (1996) 291 NJ Super 619. In this case, the Court departed from the approach in Pate v Threlkel and held that "in all circumstances, the duty to warn will be satisfied by informing the patient", p627. This decision was based on the premise that "there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion, or a threat of physical harm", p625 - 626.

321 A recent case in Australia has recognised that in certain situations, a duty of care may be owed to a third party. In BT v Oei (5 November 1999) unreported, Supreme Court, New South Wales, Bell J, 1082 it was held that a medical practitioner owed a duty of care to the sexual partner (the plaintiff) of the patient's partner. The plaintiff contracted HIV from her partner, and the court considered that the medical practitioner breached his duty of care to the plaintiff by failing to properly advise the patient about the need for an HIV test. Bell J notes, however, "there is no suggestion that the obligation on the doctor extends beyond the provision of adequate advice to the patient" (paragraph 97). Hence, that duty was not owed directly to the third party.


323 Above, 319: 481.
5.2.5. Does an individual owe his or her genetic relatives a duty to warn them of their risk?

The discussion thus far has centred on determining the situations where a *health practitioner* can or cannot disclosure a patient’s genetic information to that patient’s genetic relatives. But what about the patient? Does he or she owe his or her family members a duty to disclose relevant genetic information where doing so have the potential of preventing or lessening a genetic risk faced by those relatives?

As discussed above, an individual certainly has an ethical duty (according to the principle of beneficence) to warn his or her genetic relatives of their risk. Whether this ethical duty is translated into a legal one is uncertain.

Despite the harm that results from a genetic disease being physical in nature, it is not of the type covered under the IPRC Act. In theory then, a genetic relative could sue the individual in negligence if that individual’s failure to inform them prevents them from taking preventative measures against harm on the basis that: (a) there is almost certainly a sufficient degree of proximity between the individual and genetic relative; (b) any harm caused by a genetic disease is reasonably foreseeable; and (c) it is reasonable to impose on the individual a duty to take care to inform his or her genetic relatives of genetic information in order to avoid that foreseeable harm.

There are, however, no reported cases of any such actions being brought by a genetic relative against an individual in either New Zealand or England. Further, whilst legally possible, there are a number of factors which render such causes of action unlikely to arise in practice, such as the willingness of an individual to bring an intra-familial claim, and/or the financial viability of bringing a claim against an individual, as opposed to a health practitioner with “deeper pockets”.324 Further, Courts are more likely to intervene in relation to issues that arise between health practitioner and patient/genetic relative than they are in intra-familial matters.

Thus, the remainder of this thesis focuses on the scenarios (if any) in which a *health practitioner* can legally disclose his or her patient’s genetic information to that patient’s relatives.

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5.2.6. Conclusion

The common law in New Zealand imposes a duty on medical practitioners to maintain confidentiality in their patient’s health/genetic information. That duty:

(a) arises in tort, and in more limited circumstances, contract and equity;

(b) is not absolute, and is limited when: (i) the public interest in disclosing confidential health information to third parties outweighs the public interest in maintaining confidentiality; and (ii) when the life of another individual is in immediate danger.

None of the common law exceptions to confidentiality would justify the disclosure of an individual’s genetic information to his or her at-risk genetic relatives where the individual does not consent to such disclosure.

5.3. Privacy Legislation

The privacy and confidentiality of health information is primarily governed by legislation. The legislation in New Zealand applicable to the privacy/confidentiality of genetic information (as a component of health information) is fragmented and can be found across a number of statutes, codes and regulations. A collection of rules concerning the collection, holding, use, access to, and disclosure of genetic information is found within: (a) the Health Information Privacy Code 1994 issued under the Privacy Act 1993; (b) the Health Act 1956; (c) the Official Information Act 1982; and (d) the Health and Disability Commissioner (Code of Health and Disability Services Consumers Rights) Regulations 1996.

The following sections examine the relevant provisions in each piece of legislation, and in particular, the extent to which they justify limiting privacy and permitting the disclosure of genetic information to at-risk genetic relatives (if at all).

5.4. Privacy Act 1993 and Health Information Privacy Code 1994

5.4.1. Background

The Privacy Act 1993 was enacted in order to promote and protect individual privacy in general accordance with the Recommendation of the Council of the Organisation for Economic Co-operation and Development Concerning Guidelines Governing the Protection
of Privacy and Transborder Flows of Personal Data.\textsuperscript{325} It governs the collection, holding, access, use and disclosure of personal information.\textsuperscript{326}

The Health Information Privacy Code 1994 (HIPC) was issued in 1994 under the Privacy Act 1993,\textsuperscript{327} modifying its principles slightly to take into account the particular characteristics of the health sector and health information, such as confidentiality of collection, sensitivity of information, and ongoing use.\textsuperscript{328}

The HIPC is designed to be consistent with good clinical practice. Central to the issues examined in this paper, the HIPC contains 12 health information privacy principles which set out rules relating to collection, use and disclosure of health information.\textsuperscript{329}

Note, in April 2007, the Privacy Commissioner released proposed amendments to the HIPC.\textsuperscript{330} Relevantly, one of the proposed changes was to allow medical practitioners to disclose, in certain circumstances, patients' genetic information.\textsuperscript{331} The Privacy Commissioner sought public submissions on the proposed amendments, which were due on 28 May 2007. The Privacy Commissioner issued Amendment No 6 to the HIPC on 17 September 2007, which came into force on 1 November 2007.\textsuperscript{332}

\textsuperscript{325} Privacy Act 1993, Long Title. Note, the Recommendation of the Council of the Organisation for Economic Co-operation and Development Concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data are discussed further in Chapter 6.

\textsuperscript{326} Privacy Act 1993, s6. Note, the Privacy Act 1993 requires the Privacy Commissioner “to report to the Prime Minister from time to time on the desirability of the acceptance by New Zealand of any international instrument relating to the privacy of the individual (section 13(1)(q)). Further, it requires the Privacy Commissioner to “consider any developing general international guidelines relevant to the better protection of individual privacy” in the performance of his or her functions, an in the exercise of his or her powers, under the Privacy Act 1993 (s14(1)(c)). Accordingly, international guidelines and instruments are relevant when interpreting provisions under the Privacy Act 1993. International guidelines and instruments that relate to the privacy of genetic information (and where relevant, their application in New Zealand) are discussed in Chapter 6.

\textsuperscript{327} Section 46 of the Privacy Act 1993 authorises the Privacy Commissioner to issue a code of practice that may modify the application of any one or more of the 12 Information Privacy Principles set out in section 6 of the Act.

\textsuperscript{328} Privacy Commissioner, \textit{Health Information Privacy Code 1994: Incorporating Amendments and Including Revised Commentary} (Privacy Commissioner, Wellington, 2003) 2. The HIPC came into force on 30 July 1994: Health Information Privacy Code 1994, Clause 2(1). Note also, the HIPC applies to an individual whether they are living or deceased (Privacy Act 1993, s46(6)(a)) (in comparison with the Privacy Act 1993, where “individual means a natural person, other than a deceased natural person” (Privacy Act 1993, s2(1))).

\textsuperscript{329} As previously discussed, most 'genetic information' falls within the broader definition of 'health information' found in sub-clause 4(1)(a) of the Health Information Privacy Code 1994.


\textsuperscript{331} Privacy Commissioner. \textit{Media Release: Privacy Commissioner considering amendments to the health code.} (Privacy Commissioner, Wellington, April 2007).

\textsuperscript{332} Above, n330.
relating to genetic information were not adopted. This decision and the public submissions in relation to the proposed amendment to the HIPC are discussed and analysed in detail in Chapter 7. The remainder of this section discusses the existing provisions of the HIPC as they relate to the disclosure of genetic information.

5.4.2. Operation of the HIPC alongside the Privacy Act 1993

Under the HIPC, any action that would otherwise breach an Information Privacy Principle under the Privacy Act 1993 is not considered to be a breach of that principle, provided the action is done in compliance with the HIPC. A failure to comply with the HIPC, even when that failure is not considered to be a breach of an Information Privacy Principle under the Privacy Act 1993, is deemed to be a breach of an Information Privacy Principle under the Privacy Act 1993 for the purposes of Part VIII (complaints). Section 66 of Part VIII of the Privacy Act 1993 specifies that any action that is a breach of an information privacy principle under the Privacy Act (including a breach of a health information privacy principle under the HIPC) is an interference with the privacy of an individual where:

In the opinion of the Commissioner or, as the case may be, the Tribunal, the action:

(i) Has caused, or may cause, loss, detriment, damage, or injury to that individual; or

(ii) Has adversely affected, or may adversely affect, the rights, benefits, privileges, obligations, or interests of that individual; or

(iii) Has resulted in, or may result in, significant humiliation, significant loss of dignity, or significant injury to the feelings of that individual.

Thus, it is necessary to examine:

(a) whether genetic information constitutes health information for the purposes of the HIPC; and

(b) the health information privacy principles,

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333 Privacy Act 1993, s 53(a).
334 Privacy Act 1993, s 53(b).
335 Privacy Act 1993, s66(1)(b).
to determine whether the disclosure by a health practitioner of a patient's genetic condition to that patient's at-risk genetic relatives constitutes (or is likely to constitute) a breach of the HIPC and therefore the Privacy Act 1993.

5.4.3. Genetic information as a subset of health information

Most genetic information falls within the definition of 'health information' provided in subclause 4(1)(a) of the HIPC. Only certain genetic characteristics that do not convey information about the health of an individual, such as eye colour, would be excluded from privacy protection under the HIPC.

5.4.4. Rules relating to the collection, use and disclosure of health/genetic information

Rules relating to the collection, use and disclosure of health information are found in rules 3, 10, and 11 of the HIPC respectively.

5.4.4.1. Rule 3: Collection of health information from individual

Rule 3 of the HIPC provides that, before health information is collected (or as soon as practicable after it is collected):

(1) Where a health agency collects health information directly from the individual concerned, or from the individual's representative, the health agency must take such steps as are, in the circumstances, reasonable to ensure that the individual concerned (and the representative if collection is from the representative) is aware of:

(a) the fact that the information is being collected;
(b) the purpose for which the information is being collected;
(c) the intended recipients of the information;
(d) the name and address of:
   (i) the health agency that is collecting the information; and

336 Clause 4(1) of the Health Information Privacy Code 1994, defines "health information" as including "information about the health of an individual, including his or her medical history" (clause 4(1)(a)) and "information provided by that individual in connection with the donation, by that individual, of any body part or any bodily substance of that individual, or derived from the testing or examination of any body part, or any bodily substance, of that individual" (clause 4(1)(d)), among other
(ii) the agency that will hold the information;

(e) whether or not the supply of the information is voluntary or mandatory and if mandatory the particular under which it is required;

(f) the consequences (if any) for that individual if all or any part of the requested information is not provided; and

(g) the rights of access to, and collection of, health information provided by rules 6 and 7.

Informing the individual about the purpose for which his or her genetic information is obtained, the intended recipients of his or her genetic information, and the consequences (if any) of not disclosing the genetic information enables the:

(a) individual to evaluate whether he or she wishes to proceed with providing genetic information by weighing up the benefit of doing so against the consequences of not doing so, thereby maintaining control over his or her genetic information;

(b) health practitioner to lawfully disclose that information to the appropriate people (for example, at-risk genetic relatives) where necessary;

(c) health agency to set its own policies in relation to the disclosure of genetic information, provided that the agency is open about its policy and conveys it at the time of collection. For example, a health agency could make it a condition of collecting genetic information from an individual that, where that information could prevent or lessen potential harm to that individual’s genetic relatives, that information will (where possible) be conveyed to the relative.\(^{337}\)

Thus, if the health practitioner and the health agency comply with Rule 3 of the HIPC, and if the patient agrees to provide genetic information on the basis that such information may be disclosed to his or her genetic relatives, no issue arises. However, where the individual is not so informed but his or her genetic information is collected in any event, before disclosing that classes of information about an identifiable individual. The classes of information specified in clauses 4(1)(a) and (d) clearly encompass genetic information, where such information relates to the health of the individual.

\(^{337}\) In a comment made by the Privacy Commissioner in 2002 about this aspect of the HIPC, he stated that: “commonsense and good judgment still have to be exercised. There are so many situations in which health professionals have the opportunity to set their own policies or to exercise discretion. Commonsense and good judgement will seldom fail foul of the New Zealand laws”. The Privacy Commissioner encourages health agencies to take responsibility for developing their own policies, to acquaint services users with the existence and content of such policies in their early contact with the service and to be open when explaining a decision made in accordance with such policies; Mental Health Commission. Review of the Implementation of the Privacy Act 1993 and the Health Information Privacy Code 1994 by District Health Boards’ Mental Health Services. (Mental Health Commission, New Zealand, 2002), 17-18.
genetic information to genetic relatives (or using the information to treat genetic relatives), the health practitioner must:

(a) Attempt to obtain the consent of the individual.

In practice, once people understand the repercussions of a genetic test for other family members, and after they have received appropriate counselling, most are generally happy for their information to be disclosed. In situations where a patient objects to disclosure after testing has taken place, alternatives such as sending a generic letter to family members, informing them of their risk, with the consent of the person who has undergone testing, but which does not identify that individual, can be arranged.

(b) Failing obtaining consent using any of the methods noted in (a) above, assess whether doing so is permitted under Rules 10 or 11 of the HIPC.

5.4.4.2.  Rule 10: Limits on use of health information

Rule 10(1) of the HIPC provides that, subject to the exceptions listed in Rule 10(1)(a) to (g):

A health agency that holds health information obtained in connection with one purpose must not use the information for any other purpose... Whilst an individual’s genetic information could be used when treating another individual (such as a genetic relative), such use will inevitably involve disclosing that information to the genetic relative, and will likely identify the individual from whom the genetic information was obtained, whether directly or indirectly. Thus, unless an individual consents to the use and disclosure of his or her genetic information for the purpose of treating his or her genetic relative, Rule 10 provides little support for genetic relatives’ interest in knowing genetic information.

338 Interview with Caroline Lintott, Senior Genetic Associate Central Region Genetic Services. (Christchurch, 12 December 2003.) Interview with Danielle James, Genetic Associate, Central Region Genetic Services. (Wellington, 7 November 2003.) Interview with Joanne Dixon, Clinical Geneticist, Central Regional Genetic Services. (Wellington, 8 March 2004.) Interview with Komudi Siriwardena, Clinical Geneticist, Northern Region Genetic Services. (Auckland, 29 January 2004.) Interview with Peter Kannu, Registrar, Northern Region Genetic Services. (Auckland, 19 January 2004.)

339 Above, n338.

340 Health Information Privacy Code 1994, Rule 10(1).
5.4.4.3. **Rule 11: Limits on disclosure of health information.**

Rule 11(1) of the HIPC expressly prohibits a health agency from disclosing health information, unless:

(a) one of the circumstances listed in Rule 11(1) applies; or

(b) disclosure is authorised under Rule 11(2).\(^{341}\)

I discuss each in turn below.

(i) **When disclosure is authorised under Rule 11(1)**

There are three circumstances listed in Rule 11(1) in which a health practitioner is authorised to disclose an individual’s genetic information:

(a) First, where the disclosure of genetic information is to the individual from whom it was obtained (or the individual’s representative), disclosure is permitted under Rule 11(a).

(b) Secondly, where the individual (or his or her representative) authorises disclosure of his or her genetic information to a third party (eg a genetic relative), disclosure to that third party is authorised under Rule 11(4)(b).

Note, any such authorisation must be direct rather than implied. In Case Note 6656,\(^ {342} \) the complainant underwent a blood test to establish whether she would be a suitable organ donor for a family member. The results of the blood test established that she was a suitable match. The respondent disclosed this information to the intended recipient of the organ on the assumption that disclosure was authorised. The complainant alleged that this amounted to a breach of the HIPC. The Privacy Commissioner held that agreeing to have the blood test did not amount to consent to the disclosure of the results of that test. As such, agreeing to have a genetic test, even where the information that arises from such a test concerns other family members, is unlikely to amount to authorisation to disclose the results of that test.\(^ {343} \)

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\(^{341}\) Exceptions are found in sub-rule 11(1)(a - (g). Note, that where disclosure is permitted by the rule, the decision to disclose remains with the health agency. The health agency must "reasonably believe" that the exception applies for it to be justified. They may take ethical codes, or duties of confidentiality into account in making that decision if those instruments impose stricter limits on disclosure than the code, and chose not to make a disclosure.

\(^{342}\) [1998] NZ PrivCmr 46.- *Physician disclosed results of blood test.*

\(^{343}\) Compare the position in the United Kingdom, where consent can be implied. See Chapter 6, paragraph 3.4.1.3.
(c) Thirdly, where the disclosure of an individual's genetic information to a genetic relative is one of the purposes in connection with which the genetic information was obtained, disclosure is permitted under Rule 11(1)(c) (provided that purpose was communicated to the individual prior to the health practitioner collecting the genetic information, on the basis that it might be disclosed to his or her genetic relatives, and the individual agrees to proceed with providing the genetic information). 344

(ii) When disclosure is authorised under Rule 11(2)

Disclosure of an individual's health/genetic information is authorised under Rule 11(2) of the HIPC where: (a) the health agency believes on reasonable grounds that it is either not desirable or practicable to obtain authorisation from the individual concerned; and (b) one of the exceptions in Rule 11(2)(a) - (k) apply. I deal with each in turn below.

First, the Privacy Commissioner Case Notes provide some guidance in relation to what constitutes a "reasonable ground" for believing it is not desirable or practicable to obtain authorisation for the disclosure of health/genetic information.

In Case Note 23887, 345 the individual attended a pain clinic to see a specialist. In giving his personal history to one of the health practitioners at the pain clinic, the individual mentioned he had had previous dealings with a community mental health centre. The health practitioner passed the individual's personal history onto the specialist, and advised the individual that he also intended to pass it to the community mental health centre because, upon analysis of the individual's personal history, he considered the individual may be suffering from depression and may need treatment from the mental health centre. The individual objected and advised the health practitioner that he wanted nothing further to do with the centre. Nevertheless, the health practitioner disclosed the individual's personal health information onto the community mental health centre. The individual alleged that the health practitioner had, in making such a disclosure, breached his privacy. The Privacy Commissioner held that it was not practicable to obtain the individual's authorisation to disclose the information as the individual had already said he wanted nothing further to do with the mental health centre.

Thus, in this particular case, refusal to allow disclosure (whether directly or indirectly) was a reasonable ground for believing it was not practicable to obtain authorisation.

344 See discussion in relation to Rule 3 of the HIPC at paragraph 5.4.4.1 above.

345 [2003] NZ PrivCmr 7 - Patient objects to doctor disclosing information about mental state to a mental health centre.
In Case Note 21451, the Privacy Commissioner confirmed that where a health agency disclosed the complainant’s file, and the files of all patients treated by the health agency’s clinical director of mental health, to a reviewing psychiatrist (for the purpose of reviewing the competence of the director), it was not desirable to obtain the complainant’s authorisation on the basis that the number of people involved, and the vulnerable position of those people. In particular, the health agency did not wish to unnecessarily raise concerns with those people in relation to the adequacy of their treatment. The health agency’s preference was to write to the patients in the event the reviewing psychiatrist identified any issues with their treatment.

In Case Note 30372, the Privacy Commissioner confirmed that it was not desirable or practicable to obtain the patient’s authorisation to disclose information about his mental state to the police. This was because the patient previously expressed suicidal thoughts, failed to attend a clinical appointment, and left a message explaining that he had been delayed because he had been purchasing a gun.

In summary, it seems that a health practitioner could have reasonable grounds (depending on the circumstances of the case) for believing it is not desirable or practicable to obtain the authorisation of an individual before disclosing his or her health information where the patient:

(a) refuses to allow the disclosure (eg Case Note 23887); and/or

(b) is in a vulnerable position, and alerting him or her about the proposed disclosure of his or her health information may cause distress or harm (eg Case Notes 21451 and 30372).

The Privacy Commissioner has not yet considered whether or not it is “desirable or practicable” to obtain authorisation of an individual to disclose his or her genetic information to his or her genetic relatives for the purpose of preventing potentially serious health consequences for those relatives (by, for example, enabling the early detection and treatment of a genetic disorder) where the individual refuses to do so himself/herself. The scenarios discussed in the Case Notes above are to a certain extent analogous to this scenario (ie refusal to disclose; potential harm to a third party etc) and might therefore offer some insight into the approach the Privacy Commissioner might take in relation to it. It is important to note,

346 [2001] NZ PrivCmr 95,96 – Patient complains hospital disclosed file to reviewing psychiatrist.

however, that the Case Notes above dealt primarily with mental health issues, so can also be distinguished.

Secondly, in relation to whether any of the exceptions in Rule 11(2)(a) - (k) of the HIPC apply, three exceptions exist that may have a bearing on whether a health practitioner can lawfully disclose his or her patient’s genetic information to that patient’s at-risk genetic relatives if it is established that it is 'not desirable or practicable' to obtain authorisation:

(a) First, Rule 11(2)(a) permits disclosure where it directly relates to the purpose in connection with which the information was obtained.\textsuperscript{348} The commentary to the HIPC explains that these are purposes that could reasonably be assumed (by the health agency, at least) to be within the expectations of the person from whom the information was collected, such as, for example, disclosure of information for peer reviews and quality audits.\textsuperscript{349}

In terms of genetic information, if the health practitioner informs the patient that information derived from a genetic test will inevitably provide information about both the patient and his or her genetic relatives, and that such information should be disclosed to such relatives, then arguably disclosure to those genetic relatives will fall within the expectations of the patient. In light of Case Note 6656\textsuperscript{350} however, where the Privacy Commissioner held that authorisation for disclosure must be direct rather than implied, it is unlikely that any such disclosure would be supported by the Privacy Commissioner. Further, it is only necessary to use this exception where the health practitioner does not (or cannot) directly inform the patient of the intended purpose of collecting the information (that is, to identify the presence of a genetic condition), and the potential recipients of the information (that is, genetic relatives), prior to the collection of the genetic information, as required under Rule 3 of the HIPC.

(b) Secondly, Rule 11(2)(c)(i) permits disclosure of an individual’s health information where it is to be used in a form in which the individual concerned is not identified.\textsuperscript{351} The example provided in the commentary to the HIPC in relation to disclosure under

\textsuperscript{348} Compare this with HIPC, Rule 11(1)(c) where disclosure is permitted where it is one of the purposes (rather than directly relating to the purpose) for which the information was obtained.

\textsuperscript{349} Above, n 328: 49.

\textsuperscript{350} Above, n342.

\textsuperscript{351} Health Information Privacy Code 1994, Rule 11(2)(c)(i).
Rule 11(2)(c)(i) involves a health practitioner disclosing the information during discussions of actual case studies with other health practitioners for training purposes. Applying this rule to the present issue, arguably a health practitioner could notify a patient's genetic relatives of the existence of a disease-causing gene mutation that has been identified within their family and that they may be at risk of carrying the affected gene, provided that the identity of the patient (i.e., the individual who was tested) is not disclosed.\textsuperscript{352} It is questionable, however, as to whether genetic information can be deemed 'anonymous' within a family setting, as the pool of people from whom the information could have been obtained is narrow, and the information is unlikely to remain anonymous indefinitely. Furthermore, such action would not be deemed to fall within the principles of 'good clinical practice', as it is considered inappropriate to 'cold call' an individual about a potential genetic condition.\textsuperscript{353}

Accordingly, it is unlikely that, if the matter came before the Human Rights Review Tribunal,\textsuperscript{354} it would allow a health practitioner to rely on Rule 11(2)(c)(i) to justify the disclosure of an individual's genetic information.

(c) Thirdly, Rule 11(2)(d)(ii) permits disclosure of an individual's health information when it is necessary to prevent or lessen a serious and imminent threat to the life or health of another individual. The elements which need to be established in order to justify making a disclosure under this Rule 11(2)(d)(ii) are that there are reasonable grounds for believing that:

(i) There is a serious threat to the life or health of an individual. For example:

(aa) in Case Note 5733,\textsuperscript{355} the Privacy Commissioner concluded that disclosing information regarding the fact that the patient may be on medication which

\textsuperscript{352}Note, this would only be justifiable where the individual was not immediately identifiable. For example, if an individual had only one living relative, disclosing their genetic information to their other family member would immediately identify the individual. Disclosure of anonymous genetic information would only be permitted where the family is large enough for immediate identification not to occur.

\textsuperscript{353}Interview with Danielle James, Genetic Associate, Central Region Genetic Services. (Wellington, 7 November 2003.) Note, 'Cold-Calling' is where a non-family member (such as a genetic counselor) contacts an individual 'out of the blue' and informs them of their potential risk of carrying a genetic defect, without the consent of the patient from whom the information was obtained.

\textsuperscript{354}See paragraph 5.4.7.3 below for an explanation of the procedure for bringing proceedings under the Privacy Act 1993.

\textsuperscript{355}[2001] NZPrivCmr 43 – Mental health team discloses woman's medical details to police fire emergency
could adversely affect her proposed treatment constituted a serious threat to her health;

(bb) in Case Note 2049, the Privacy Commissioner was of the opinion that the nurse in question had reasonable ground to believe that a patient who was released from a secure unit of a psychiatric hospital posed a serious and imminent threat to public safety at the time of disclosure; and

(cc) in Case Note 30372, the Privacy Commissioner concluded that the doctor had reasonable grounds for believing the complainant posed a serious and imminent threat to himself and his family based on his knowledge of the complainant's mental and physical health and his recent suicidal comments.

(ii) The threat is imminent. The threats discussed in the Case Notes referred to in paragraph (i) above were also deemed by the Privacy Commission to be “imminent” threats. For example, in Case Note 5733, the Privacy Commissioner concluded that the threat to a burns victim who was about to receive treatment to which she could potentially have had an adverse reaction, was imminent because the ambulance officers were preparing the patient for transfer to the hospital where she was to be treated immediately upon arrival.

(iii) The disclosure of the information would prevent or lessen that threat. In particular, the disclosure must be made to a person who can do something to prevent or lessen the threat. The Privacy Commissioner notes in the commentary to the HIPC, that:

To address an imminent threat, the recipient would need to have the power to act urgently to achieve a tangible result in the particular case. Disclosure to someone who does not have such power may merely be an inroad into medical confidence and privacy which does not carry with it any corresponding assurance of benefit to the public interest.
For example, in Case Note 5733, the Privacy Commissioner considered that following an accident, disclosing important health information about a patient to the Police was appropriate given their role in emergencies. The mental health team who made the disclosure in this case therefore had reasonable grounds for believing that the disclosure would prevent or lessen the threat. Further, in Case Note 30372, the police were considered the appropriate agency to respond to a potential threat involving a firearm, hence the Privacy Commissioner believed that the doctor who made the disclosure had reasonable grounds for believing that the disclosure would prevent or lessen that threat.

(iv) The disclosure of the information is reasonably necessary to prevent or lessen the threat. For disclosure to be considered necessary, the health practitioner must believe that the threat cannot be properly prevented or minimized in a way that does not involve the release of confidential/private information. The Privacy Commissioner examined the notion of necessity in Case Note 2049. He explained that:

The concept of a disclosure being “necessary” to prevent or lessen a threat also involves the notion that the threat could be prevented or lessened in some other way not involving a breach of confidence.

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360 Above, n355.
361 Above, n347.
362 The Privacy Commissioner, in Case Note 2049 [1996] NZPrivCmr 7 examines the notion of necessity. He explains that “the concept of a disclosure being “necessary” to prevent or lessen a threat also involves the notion that the threat could be prevented or lessened in some other way not involving a breach of confidence”. Hence, the person making the disclosure has to take steps to see if the perceived threat to safety could be prevented or lessened in some other way not involving a breach of patient confidentiality. This case involved a disclosure of information, concerning the mental health of a patient who was released into the community, to an opposition MP on the grounds that the nurse believed the patient posed a serious and imminent threat to public safety. The Privacy Commissioner was not satisfied that the nurse had reasonable grounds for believing that disclosure of the patient’s health information was necessary to prevent or lessen the threat posed by the patient, as the MP was not in a position to have any influence on the patient’s then-current position. See also the Human Rights Review Tribunal’s decision in Lehmann v Canwest Radioworks Ltd [2006] NZHRRT 35 in relation to the concept of “necessity” as it appears in Privacy Principle 1 of the Privacy Act 1993. In particular, the Tribunal: (a) commented that “[t]he use of the word ‘necessary’ in Principle 1(b) is not qualified. Taken at face value, the word might convey a sense of that which is essential; something but for which the purpose cannot possibly be achieved. If interpreted in that way, Principle 1 imposes a very high standard indeed for agencies to have to achieve before it can be said that the collection of personal information is justified within Principle 1” (paragraph 47); and (b) concluded “[w]e have no doubt that Principle 1 is intended to set a standard that is workable and achievable, having regard to the circumstances of each case. [Therefore] Principle 1 should be approached as setting a standard of reasonable rather than absolute necessity” (paragraph 50).
363 Above, n328: 50.
364 Above, n356: 25
Hence, the person making the disclosure has to take steps to see if the perceived threat to safety could be prevented or lessened in some other way not involving a breach of patient confidentiality. Case Note 2049\textsuperscript{365} involved a disclosure of information, concerning the mental health of a patient who was released into the community, to an opposition member of parliament (MP) on the grounds that the nurse believed the patient posed a serious and imminent threat to public safety. The Privacy Commissioner was not satisfied that the nurse had reasonable grounds for believing that disclosure of the patient’s health information was necessary to prevent or lessen the threat posed by the patient, as the MP was not in a position to have any influence on the patient’s then-current position.

Even if risk presented by genetic information is sufficiently serious, it is unlikely that genetic information would ever present an imminent threat to an individual so as to justify a disclosure under Rule 11(2)(d)(ii).\textsuperscript{366} Further, it is arguable that the risk presented by some genetic information may not even be sufficiently serious to satisfy the first limb of the test under Rule 11(2)(d)(ii). For example, can it be said that a fifty percent likelihood of carrying a mutation of the BRCA1 gene is a sufficiently serious threat to an individual’s health? Or where an individual has a particular genetic mutation that is associated with a sixty percent risk of developing a certain condition, that the threat is sufficiently serious?\textsuperscript{367} Obviously the provision requires more than ‘mere threat’ if it is to provide a justification for disclosure, however, the degree of seriousness required is not clear.

Thus, while genetic risk is as harmful as, and is no less destructive than, other life-threatening health risks, genetic conditions are not likely to satisfy the "serious and imminent" test under sub-rule 11(2)(d)(ii) of the HIPC.

Even if disclosing genetic information was permitted under the HIPC without the authorisation of the person from whom the genetic information was taken, as per Rule 11(3) of the HIPC, any such disclosure should only be made to the extent necessary to satisfy the

\textsuperscript{365} Above, n356.

\textsuperscript{366} Genetic disorders rarely, if ever, present an immediate threat to the life or health of an individual. The harm presented by genetic conditions may not occur for some months or even years. See Australian Law Reform Commission and Australian Health Ethics Committee. \textit{Essentially Yours: The Protection of Human Genetic Information in Australia - Report 96}. (Australian Law Reform Commission, Sydney, 2003), 519.

\textsuperscript{367} Above, n366: 559.
purpose of disclosing the information, and ideally, without disclosing any personally identifying information at all.\textsuperscript{368}

Note, however, that in the context of genetic information, while it would be possible to make a disclosure to a genetic relative of the individual from whom the information was originally taken without identifying that individual, given that the information will inevitably be from a family member, it is likely that eventually the source individual will be identified, albeit indirectly.

5.4.5. Disclosure authorised by Privacy Commissioner

In some circumstances, the Privacy Commissioner may authorise a health agency to disclose health/genetic information, even though such a disclosure would otherwise breach Rule 11 of the HIPC.\textsuperscript{369} Any such authorisation may be granted where:

(a) the disclosure would substantially benefit the public interest or would result in a clear benefit to the individual from whom the information was obtained; and

(b) any such benefit would clearly outweigh any interference with the privacy of the individual that might result from the disclosure.

The Privacy Commissioner will not make an authorisation under section 54 of the Privacy Act 1993, however, if the individual from whom the information was obtained has refused to authorise the disclosure. Accordingly, a health practitioner is unlikely to obtain authorisation under section 54 of the Privacy Act 1993 in order to legitimately disclose a patient’s genetic information to that patient’s genetic relatives, even though the genetic information could provide significant health benefits to those relatives because:

(a) the benefit is to the genetic relatives and no: to the wider public;

(b) there is no benefit to the individual concerned; and

(c) the only situation in which a health practitioner is likely to want to make such a disclosure without the consent of his or her patient is where that patient has refused to make the necessary disclosure himself/herself.

\textsuperscript{368} Above, n328: 52.

\textsuperscript{369} Privacy Act 1993, s54.
(Note also, in any event, the power under section 54 of the Privacy Act 1993 is very rarely exercised by the Privacy Commission.\textsuperscript{370})

5.4.6. Establishing a Privacy Interference

A breach of one of the Health Information Privacy Principles (and therefore a breach of an Information Privacy Principle, for the purposes of Part VIII of the Privacy Act 1993)\textsuperscript{371} is not sufficient in itself to constitute an interference with an individual's privacy. In the context of a wrongful disclosure of health/genetic information, the disclosure is only an interference with the privacy of an individual if:

(a) in relation to that individual, the disclosure breaches an information privacy principle;\textsuperscript{372} and

(b) in the opinion of the Privacy Commissioner (or the Human Rights Review Tribunal), the disclosure:

(i) has caused or may cause loss, detriment, damage, or injury to that individual;\textsuperscript{373}

(ii) has adversely affected, or may adversely affect, the rights, benefits, privileges, obligations, or interests of that individual;\textsuperscript{374} or

(iii) has resulted in, or may result in, significant humiliation, significant loss or dignity, or significant injury to the feelings of that individual.\textsuperscript{375}

Thus, it is possible that even when there is a breach of the HIPC, no interference with the complainant’s privacy will be established.

Decisions of the Privacy Commissioner and of the Human Rights Review Tribunal (formerly the Complaints Review Tribunal) in relation to complaints concerning the disclosure of personal information offer some guidance in determining what may constitute either “loss,

\textsuperscript{370} Paul A. Roth \textit{Privacy Law and Practice} (Butterworths, Wellington, 1994), PVA54.5 (service 57).

\textsuperscript{371} Privacy Act 1993, s53(1)(b). See also paragraph 5.4.2 above.

\textsuperscript{372} Privacy Act 1993, s66(1)(a).

\textsuperscript{373} Privacy Act 1993, s66(1)(b)(i).

\textsuperscript{374} Privacy Act 1993, s66(1)(b)(ii).

\textsuperscript{375} Privacy Act 1993, s66(1)(b)(iii).
detriment, damage, or injury” or “significant humiliation, loss of dignity, or injury to the feelings” to an extent necessary to satisfy an interference with privacy.

5.4.6.1. "Loss, Detriment, Damage, or Injury"

Whether an individual has suffered “loss, detriment, damage or injury” as a result of the disclosure of his or her health information has been considered in the following cases.

First, in Case Note 35361376 the Privacy Commissioner held that there was no causal link between the disclosure of health information and the injury claimed under s66(a)(b)(i) of the Privacy Act 1993. The case involved a seaman who injured his finger on board a ship. His doctor initially certified that the seaman was unfit for work for 10 days. After discussion with the seaman's manager, he changed his diagnosis, without consultation with the seaman, to “fit for light duties”. The seaman alleged that this disclosure caused him to suffer adverse consequences due to the fact that he had to remain at sea while suffering trauma from the injury. The Privacy Commissioner considered that the detriment or harm claimed was due to the seaman's physical injury.

Secondly, Illich v Accident Rehabilitation & Compensation Insurance Corporation377 was a case that came before the Complaints Review Tribunal involving a disclosure by ACC of information held in an individual's file. The plaintiff claimed that this caused the relationship between him and his brother to deteriorate. The Tribunal held that the plaintiff failed to provide sufficient evidence that the damage occurred (that is, more than a mere assertion of loss or damage is required to satisfy that loss or damage indeed occurred), and that the disclosure caused the damage. Accordingly, no interference with the plaintiff’s privacy was established for the purposes of 66(1)(b)(i) of the Privacy Act 1993.

Thus, even if an individual could establish that his or her health practitioner had wrongfully disclosed his or her genetic information in breach of a Health Information Privacy Principle, it is unlikely that he or she will be able to properly establish that the disclosure caused loss, detriment, damage or injury. First, in the circumstances of disclosure of genetic information to a genetic relative, the individual will suffer no financial or physical loss. Secondly, the individual may cause the individual’s relationship within the family to deteriorate (assuming

the family was functional in the first instance). However, as held by the Complaints Review Tribunal in *Illich v Accident Rehabilitation & Compensation Insurance Corporation*, a mere assertion of the deterioration of a relationship is not adequate to establish loss, detriment, damage or injury.

It is more likely that an individual could successfully claim that the disclosure of his or her genetic information to genetic relatives caused significant humiliation, loss of dignity, or injury to feelings.

### 5.4.6.2. "Significant Humiliation, Loss of Dignity, or Injury to Feelings"

The Complaints Review Tribunal discussed the level of humiliation, loss of dignity or injury to feelings required in order to satisfy this limb of section 66(1)(b)(iii) of the *Privacy Act 1993* in the following cases.

First, in *H v Westpac Trust*, the Complaints Review Tribunal emphasised that the word "significant" establishes a higher threshold than ordinary stress and humiliation.

Secondly, the Complaints Review Tribunal noted in *K v Police Commissioner*, that while this test is subjective, the plaintiff must satisfy the Tribunal that the harm suffered was greater, or more significant than usual. The Tribunal pointed out whether harm is significant might depend, for example, on the identity and number of those before whom the complainant is humiliated. The Complaints Review Tribunal explained that the more familiar the plaintiff is with a complainant, the less likely the humiliation will be accepted as significant.

Thirdly, consistent with the Complaints Review Tribunal’s comment in *K v Police Commissioner*, in Case Note 2049380 the Privacy Commissioner recognised that, to an extent, humiliation will be the inevitable consequence of any disclosure of highly sensitive information, but that mere humiliation was not enough to find an interference of privacy under section 66(1)(b)(iii) of the Privacy Act 1993.

Finally, and perhaps most significantly in the context of the wrongful disclosure of genetic information to genetic relatives, in *W v P* the Complaints Review Tribunal considered that

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379 (unreported, Decision No 33/99, CRT 17/99, 26 November 1999).
381 (unreported, Decision No 2/99, CRT 24/98, 16 Feb 1999).
the plaintiff's loss of relationship with her mother caused “significant injury to her feelings or emotional state”. The extent of the loss of relationship was such that the plaintiff's mother (as well as her two siblings) refused to have any contact with her after the disclosure was made. Thus, it appears that a significant breakdown in relationship is required to constitute "significant injury to one's feelings".

From the examples discussed above, it seems that disclosure of an individual's genetic information to his or her genetic relatives in breach of a Health Information Privacy Principle:

(a) is unlikely to result in a sufficient degree of humiliation or loss of dignity on the basis of the recipients' relationship (ie familiarity) with the individual;

(b) might result in "significant injury to feelings" where such disclosure causes a major breakdown in the family relationship;

(c) is highly likely to result if disclosure results in deep depression or other serious mental conditions.

Whether such disclosures result in an interference with an individual's privacy under the Privacy Act 1993 will, however, depend on the particular circumstances of the case.

If an individual considers that a health practitioner has, by disclosing his or her genetic information to genetic relatives, interfered with his or her privacy, he or she may bring a complaint under the Privacy Act 1993, as per the process set out below.

5.4.7. Remedies available for interference with privacy under the Privacy Act 1993

5.4.7.1. Bringing a complaint under the Privacy Act 1993 for a privacy interference

If a health practitioner discloses a patient's genetic information to that patient's genetic relatives, in the event the patient considers the disclosure to be an interference with his or her privacy, the patient may make a complaint to the Privacy Commissioner under the Privacy Act 1993.  

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382 Privacy Act 1993, ss67and 71(g). Note, individual health agencies may have their own complaints procedure. This does not, however, prevent an individual from raising a complaint directly with the Privacy Commissioner under the Privacy Act 1993.
5.4.7.2. *Investigation of complaint by Privacy Commissioner*

Upon receiving a complaint by an individual (or on the Privacy Commissioner's own initiative), the Privacy Commissioner is to:

(a) Either:

(i) investigate the alleged interference with the complainant's privacy;\(^{383}\) or

(ii) where the Privacy Commissioner considers the complaint is trivial, frivolous, vexatious, not made in good faith, or is unnecessary or inappropriate (among other grounds listed in section 71(1) and (2) of the Privacy Act 1993), she may decide to take no further action in relation to the complaint.

(b) Act as a conciliator between the complainant and the person to whom the claim relates in relation to the alleged interference.\(^{384}\)

(c) Take any further action required under the Privacy Act 1993.\(^{385}\)

I explain below each of the steps involved in a complaint, as referred to above.

First, where the Privacy Commissioner considers that a complaint requires investigation she must inform the:

(a) Relevant parties of her intention to investigate the complaint.\(^{386}\)

(b) Person to whom the complaint relates (hereinafter referred to as the respondent) of the details of the complaint and the respondent's right to submit a written response to the complaint.\(^{387}\)

Where the Privacy Commissioner considers, either from the details of the complaint or from the respondent's written response (if any), that it may be possible to reach a settlement (and where appropriate, assurance against repetition of the alleged wrongful disclosure) she may,

\(^{383}\) Privacy Act 1993, s69(1)(a).

\(^{384}\) Privacy Act 1993, s69(1)(b).

\(^{385}\) Privacy Act 1993, s69(1)(c).

\(^{386}\) Privacy Act 1993, s73(a).

\(^{387}\) Privacy Act 1993, s73(b).
without investigating the complaint further, use her best endeavours to secure such a settlement (and assurance).\footnote{Privacy Act 1993, s74.}

If, as a result of an investigation, the Privacy Commissioner considers that a complaint has substance, she must use her best endeavours to secure a settlement (and assurance, as above).\footnote{Privacy Act 1993, s77(1).}

5.4.7.3. Bringing proceedings

If no such settlement and assurance is forthcoming (either under section 74 or 77 of the Privacy Act 1993), the Privacy Commissioner may refer the matter to the Director of Human Rights Proceedings for the purpose of deciding whether proceedings under section 82 of the Privacy Act 1993 should be initiated against the respondent.\footnote{Privacy Act 1993, s77(2).}

Where the Director of Human Rights Proceedings (Director) considers that initiating proceedings is justified, and that proceedings should in fact be brought,\footnote{Note, both decisions are at the discretion of the Director of Human Rights Proceedings as per section 77(3) of the Privacy Act 1993.} the Director may bring civil proceedings before the Human Rights Review Tribunal against the respondent.\footnote{Privacy Act 1993, s82(2). Note, section 82(3) of the Privacy Act 1993 provides that any such proceedings may only be brought where the respondent has given an opportunity to be heard.}

The complainant may bring proceedings him/herself where: (a) the Privacy Commissioner or the Director considers that the complaint lacks substance or ought not to be proceeded with; or (b) where the Director would be entitled to bring proceedings, but he or she either: (i) agrees to the complainant bringing the proceedings; or (ii) declines to take proceedings.\footnote{Privacy Act 1993, s83.}

5.4.7.4. Remedies available under the Privacy Act 1993

Where, after hearing the complaint, the Human Rights Review Tribunal is satisfied, on the balance of probabilities, that the disclosure is an interference with the complainant's privacy, it may grant:

\footnotesize{\begin{center}
\begin{itemize}
\item \footnote{Privacy Act 1993, s74.}
\item \footnote{Privacy Act 1993, s77(1).}
\item \footnote{Privacy Act 1993, s77(2).}
\item \footnote{Note, both decisions are at the discretion of the Director of Human Rights Proceedings as per section 77(3) of the Privacy Act 1993.}
\item \footnote{Privacy Act 1993, s82(2). Note, section 82(3) of the Privacy Act 1993 provides that any such proceedings may only be brought where the respondent has given an opportunity to be heard.}
\item \footnote{Privacy Act 1993, s83.}
\end{itemize}
\end{center}}
(a) A declaration that the decision is an interference with privacy.394

(b) An order restraining the respondent from continuing or repeating the interference or engaging in or permitting others to engage in conduct of the same kind, or conduct of a similar kind specified in the order.395

(c) Damages.396

(d) An order that the respondent health agency perform any specified acts with a view to remedying the interference, or redressing any loss or damage suffered by the complainant as a result, or both;397 and/or

(e) Such other relief as the Tribunal thinks fit.398

In deciding what, if any, remedy to grant, the Tribunal will consider the conduct of the respondent.399

Further, costs may be awarded against either party, as the Tribunal sees fit.400 (Note, where the plaintiff is the Director, any adverse costs award will be paid by the Privacy Commissioner, and the Privacy Commissioner cannot be indemnified by the complainant.401)

Thus, if an individual brought a successful claim against his or her health practitioner for breach of under the Privacy Act 1993 (in relation to the wrongful disclosure of his or her genetic information) adequate compensation is available.

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394 Privacy Act 1993, s85(1)(a).
395 Privacy Act 1993, s85(1)(b).
396 Privacy Act 1993, s85(1)(c).
397 Privacy Act 1993, s85(1)(d).
398 Privacy Act 1993, s85(1)(e).
399 Privacy Act 1993, s85(4).
400 Privacy Act 1993, s85(2).
401 Privacy Act 1993, s85(3).
5.4.8. The Health Act 1956

The Health Act 1956 was drafted as "[a]n Act to consolidate and amend the law relating to public health".402

Under the Health Act 1956:

(a) The term "Health Information" has the following meaning:

Health information, in relation to an identifiable individual, means—

(a) Information about the health of that individual, including that individual's medical history:

(b) Information about any disabilities that individual has, or has had:

(c) Information about any [[services]] that are being provided, or have been provided, to that individual:

(d) Information provided by that individual in connection with the donation, by that individual, of any body part, or any bodily substance, of that individual:

(e) For the purposes of section 22E of this Act and for that purpose only, information—

(i) Derived from the testing or examination of any body part, or any bodily substance, donated by an individual; or

(ii) Otherwise relating to any part or substance so donated, or relating to the donor and relevant (whether directly or indirectly) to the donation.403

(b) The term "Individual" means "a natural person and includes a deceased natural person".404

The provisions relating to the disclosure of personal health information under the Health Act 1956 are framed with a focus on access to such information.405 Thus, limits on disclosure are

402 Health Act 1956, Long Title.

403 Health Act 1956, s22B. Note, the definition of "health information" in the HIPC is identical to this definition.

404 Health Act 1956, s22B. Note, section 46(6)(a) of the Privacy Act 1993 requires that, in any code of practice relating to health information, the definition of the term "individual" is to mean any individual, whether living or deceased. This definition is, however, only applicable under rule 11, and the regular definition of "individual", found in s2(1) of the Privacy Act 1993 applies under the other rules.

405 The provisions relating to personal health information are found in sections 22B – 22J Health Act 1956. Two of the provisions authorize persons who hold health information to disclose that information in some situations (sections 22C and 22H); Four of the provisions impose a duty of disclosure in certain circumstances (sections 22D, 22E, 22F and 22G).
an exception to the rule. 406 Provisions that may have bearing on the disclosure of genetic information to genetic relatives include sections 22C, 22F and 22H.

Section 22C of the Health Act 1956 authorises health agencies to release certain information to the persons listed in section 22C(2), and in particular, in most cases, persons who require knowledge of another individual's personal health information for the purpose of carrying out their powers, duties or functions. Otherwise, health information may only be disclosed where it is permitted under the HIPC. 407 Hence, s22C does not extend the set of circumstances in which disclosure of an individual's genetic information to at-risk genetic relatives may be justified under the HIPC. 408

Section 22F of the Health Act is a complex provision that deals with the communication of health information for diagnostic or other purposes.

Section 22F(1) provides that where an individual about whom the information is held, or a person who provides, or is to provide services to that individual, requests the health information of that individual, the person who holds the health information is to disclose that information to the requester. Thus, a duty to disclose health information, on request, to a limited group of people exists. It does not, however, extend to the disclosure of an individual’s genetic information to that individual’s genetic relatives (or even to the genetic relatives’ health practitioners) without his or her consent. In particular, section 22F(2) lists circumstances where the person who holds the health information may refuse to disclose the information. Such refusals may take place where:

(a) the person who holds the information has a lawful excuse for not disclosing the information; 409

(b) where the person requesting the information is someone other than the individual about whom the individual is held, and the holder of information has reasonable grounds for believing that the individual does not wish the information to be disclosed; 410 or

406 Compare with the HIPC, where disclosure of health information is the exception to the rule.

407 Section 22C(1)(b)(i) of the Health Act 1956 states that a health agency may disclose health information if that disclosure is permitted by or under a code of practice issued under section 46 of the Privacy Act 1993.

408 See above for a discussion of when disclosure of genetic information to family members may be justified under the Health Information Privacy Code 1994.

409 Health Act 1956, s22F(2)(a)
Section 22H of the Health Act 1956 allows the disclosure of health information to any person provided it does not reveal the identity of the person to whom it relates.\(^4\) As discussed above, genetic information is unlikely to remain ‘anonymous’ within the family setting, and further, it is inappropriate to ‘cold-call’ an individual. Hence, section 22H is not likely to enable the lawful disclosure of genetic information to at-risk relatives, and is contrary to good clinical practice.

5.4.9. The Official Information Act 1982

The Official Information Act 1982 (OIA), among other things, is an Act to make official information more freely available, to provide for proper access by each person to official information relating to that person, and to protect official information to the extent consistent with the public interest and the preservation of personal privacy.\(^5\) The potentially competing interests between: (a) maintaining privacy; and (b) disclosing information in order to avoid harm to a third person, are addressed within the Act.

“Official Information” means “any information held by a department,\(^6\) a Minister of the Crown,\(^7\) or an Organisation.\(^8\) Relevant departments, Ministers and organisations covered by the OIA are listed in Part I and II of the First Schedule of the Ombudsman Act 1975, or the First Schedule of the OIA.\(^9\) In the health sector, the OIA applies to the Ministry of Health,\(^1\) and District Health Boards.\(^2\)

\(^{4}\) Health Act 1956, s22F(2)(b)

\(^{5}\) Health Act 1956, s22F(2)(c)

\(^{6}\) Note, this provision overrides any enactment, rule of law, or other obligation.

\(^{7}\) Official Information Act 1982, Long Title.

\(^{8}\) Official Information Act 1982, s2(1)(a)(i).

\(^{9}\) Official Information Act 1982, s2(1)(a)(ii).

\(^{10}\) Official Information Act 1982, s2(1)(a)(iii).

\(^{11}\) Official Information Act 1982, s2.

\(^{12}\) Ombudsmen Act 1975, First Schedule, Part I. The Ministry Health is the Government’s principal agent and advisor on health and disability. It provides policy advice to the Government on health and disability issues and administers health regulations and legislation. It has a crown funding agreement with the 21 District Health Boards throughout New Zealand, which are in turn responsible for the health of their local populations. District Health Boards fund primary health care services and provide hospital services for their communities. Thus, in terms of health information, the Official Information
Sections 4 and 5 are the primary provisions of the OIA, setting out:

(a) In section 4, the purposes of the OIA (including the provision of proper access by each person to official information relating to that person) and the protection of official information to the extent consistent with the public interest and preservation of personal privacy.

(b) In section 5, the key principle of the OIA, being the principle of availability. That is, the OIA is to operate according to the principle that information shall be made available unless there is a good reason for withholding it.

Thus, despite the purposes and principle of the OIA being to promote access to information, the OIA nevertheless recognises that there should be constraints on the disclosure of information (ie in recognition of the principles of the preservation of privacy by limiting protection of official information to the extent consistent with the public interest, as per (a) above). Specifically, section 9(2)(a) of the OIA provides that information should be withheld where it is necessary to protect the privacy of an individual; and section 9(2)(ba)(ii) provides that information should be withheld when this is necessary to protect information which is subject to an obligation of confidence, and disclosing such information would be likely to damage the public interest (in a way other than that specified in section 9(2)(ba)(i)). Section 9(1) of the OIA requires the department or organisation holding the information to identify countervailing policy factors which favour disclosure, and weigh them against the criteria found in section 9(2), when considering whether to make a disclosure under the OIA.

Before embarking on a discussion of section 9(2), I note that any disclosure under this section would first require an individual to request the information, and in the context of a genetic relative requesting an individual’s genetic information, would require the genetic relative to be aware of (or at least the possibility of) the information existing in the first place. Thus, the discussion below is largely hypothetical, but nevertheless applicable to the issue in question.

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420 Official Information Act 1982, s4(b).

421 Official Information Act 1982, s4(c).
(ie how existing health information privacy laws in New Zealand apply to personal genetic information, and when (if at all) they allow such information be disclosed to an individual’s genetic relatives).

Now, looking at section 9(2)(a) and s9(2)(ba) in turn:

First, under section 9(2)(a), disclosing genetic information obtained by a health agency in the public sector, to an individual other that from whom the information was collected, would constitute a breach of that individual’s privacy where such a disclosure is not required or authorised by law. This reason for withholding information is, however, discretionary, and the Ombudsmen has noted that, when making a decision as to whether or not to disclose the information, a health agency should consider a number of matters in accordance with section 9(2).\textsuperscript{422} These include:

(a) identifying the actual privacy interest in question;
(b) assessing the strength of that privacy claim;
(c) identifying any considerations favouring disclosure;
(d) assessing the strength of those considerations; and
(e) assessing whether these considerations outweigh the need to withhold the information in order to protect privacy.

Hence, effectively, the health agency is encouraged to undertake a balancing operation and weigh up the competing interests that may be involved when a request for genetic information is made, as the Court would be required to do in relation to a common law action for breach of confidence.\textsuperscript{423}

If a complaint is made to the Ombudsman regarding the health agency’s disclosure, the Ombudsman is obliged to consult the Privacy Commissioner before forming a final opinion on the matter.\textsuperscript{424} If a disclosure is made in good faith under the OIA, the health agency will


\textsuperscript{423} See paragraph 5.2.4 above.

\textsuperscript{424} Official Information Act 1982, s29B.
not generally face civil or criminal proceedings, for example, an action for breach of privacy/confidentiality.\textsuperscript{425}

Hence, the Official Information Act may allow disclosure of an individual’s genetic information to his or her genetic relatives in certain circumstances where a request is made for such information, provided the disclosure is made in good faith, and the agency has considered the competing interests to genetic information.

Secondly, section 9(2)(ba) provides that information can be withheld (subject to the balancing exercise required under section 9(1)), where withholding information is necessary to:

\begin{itemize}
  \item[(ba)] Protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information—
    \begin{itemize}
      \item[(i)] Would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
      \item[(ii)] Would be likely otherwise to damage the public interest.\textsuperscript{426}
    \end{itemize}
\end{itemize}

An individual’s medical or genetic information is subject to a duty of confidentiality on the part of the health practitioner. Hence, in relation to the disclosure of genetic information, the first part of the withholding provision in section 9(2)(ba) is established. Further, it is also possible that any disclosure might discourage individuals from providing full information to their health practitioners. Therefore, in some circumstances, the requirement in section 9(2)(ba)(i) will be satisfied. However, it is unlikely that disclosing an individual’s genetic information to family members to reduce potential risk of genetic disease will have a sufficient impact on the public interest in maintaining confidentiality to outweigh it.\textsuperscript{427} As such, section 9(2)(ba)(ii) is not likely to protect an individual’s genetic information from disclosure if a request is made, and the individual to whom the information relates would have to rely on section 9(2)(a) in such an instance.

An analysis of the withholding provisions under the OIA indicates that only a weak constraint on the disclosure of an individual’s genetic information exists. It is possible, if a genetic

\textsuperscript{425} See Official Information Act 1982, s48(1)(a) and above, n422.

\textsuperscript{426} Official Information Act 1982, s9(2)(ba).

\textsuperscript{427} The notion of a public interest exception is discussed above at paragraph 5.2.4.1.
relative requests such information, that disclosure may be granted in light of the fact that section 9(2)(a) is discretionary in nature, and the health practitioner may not always withhold such information if he or she considers, after weighing up the privacy interest and any considerations which favour disclosure, that a disclosure should be made.

However, using the OIA as a mechanism to obtain relevant genetic information can only occur, and is only of benefit, where the individual seeking the information: (a) is aware that a genetic family member has undergone testing; and (b) any such testing took place at a public health agency.

5.4.10. Code of Health and Disability Services Consumers’ Rights 1996

The task of preparing a draft Code of Health and Disability Services Consumers’ Rights (HDSCR Code) was assigned to the Health and Disability Commissioner under section 19 of the Health and Disability Commissioner Act 1994. The complete Code of Health and Disability Consumers’ Rights subsequently came into force on the 1st July 1996 and is set out in the Schedule to the Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996 (drafted pursuant to section 74(1) of the Health and Disability Commissioner Act 1994).

The content of the HDSCR Code was prescribed in section 20 of the Health and Disability Commissioner Act 1994. One of the requirements listed in section 20 provides that the Code shall contain provisions regarding the rights of health consumers and the duties of obligations of health care providers as they relate to matters of privacy.428

The HDSCR Code does not apply, however, to matters that may be the subject of complaints under Part 7 or Part 8 of the Privacy Act 1993,429 and consequently excludes complaints made in relation to the breach of an Information Privacy Principle430 or Health Information Privacy Principle.431 Thus, while the code lists a number of health and disability consumer rights and

428 Health and Disability Commissioner Act 1994, s20(1)(c)(i).


430 Privacy Act 1993, s66(1)(a)(i).

health provider duties,\textsuperscript{432} one of which includes a provision protecting the privacy of a health consumer,\textsuperscript{433} the type of privacy concerned is spatial rather than informational. As such, the HDSCR Code does not have bearing on whether or not a health practitioner is authorised to disclose his or her patient's genetic information to that patient's genetic relatives.\textsuperscript{434}

\section*{5.5. Conclusion: disclosure of genetic information to genetic relatives unlikely to be justified under New Zealand health information privacy law}

An analysis of existing health (and genetic) information privacy and confidentiality law in New Zealand illustrates that the privacy of health/genetic information is not absolute, and that disclosure of that information is justified in certain circumstances.

First, under the NZMA Code of Ethics, a health practitioner can justifiably disclose an individual's health information where:

(a) the individual has consented to such disclosure;

(b) the law requires it; and/or

(c) an overriding public interest justifies it.

It is unlikely that any of these exceptions to health information privacy, however, justify the disclosure of an individual's genetic information to his or her genetic relatives for the purpose of averting harm to that relative where the individual concerned refuses to authorise such disclosure.

Secondly, the common law duty of confidentiality is not absolute and, much like the justifications available under the NZMA Code of Ethics, disclosure of health information may not be prohibited where:

(a) the individual consents to the disclosure; or

\textsuperscript{432} Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, SR1996/78, r2.

\textsuperscript{433} In particular, right 1(2) of the HDSCR Code provides that "every consumer has the right to have his or her privacy respected".

\textsuperscript{434} I acknowledge that the HDSCR Code sets out the rights of health consumers that have general relevance to the issues discussed in this thesis, such as the right to be treated with respect (Right 1), the right to be fully informed (Right 6) and the right to make an informed choice and give informed consent (Right 7). I have, however, confined the focus of this section to
(b) an overriding public interest exists which justifies disclosure.

Case law suggests, however, that the public interest exception is unlikely to extend to justify a health practitioner disclosing a patient’s genetic information to that patient’s genetic relatives where the patient has refused to consent.

Finally, statutory limits to the right to privacy/confidentiality exist under the HIPC, Health Act and the OIA.

The disclosure of personal information is permitted under these instruments where:

(a) an individual consents to such disclosure (or, consents to a genetic test on the basis that the resulting information may be disclosed to his or her genetic relatives, under rule three of the HIPC); or

(b) where the legislation expressly permits it.

An analysis of these statutory exceptions to privacy and confidentiality indicates that health information privacy legislation in New Zealand fails to recognise the rights of genetic relatives in knowing relevant genetic information. That is, the statutory exceptions to privacy: (a) are unlikely to justify the disclosure of genetic information to genetic relatives, even where such disclosure could prevent harm or suffering; and (b) do not otherwise provide any express recognition of genetic relatives’ rights or interests in knowing such information. Further, none of the instruments expressly address a genetic relative’s right not to know. (The right not to know is, however, indirectly protected on the basis that disclosure is not authorised.)

Summarising each instrument in turn:

(a) HIPC limits to privacy/confidentiality: even if a genetic disease is sufficiently serious, it is unlikely to satisfy the “imminent” test under Rule 11(2)(d)(ii).

(b) The Health Act limits to privacy/confidentiality do not extend beyond those that exist under the HIPC.

(c) Whilst the OIA is premised on the principle of availability, and in some instances may enable a health practitioner to disclose a patient’s genetic information to that patient’s genetic relatives without facing civil or criminal proceedings (given that the legislative provisions relating directly to the health practitioner’s ability to lawfully disclose an individual’s genetic information, rather than broad principles underlying good clinical practice.
requirement to withhold information where it would breach an individual’s privacy under section 9(2)(a) is discretionary), it only applies where the genetic relative is aware that information is being withheld from him or her, and such information is held by a public body. The OIA does not, therefore, expressly recognise the rights or interests of genetic relatives in knowing genetic information.

Thus, the competing interests that exist in relation to the right to know and the right not to know are not resolved under the existing health information law in New Zealand. Such laws place greater weight on the rights or interests of the individual, and do not recognise genetic relatives’ interests or rights in knowing (or not knowing) genetic information.

The position under New Zealand’s health information privacy law is further illustrated when applying it to the hypothetical clinical scenarios set out in Appendix One.
6. APPLYING NEW ZEALAND’S HEALTH INFORMATION PRIVACY LAW TO HYPOTHETICAL CLINICAL SCENARIOS

Applying New Zealand’s existing health information privacy laws to the hypothetical clinical scenarios set out in Appendix One illustrates that such laws need tailoring to take into account the competing interests between individuals and their genetic relatives in light of developments in genetics. A law that focuses primarily on the rights of the individual is no longer appropriate in the age of genetic medicine. In particular, this process emphasises that the law fails to adequately recognise a genetic relative’s right to know and not to know.

A factor that is common to each scenario is that, if the health practitioner complies with Rule 3 of the HIPC when collecting the genetic information in question, the legal issues that may arise in relation to disclosing such information to the patient’s genetic relatives are averted. The analysis below therefore assumes that Rule 3 of the HIPC has not been complied with, or for some reason, the patient subsequently revokes his or her authorisation to disclose (see, for example, scenario two).

6.1. Scenario one: familial adenomatous polyposis

John was 15 when his father died of colon cancer. John’s parents knew that the cancer was caused by familial adenomatous polyposis (FAP) (a disease caused by mutations on the APC gene), but did not discuss it with John. Instead the cause of John’s father’s cancer was “swept under the carpet” and not mentioned after he died, even though there was a 50 percent chance that John may have inherited the gene mutation associated with FAP.

At age 20, John was diagnosed with FAP and advanced colon cancer. He faces limited prospects of survival.435

John’s cancer could have been prevented if he had been aware of his risk and had had preventative surgery, or cured if diagnosed early enough.

Under New Zealand’s existing health information privacy law:
(a) John’s father’s right to privacy is recognised, and there are no exceptions that would allow a health practitioner to lawfully disclose his genetic information to John, because:

(i) John’s father did not consent to the disclosure of the information.

(ii) The threat posed to John was not immediate/imminent.

(iii) On that basis it is unlikely that the public interest exception to the duty of confidentiality would not apply.

(iv) John was not aware that his father’s cancer was genetic in origin, so it would not have crossed his mind to make a request for his father’s genetic information under the OIA.

(b) John’s right not to know genetic information is upheld by default, even though it is unlikely he would have chosen to enforce this right in the circumstances.

Thus, the law is weighted heavily in favour of protecting John’s father’s rights, and thus denies John’s rights, in relation to genetic information.

Where: (i) there is a 50 percent chance that John had inherited FAP; (ii) if John did inherit it, developing cancer was a certainty; and (iii) options for intervention existed that could have prevented or cured the cancer, arguably the law ought to recognise his right to know, and we can generally assume that John would not wish to exercise his right not to know in the circumstances.

6.2. Scenario Two

Susan, who is 40, discovers during an exploration of her family history that her mother’s sisters and some of her cousins had been diagnosed with breast cancer (some at an early age). Susan also knew that her mother had been diagnosed with the disease at about the same age as she is now. Concerned with her own risk, she was informed by her doctor (with the consent of her deceased mother) that, because a genetic test on her mother identified the BRCA gene that caused her cancer, a genetic test was available for Susan.

Before having the test, Susan agreed that she and other relatives, including her daughter could be informed of the outcome, so that her unaffected relatives could be tested. Susan undertook the genetic test and was told that she had the BRCA gene and therefore had around a 60% chance of developing breast cancer. Upon receiving the result, and despite her genetic counsellor advising her otherwise, she revoked permission for this information to be disclosed to her relatives, so that she could protect them from what she considered to be unnecessary worry.

Two years later, Susan’s older sister was shocked to be diagnosed with advanced breast cancer, being otherwise unaware of her risk.

The legal response to this scenario is similar to that in scenario one. That is, under New Zealand’s existing health information privacy law:

(a) Susan’s right to privacy is recognised, and there are no exceptions that would allow a health practitioner to lawfully disclose his genetic information to her relatives, because:

(i) Susan refused to consent to the disclosure of the information.

(ii) The threat posed to her relatives is not certain nor imminent.

(iii) On that basis it is unlikely that the public interest exception to the duty of confidentiality would not apply.

(iv) Susan’s relatives were not aware that she had had a test so would not have considered requesting this information under the OIA.

(b) Susan’s relatives’ right not to know is upheld by default.

Determining where the balance ought to lie in this scenario, however, is not as “black and white” as it was in scenario one.

Where: (i) there is 50 percent chance that Susan’s sister inherited the BRCA gene; but (ii) the risk of Susan’s sister subsequently developing breast cancer is not certain (i.e. there is only a 60 percent chance), it is not as clear that her right to know ought to outweigh Susan’s right to privacy, and a careful balancing exercise of the rights in question should take place before any disclosure is made. The law, however, does not provide for any such balancing exercise to be undertaken. Thus, despite this uncertainty involved in this scenario, the law still fails to adequately deal with the competing interests in question.
Further, the right not to know may play a more significant role here. It may not be appropriate to make a blanket assumption that a relative will want to be informed of his or her risk in this scenario. Indeed some women, despite knowing that breast cancer is prevalent in their family, would prefer not to know whether they carry the gene, and instead conduct regular checks for cancer and/or have preventative surgery. This right ought to be expressly recognised, rather than by default.

6.3. Scenario Three

Mary has a daughter with primary amenorrhoea. Tests indicate her daughter has complete testicular feminisation (that is, she is genetically male and cannot reproduce).

This disease follows an X-linked recessive pattern of inheritance. Therefore, her daughter's test result infers that Mary is likely to be a carrier of the gene. There is a 50% chance that her daughters and sisters without the syndrome are also carriers with a 25% chance of having an afflicted child.

Due to the social stigma of the syndrome, Mary refuses to inform her sisters and/or their daughters of the risk, even though intervention may prevent potential malignancies.436

Again, the legal response to this scenario is comparable to the responses in scenarios one and two. That is, under New Zealand’s existing health information privacy law:

(a) Mary’s right to privacy is recognised, and there are no exceptions that would allow a health practitioner to lawfully disclose his genetic information to her relatives, because:

(i) Mary refused to consent to the disclosure of the information.

(ii) It is arguable that Mary’s unaffected sisters or daughters do not face any risk. If they are, the threat posed is not imminent.

(iii) Therefore, the public interest exception to the duty of confidentiality is unlikely to apply.

(iv) Mary’s relatives were not aware that she had had a test so would not have considered requesting this information under the OIA.

(b) Mary’s relatives’ right not to know is upheld by default.

This scenario raises entirely different issues to scenarios one and two, in that there is no direct risk of physical harm faced by Mary’s relatives. Rather, the risk is faced by their future offspring. Thus, rather than preventing physical harm as in scenario one and two, being aware of the genetic information would allow Mary’s relatives to make informed reproductive decisions. (An analysis of the risks and benefits involved in, and the ethical considerations to be made in relation to, reproductive decision making and/or pre-birth genetic testing, is beyond the scope of this thesis. It does, however, illustrate that the benefit that results from disclosing an individual’s genetic information to his or her genetic relatives will not always outweigh the harm suffered as a result of an interference with the individual’s privacy.)

The right not to know also plays a significant role here. Mary’s relatives may not want to let the knowledge of the potential risk faced by their future children influence their reproductive decision making.

6.4. Scenario Four

| Anna’s grandmother developed Huntington’s Disease (HD) when she was 45, and later died, aged 55. There is a 50 percent chance that Anna’s mother has inherited the disease, and therefore a 25 percent chance that Anna has too. People who have the HD gene invariably develop the disease. |
| Anna has lived with the knowledge that she might develop HD since she was in her teens, and now wants to have a predictive genetic test to determine whether or not she has inherited the HD gene, before deciding whether to start a family. Anna’s mother is adamant that she does not want to know. If Anna’s test results reveal that she has inherited the HD gene, it means her mother must also have the gene. If Anna’s test results reveal that she has not inherited the HD gene, this does not rule out her mother’s risk of having inherited it (seeing as there is only a 50 percent chance of passing the gene on to one’s children). |
| The results of Anna’s genetic test reveal that she has inherited the HD gene, and she wants to turn to her mother for support. |
Again, the legal response to scenario four is slightly different to the response in scenarios one to three. Under New Zealand’s health information privacy law:

(a) Anna’s right to privacy is recognised, but no question arises in relation to the health practitioner’s ability to lawfully disclose her genetic information, because Anna wishes to disclose the information herself. (If Anna did not disclose her genetic information, or refused to consent to the health practitioner disclosing it, there are no exceptions under New Zealand’s health information privacy law that would justify disclosure.)

(b) Anna’s mother’s right not to know is disregarded, and she may face adverse psychological consequences from being informed of information she did not want to know.

Where: (i) there is a 50 percent chance that Anna’s mother has inherited HD; (ii) if Anna’s mother has inherited it, developing HD is a certainty; and (iii) there are no available interventions, arguably the law ought to expressly recognise her right not to know, and we can generally assume that Anna’s mother would be tested herself if she did want to find out her genetic status. Whilst it is difficult to legislate against Anna disclosing her test results to her mother, any ethical guidelines or the commentary to the HIPC should require health practitioners to strongly encourage her to respect her mother’s right not to know in these circumstances.
PART D

7. CONCLUSION

The right to privacy is a recognised as a fundamental human right. It goes without saying that sensitive information such as genetic information is, by its very nature, worthy of legal protection.

The ethical bases for the respect for privacy lie in: (a) the principle of autonomy; (b) the obligation of fidelity; and (c) ensuring people are not reluctant to disclose sensitive information where doing so is necessary to, for example, provide medical treatment.

The right to privacy, however, is not absolute, and just as there are ethical justifications for maintaining privacy, so too are there ethical justifications for limiting it. The justifications for limiting the right to privacy apply where competing moral values, such as the principle of beneficence, outweigh the principle of autonomy. The principle of beneficence involves concern for the safety of other identifiable individuals, and in some circumstances, justifies the imposition of an ethical obligation on individuals and health practitioners to warn genetic relatives of the risk of developing a genetic disease (for example, where the disclosure is necessary to prevent or lessen harm, and any such benefit (ie in avoiding harm) outweighs the likely cost or burden to the individual and/or to the health practitioner).

Such ethical justifications for disclosing genetic information to at-risk genetic relatives are not, however, reflected under New Zealand's health information privacy law. Neither common law nor statutory limitations to the right to privacy are broad enough to permit the disclosure of genetic information to genetic relatives, even where such disclosure would potentially lessen or prevent serious harm. Accordingly, the rights and interests of genetic relatives in knowing genetic information are not adequately recognised. On the flipside, the rights and interests of genetic relatives in not knowing genetic information, whilst not expressly recognised, are upheld by default, even where it is unlikely that such persons would elect to enforce such a right.

This imbalance between the rights and interests of individuals and their genetic relatives recognised under New Zealand's existing health information privacy law is demonstrated by
applying it to the hypothetical clinical scenarios set out in Appendix One, illustrating that in most instances, only the interests of the individual and not genetic relatives are recognised.

It follows that New Zealand’s health information privacy law does not provide an appropriate balance between the competing interests at stake, that is the competing interests between individuals and their genetic relatives, in knowing or not knowing genetic information.

How then do we achieve an appropriate balance between these competing interests? To answer this question:

(a) In chapter 6, I provide a comprehensive review of: (a) health information privacy law in Australia and England and Europe (at an inter-governmental level) and (b) relevant instruments developed by inter-governmental bodies such as UNESCO and the OECD, in order to assess whether the approaches taken in these jurisdictions provide useful solutions to the issue at stake.

(b) In chapter 7, I review and critique the proposals made by the Privacy Commissioner in relation to the dilemma, and, drawing on solutions proposed in other jurisdictions, make recommendations as to how to achieve a balance between an individuals and his or her genetic relatives’ rights and interests.
CHAPTER 6
OTHER JURISDICTIONS

1. INTRODUCTION

The challenges involved in deciding how best to regulate the privacy of genetic information are universal. In particular, the challenge of balancing an individual's presumptive right to privacy and confidentiality in his or her genetic information with the competing rights of that individual's genetic relatives in knowing such information has been contemplated across a number of jurisdictions, and at an inter-governmental level.

The purpose of this chapter is to:

(a) examine the legal approaches taken in Australia, England, Europe and at an inter­governmental level in dealing with the challenges raised by the familial nature of genetic information; and
(b) consider such approaches against those taken in New Zealand.

2. AUSTRALIA

2.1. Introduction – existing privacy regulation in Australia

Health or genetic information privacy law in Australia consists of a combination of:

(a) professional codes of ethics;
(b) common law doctrines; and
(c) a complex, fragmented, and sometimes overlapping set of legislation at Federal, State and Territory levels.\(^{437}\)

2.2. Duty of confidentiality under the Australian Medical Association Code of Ethics and Australian Common Law

The duty of confidentiality owed by health practitioners to their patients under the Australian Medical Association Code of Ethics (AMA Code of Ethics) and Australian common law (except in relation to a potential "duty to warn", which is discussed at paragraph 2.3 below) is comparable to the duty owed in New Zealand under the New Zealand Medical Association Code of Ethics and New Zealand common law. That is, health practitioners must not disclose their patients' sensitive health information to third parties for purposes other than those for which the health information was collected unless:

(a) the patient consents;

(b) the law requires it;

(c) the public interest in disclosing confidential health information to third parties outweighs the public interest in maintaining confidentiality; and/or

(d) the life of another individual is in immediate danger. 438

As concluded in Chapter 5, none of these exceptions to confidentiality would likely justify the disclosure by a health practitioner of an individual's genetic information to his or her at-risk genetic relatives where the individual did not consent to such disclosure.

2.3. Duty to warn under Australian common law?

In contrast to the position taken by the New Zealand High Court in Maulolo v Hutt Valley Health Corporation,439 in BT v Oei,440 the Supreme Court of New South Wales recognised that a health practitioner may owe a duty of care to a third party. In particular the Court held that a health practitioner owes his or her patient's partner a duty of care to:


439 [2002] NZAR 375, 383. See also Chapter 5, paragraph 5.2.4.2.

(a) explain to the patient the implications a positive HIV test has for that partner; and

(b) advise the patient to inform his or her partner that they need to be tested also.

In light of this, a health practitioner may owe a duty of care to his or her patient’s genetic relatives to explain to the patient the implications that a genetic test may have on his or her genetic relatives, and to advise the patient to disclose the genetic information derived from the test where disclosure could reduce or prevent harm. This does not, however, translate into a positive and direct duty to warn a patient’s genetic relatives of their risk of developing a genetic disorder.

2.4. Australian legislation relating to the privacy of genetic information

2.4.1. Background

The question of how best to legislate the right to privacy of genetic information has received considerable attention in Australia.

Initially there was some debate as to whether a genetic-specific legislative instrument was required in order to protect the privacy of genetic information. In response to that debate, on 11 March 1998, Senator Natasha Stott Despoja (the Deputy Leader of the Australian Democrats at the time) introduced the Genetic Privacy and Non-Discrimination Bill 1998 (Bill), which differentiated genetic information privacy and general information privacy. The Bill was referred to The Senate Legal and Constitutional Legislation Committee for inquiry, who recommended that it did not proceed until:

(a) further examination of the issues had taken place; and

(b) appropriate amendments to existing legislation in relation to genetic privacy and discrimination had been developed.441

Consequently, the Australian Government asked the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) to jointly inquire into the issues associated with the development of genetic science.

In March 2003, ALRC and AHEC released their final report (ALRC Report), which contained 144 recommendations for reform in relation to the protection of human genetic information in Australia.442 These recommendations were based on extensive research and community consultation, and took into account hundreds of submissions received from the general community, experts and interest groups.

The ALRC Report examined how best to:

(a) protect an individual’s right to privacy of genetic information;

(b) protect against unfair discrimination in respect of genetic information; and

(c) ensure that the highest ethical standards were used in conducting research in relation to genetic information.443

Notably, the ALRC discussed issues, and made recommendations to amend existing privacy legislation, in relation to how individual patients and health practitioners should deal with genetic information about genetic relatives derived in the course of diagnosis and treatment of, and counselling in relation to, genetic disease.444

On 9 December 2005, the Australian Government issued a formal response to, and accepted many of, the recommendations in the ALRC Report (which led to a number of amendments to the Privacy Act 1988 (Cth)).445

Accordingly, in the remainder of this section I discuss:

(a) existing privacy law in Australia, at the Federal, State and Territory level, as it applies to the disclosure of genetic information;

(b) summarise the recommendations made in the ALRC Report, and in particular, those recommendations that were adopted by the Australian Government; and

442 Above, n437: 53.

443 Above, n437: 33.

444 Above, n437: 547 - 571.

(c) assess where the balance now lies under existing Australian legislation between the interests of individuals and their genetic relatives in knowing/not knowing genetic information.

2.4.2. The interplay between Federal, State and Territory health information privacy legislation

Information privacy is regulated at Commonwealth, State and Territory levels through:

(a) specific information and/or health information privacy legislation; and
(b) confidentiality and secrecy provisions contained in other legislation.\(^446\)

As a result of health information privacy being regulated in Australia at Federal, State and Territory levels, and Australia’s public and private sectors being regulated separately, Australia’s health information privacy regime is complicated, with some activities being regulated by more than one piece of legislation.

Health information held by private sector health service providers is regulated by the Privacy Act 1988 (Cth), and in particular by the National Privacy Principles (NPPs) set out therein, and also:

- in Australian Capital Territory, by the Health Records (Privacy and Access) Act 1997;
- in New South Wales, by the Health Records and Information Privacy Act 2002; and

Further, on 28 March 2007, the Information Privacy Bill 2007 was introduced to the Western Australian Parliament, which if enacted, will apply to both public and private sector health service providers.\(^447\)

Health information held by public sector health service providers is regulated by the following legislation:


• at the Federal level, the Privacy Act 1988 (Cth), an in particular by the Information Privacy Principals (IPPs) set out therein (which relate generally to "personal information");
• in the Australian Capital Territory, by the IPPs in the Privacy Act 1988 (Cth) and the Health Records (Privacy and Access) Act 1997;
• in New South Wales, by the Health Records and Information Privacy Act 2002;
• in South Australia, by the Information Privacy Principles Instruction 1992;
• in Tasmania, by the Personal Information Protection Act 2004;
• in Victoria, by the Health Records Act 2001;
• in the Northern Territory, by the Information Act 2003; and
• if enacted in Western Australia, by the Information Privacy Act 2007 (see above).

Further, at the request of Australian Government's Health Ministers, a National Health Privacy Working Group was set up in 2000 to oversee the development of a national framework for health privacy, with the aim of (among other things) achieving national consistency in health privacy protection, both across jurisdictions and between the public and private sectors. The proposed framework (the draft National Health Privacy Code) was released in August 2003, together with a paper outlining options for implementation.

Note, in States and Territories where the Privacy Act 1988 (Cth) and the State and Territory laws listed above both apply:

(a) Section 3 of the Privacy Act 1988 (Cth) specifies that:

3. Saving of certain State and Territory laws

It is the intention of Parliament that this Act is not to affect the operation of a law of a State or Territory that makes provision with respect to the collection, holding, use, correction, disclosure of transfer of personal information (including such a law relating to the use of information held in connection with credit reporting) and is capable of operating concurrently with this Act.
That is, if the Privacy Act 1988 (Cth) and the State and Territory laws are different, but can operate concurrently, health practitioners must comply with both sets of legislation.

(b) To the extent that there are *direct* inconsistencies between Commonwealth and State or Territory laws (ie they cannot operate concurrently), generally, the Commonwealth law will prevail.\(^{449}\)

For the purpose of this thesis, I have confined my focus to relevant features of the Commonwealth legislation (ie the Privacy Act 1988 (Cth)) because the Privacy Act 1988 (Cth) specifically deals with the issues presented by the familial nature of genetic information, and therefore provides a meaningful comparison against which to assess New Zealand health information privacy legislation (which, to date, does not directly deal with such issues), and in light of (b) above.\(^{450}\)

### 2.4.3 Privacy Act 1988 (Cth)

Until 2001, the Privacy Act 1988 (Cth) only applied to personal information held by Commonwealth agencies (including Ministers, Departments and other bodies established for a public purpose of the Commonwealth).\(^{451}\) In December 2001, however, the Privacy Amendment (Private Sector) Act 2000 (Cth) came into force, which extended the jurisdiction of the Privacy Act 1988 (Cth) to cover personal information held by private sector organisations including all health service providers.\(^{452}\) Thus, the Privacy Act 1988 (Cth) also covers private sector entities such as private hospitals and health practitioners.

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450 Note, in confining the focus of this thesis to Commonwealth legislation, I do not intend to dismiss the relevance of some State and Territory health information privacy law to the protection of genetic information. In particular, the Health Records and Information Privacy Act 2002 (New South Wales), Information Act 2002 (Northern Territory), Personal Information Protection Act 2004 (Tasmania), Health Records Act 2001 (Victoria), and the Information Privacy Bill 2007 (Western Australia), all deal specifically with genetic information. Not all of these statutes are consistent with the amended Privacy Act 1988 (Cth), with some providing more constraint on a health practitioners' disclosure of genetic information to genetic relatives than the Privacy Act 1988 (Cth) (ie by retaining the "serious and imminent" test, discussed further below). However, given the recency of the amendments to the Privacy Act 1988 (Cth), in light of the fact that the Commonwealth legislation will likely prevail where there are inconsistencies between it and State/Territory legislation, and for the sake of brevity, I have not conducted an in-depth analysis of State and Territory legislation.

451 Privacy Act 1988 (Cth), s6C

452 Above, n451.
The Privacy Act 1988 (Cth) gives individuals control over (among other things) how their personal information is collected, used and disclosed. In particular, the Privacy Act 1988 (Cth) requires:

(a) Commonwealth agencies to comply with the IPPs. (See section 14, Principles 1, 10 and 11 for principles in relation to the collection, use and disclosure of personal information.)

(b) Private sector organisations, including health service providers, to comply with the NPPs. (See Schedule 3, clauses 3(1) and (2) for principles in relation to the collection, use and disclosure of personal information, and schedule 3, clause 10 for principles in relation to the collection of sensitive information.)

Relevantly, the NPPs specifically deal with (among other things) the collection, use and disclosure of health information and, since the enactment of the Privacy Legislation Amendment Act 2006, genetic information. Accordingly, in the remainder of this section 2.4.3, I discuss:

(a) the amendments to the Privacy Act 1988 (Cth) which make specific reference to genetic information, and in particular, that relate to the disclosure by a health practitioner of an individual’s genetic information to his or her genetic relatives; and

(b) the reasoning behind such amendments.

### 2.4.3.1 Amendments to the Privacy Act 1988 (Cth)

In the ALRC Report, the ALRC and AHEC recommended that:

(a) States, Territories and privacy regulators should consider harmonising their privacy regimes, as applicable, in a manner consistent with the recommendations in the ALRC Report. 453

(b) The Privacy Act 1988 (Cth) definition of “health information” be amended to include genetic information. 454

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453 Above, n437: Recommendation 7-2: 55.

454 Above, n437: Recommendation 7-4: 55.
(c) The Privacy Act 1988 (Cth) definition of “sensitive information” be amended to include genetic information.455

(d) The Privacy Act 1988 (Cth) be amended 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 prevent a serious threat to an individual’s life, health or safety, even where the threat is not imminent.456

(e) The NHMRC, in consultation with the Office of the Federal Privacy Commissioner, should develop guidelines for health professionals dealing with the disclosure of genetic information to the genetic relatives of their patients, and those guidelines should:

(i) address the circumstances in which disclosure to genetic relatives is ethically justified or required, and the need for patients to be counselled about the disclosure of information in these circumstances;

(ii) be made pursuant to either new provisions of the Privacy Act 1988 (Cth) of section 7 of the National Health and Medical Research Council Act 1992 (Cth); and

(iii) include advice to health professionals in dealing with requests for access to genetic information by the genetic relatives of their patients.457

(f) The Privacy Act 1988 (Cth) be amended to provide that individuals have a limited right to access genetic information about first-degree genetic relatives.458

The recommendations set out at paragraphs 2.4.3.1(b) - (e) above were adopted in the Privacy Legislation Amendment Act 2006 (which came into force on 14 September 2006), and resulted in the following provisions being incorporated into the Privacy Act 1988 (Cth):

(a) The definition of “genetic relative” was inserted at section 6(1) of the Privacy Act 1988 (Cth):

455 Above, n437: Recommendation 7-5: 55.
genetic relative of an individual (the first individual) means another 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.459

(b) Genetic information was included within the definition of health information at sub-section 6(1) of the Privacy Act 1988 (Cth), ie:

health information means:

...  
(d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.460

(c) Genetic information was included within the definition of “sensitive information” at sub-section 6(1) of the Privacy Act 1988 (Cth), ie:

sensitive information means:

...  
(b) health information about an individual; or
(c) genetic information about an individual that is not otherwise health information.461

(d) Under a new section 95AA of the Privacy Act 1988 (Cth):

For the purposes of subparagraph 2.1(ea)(ii) of the NPPs, the Commissioner may, by legislative instrument, approve guidelines that relate to the use and disclosure of genetic information for the purposes of lessening or preventing a serious threat to the life, health or safety (whether or not the threat is imminent) of an individual who is a genetic relative of the individual to whom the genetic information relates.462

(e) Most significantly, under Schedule 3, new subparagraph 2.1(ea) of the Privacy Act 1988 (Cth):


459 Privacy Legislation Amendment Act 2006, Sch 2, s1
460 Above, n459: Sch 2, s2.
461 Above, n459: Sch 2, s3. Note, under Schedule 3, Clause 10 of the Privacy Act 1988 (Cth), an organisation must not collect “sensitive information” about an individual unless the individual consents (among other factors) to such collection.
462 Above, n459: Sch 2, s4.
2.1 An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless:

(ea) if the information is genetic information and the organisation has obtained the genetic information in the course of providing a health service to the individual:

(i) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of an individual who is a genetic relative of the individual to whom the genetic information relates; and

(ii) the use or disclosure is conducted in accordance with guidelines approved by the Commissioner under section 95AA for the purposes of this subparagraph; and

(iii) in the case of disclosure—the recipient of the genetic information is a genetic relative of the individual...

2.4.3.2 Reasoning behind amendments to the Privacy Act 1988 (Cth)

The above recommendations and amendments result primarily from the difficulties associated with applying the "serious and imminent" test to genetic information.

In particular, the ALRC Report highlighted the problems inherent in applying the "serious and imminent" under the old provisions of the Privacy Act 1988 (Cth) to genetic risk, and in particular, the disclosure of an individual's genetic information to his or her genetic relatives to avert potential harm where the individual does not consent to such disclosure. Under the old regime, like under the New Zealand HIPC, any such disclosure:

(a) Could only be made where the health practitioner reasonably believed that the use or disclosure was necessary to lessen or prevent:

(i) a serious and imminent threat to an individual's life, health or safety; or

(ii) a serious threat to public health or public safety.\(^{463}\)

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\(^{463}\) Privacy Act 1988 (Cth), Sch 2, s2.1(e).
(b) Would not be permitted, even where the genetic relatives might suffer serious harm from not knowing the relevant genetic information, on the basis that such harm (or threat of such harm) is rarely (if ever) imminent.

The ALRC and AHEC concluded that the old privacy regime:

> inappropriately constrains health professionals’ decisions about the disclosure of clinically relevant information to genetic relatives.\(^\text{464}\)

The ALRC and AHEC identified the “serious and imminent” test in NPP 2.1(e)(i) as one of the fundamental reasons for this “inappropriate constraint” on the basis that:

(a) Genetic risks would not likely ever pose a serious and imminent threat because:

(i) Most genetic conditions take time to manifest.

(ii) For some genetic conditions, the threat is to future children, rather than living individuals.\(^\text{465}\)

(b) Despite the lack of imminent threat, genetic risks have the potential to cause serious harm if not identified early. This point is illustrated in a submission to ALRC and AHEC by Dr Finlay Macrae in relation to the application to the “serious and imminent” test to the genetic condition FAP. Dr Macrae stated that:

> The lack of imminence precludes more direct contact [with genetic relatives] at that stage according to the Privacy Laws, but does not preclude the development of cancer at a later stage which is not less lethal for its lack of imminency, and no less destructive within the family.

The ALRC and AHEC provided two potential solutions to overcome the issues associated with applying the “serious and imminent” test to genetic information.

The first was to amend NPP 2.1(e)(i) by removing the reference to “imminent”, in order to make the exception under NPP2.1(e) more permissive.\(^\text{466}\)
The second was to enact a new NPP 2.1(e)(iii), whereby health practitioners would be entitled, subject to guidelines issued by the NHMRC and approved by the federal Privacy Commissioner to:

 disclosed an individual's genetic information to a genetic relative where such disclosure is reasonably believed to be necessary to lessen or prevent serious harm to any individual. 467

The ALRC and AHEC considered that adopting guidelines to provide direction in relation to the relaxation of the "serious and imminent" test was desirable on the basis that such guidelines would:

(a) Overcome the difficulty in legislating in relation to disclosure of genetic information where the circumstances in which such disclosure should be permissible are not easily defined and will vary depending upon the type of genetic condition involved (ie depending on the penetrance and expression of the disease, and prevention and treatment options). In particular, the ALRC and AHEC noted that guidelines:

 are capable of accommodating the impact of rapid scientific advance in genetic medicine and taking account of the multiplicity of factors relating to risk and perceptions of risk. 468

(b) Record accepted standards of professional practice, and therefore provide health practitioners protection from complaints/litigation if they make any disclosure in accordance with the guidelines. 469

The ALRC and AHEC did not go as far as recommending that the Privacy Act 1988 (Cth) be amended to allow disclosure of genetic information to inform prospective parents that their future children might be born with genetic disorders, because they considered that the threat of harm was too remote to justify further limiting privacy protection. 470

467 Above, n437: 560.

468 Above, n437: 565, citing submissions by Victoria Breast Cancer Laboratory – Walter and Eliza Hall Instituted of Medical Research, Submission G258, 20 December 2002; and Department of Health Western Australia, Submission G271, 23 December 2002.

469 Above, n437: 565.

470 Above, n437: 563.
The Office of the Federal Privacy Commissioner supported the ALRC's second solution, on the basis that the first required broader policy arguments to justify weakening privacy protection to the degree contemplated. Consequently, the amendments set out in paragraph 2.4.3.1 above were enacted.

2.4.4. Summary and critique

Australia is one step ahead of New Zealand in terms of: (a) considering the privacy implications that have arisen as a result of increased knowledge surrounding genetic diseases; and (b) amending its health information privacy legislation (at least at the Commonwealth level) so that it adequately deals with those implications.

The Privacy Act 1988 (Cth) goes some way towards providing an appropriate balance between individual and familial rights in that it recognises both an individual’s right to privacy, and in certain circumstances (ie where disclosing genetic information could prevent or lessen serious risk to a genetic relative), his or her genetic relatives right to know genetic information.

The following issues, however, remain to be resolved before Australia’s health information privacy legislation provides an appropriate degree of protection, for individuals and their genetic relatives, in relation to genetic information:

(a) First, a parallel amendment to those made in relation to NPP 2.1(ea) must be made to the equivalent IPP11, which applies to doctors and other health professionals working for Commonwealth government agencies, so that the same privacy rules apply, regardless of the sector within which a health practitioner works.

(b) Secondly, parallel amendments to State and Territory privacy legislation should be implemented across the board, so that the inconsistencies between Federal, State and Territorial privacy protection are dispelled.

(c) Thirdly, the NHMRC should issue guidelines forthwith. (Ideally, these should have been in place before the commencement of the Privacy Legislation Amendment Act 2006.)
(d) Fourthly, it remains to be seen whether acting in accordance with the amended *Privacy Act 1988 (Cth)* will breach a health practitioner's common law duty of confidentiality. This matter has yet to be considered by the Court.

(e) Finally, the Privacy Act 1988 (Cth) ought to expressly recognise an individual's right not to know genetic information.

3. **UNITED KINGDOM**

3.1. **Introduction – existing privacy/confidentiality law in the United Kingdom**

The protection of personal genetic information in the United Kingdom, like in New Zealand and Australian privacy regimes, is regulated by:

(a) reports, guidelines, and codes of practice issued by various regulatory and representative bodies, including by the General Medical Council (GMC), the British Medical Association (BMA), and the Department of Health (DH).

(b) common law duties of confidentiality; and

(c) legislation including the Data Protection Act 1998 and Health Records Act 1990.

While most of these forms of regulation do not specifically mention it, they nevertheless apply to genetic information.

There is a considerable overlap between United Kingdom, Australian and New Zealand privacy and confidentiality laws. Accordingly, in this section I provide only a brief overview of how personal genetic information is protected in the United Kingdom, and on any recommendations that have been made in this regard.

3.2. **Guidelines and Codes of Practice.**

3.2.1. **Introduction to UK Guidelines/Codes of Practice**

Health service providers in the United Kingdom must comply with guidelines issued by different regulatory and representative bodies, including the GMC, BMA and the DH (among other organisations, and depending upon membership/registration with such bodies) in order to stay registered on applicable professional registers which permit health practitioners to practice. Failure to comply with such guidelines can lead to disciplinary proceedings with
sanctions, including restriction of practice, suspension and being struck off the register. On the flipside, it was held in Bolam v Friern Hospital Management Committee that, where health practitioners act in accordance with a reputable body of opinion, they are not likely to be held to have acted negligently (provided the guidance itself does not recommend acting unlawfully and the guidance is still current within the profession).

The GMC, BMA and DH have each issued guidelines relating specifically to privacy and/or confidentiality. In addition, the Human Genetics Commission (HGC) has published recommendations in relation to balancing interests in the use of genetic information.

3.2.2. GMC: Good Medical Practice

The GMC is a professional regulatory body, established under section 1 of the Medical Act 1983, and developed to protect, promote and maintain the health and safety of the public. It has a statutory authority, under section 35 of the Medical Act 1983, to:

provide, in such manner as the Council think fit, advice for members of the medical profession on standards of professional conduct, or performance, or on medical ethics.

In W v Edgell, Scott J begins his discussion on issues of medical confidentiality by examining guidelines issued by the GMC, which illustrates the weight placed by the Courts on such guidelines.

The GMC's core guideline is entitled Good Medical Practice which sets out the:

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471 For example, the GMC's Good Medical Practice guideline states that "[s]erious or persistent failure to follow this guidance will put your registration at risk." See General Medical Council. Good Medical Practice. (General Medical Council, London, 2006), 5. (Note, the GMC, rather than the BMA and/or DH, is responsible for registering and disciplining medical practitioners.)

472 [1957] 1 WLR 583, 587. Note, the decision in Bolam has been subject to scrutiny by the Courts due to its paternalistic approach, but has relatively recently been applied by the Court of Appeal in Gold v Haringey Health Authority [1988] QB 481 (CA).


474 Medical Act 1983, s35

475 [1989] 1 All ER 1089.

(a) principles and values on which good practice is founded; and

(b) standards of conduct and care which society and the profession expects of all doctors.

One of the duties of a doctor registered with the GMC is to respect patients’ rights to privacy and confidentiality. Similar to the NZMA and AMA Codes of Ethics, Paragraph 37 of Good Medical Practice states that:

Patients have a right to expect that information about them will be held in confidence by their doctors. You must treat information about patients as confidential, including after a patient has died. If you are considering disclosing confidential information without a patient's consent, you must follow the guidance in Confidentiality: Protecting and providing information.

Confidentiality: Protecting and Providing Information (GMC Confidentiality Guideline) provides more detailed information on how to comply with Principle 37 of Good Medical Practice. In particular, where a health practitioner is asked to disclose a patient’s health information to a third party, paragraph 1 of the GMC Confidentiality Guideline states that the health practitioner must seek that patient’s express consent to disclosure such information where the disclosure of identifiable data is needed for any purpose other than the provision of care for that patient, unless any of the exceptional circumstances described in the GMC Confidentiality Guideline apply. Those exceptional circumstances are comparable to, but perhaps broader than, those that apply in New Zealand and Australia. In particular, disclosure without consent is permitted where it is:

(a) Required by law.

(b) Justified in the public interest, including where failing to disclose the relevant health information may expose the patient or others to risk of serious harm.

477 Above, n476: 4.


479 Above, n476, paragraph 21(d): 15.

480 Above, n476, paragraph 37: 20.


482 Above, n481: paragraph 18.

483 Above, n481: paragraphs 24 and 27.
In relation to this justification, the GMC Confidentiality Guideline explains that:

(b) The risk must be so serious that it outweighs the patient’s privacy interest. In particular, the third party must be exposed to “risk of death or serious harm”.

(ii) The health practitioner should seek the patient’s consent to the disclosure where practicable.

(iii) The health practitioner should take into account any reasons offered by the patient for his or her refusal to disclose the information.

(iv) Even where consent is not forthcoming, the health practitioner should generally inform the patient before disclosing the information.

(v) If the health practitioner still considers that disclosure is necessary to protect a third party from death or serious harm, he or she should disclose information promptly to an appropriate person or authority.484

While the GMC Confidentiality Guidelines do not specifically refer to genetic information, the disclosure by a health practitioner of an individual’s genetic information to his or her at-risk genetic relatives without consent, where not doing so would pose a serious risk to those genetic relatives, fits neatly within the public interest exception described at (b) above.

Whether such disclosure is permitted at law in the United Kingdom is discussed at paragraphs 3.3 and 3.4 below.

3.2.3. BMA: Human Genetics: Choice and Responsibility

The BMA is a professional association of doctors, representing their interests and providing services for its members. It is a voluntary association with over two thirds of practising doctors in membership.485 Among other things, the BMA keeps members up to date with clinical and other medical issues.486 The Medical Ethics Committee of the BMA produces

484 Above, n481: paragraph 27.


reports, codes of practice and discussion documents on topical and often controversial issues in order to inform and assist doctors in practice and promote ethical and legal conduct.\(^{487}\)

In 1998, the BMA released a publication entitled *Human Genetics: Choice and Responsibility*\(^{488}\) (BMA Publication) regarding the implications of human genetic information on medical practice. The BMA Publication, though dated, still provides relevant guidance on questions about confidentiality and disclosure of such information, taking into account legal and ethical standards.

In its publication, the BMA: (a) emphasises that in all areas of health care, the doctor’s duty of confidentiality to their patients is of fundamental importance and should only be breached for justifiable reasons; and (b) provides a thorough analysis of the factors that may warrant disclosure of genetic information, taking into account the fact that developments in genetic testing means that doctors increasingly hold genetic information that may have relevance for the entire family as opposed to just one individual.

In relation to the disclosure of genetic information, the BMA acknowledged that while individuals have a *moral* obligation to share relevant genetic information with their genetic relatives, health practitioners cannot compel individuals to fulfil that obligation.\(^{489}\) On that basis, the BMA advised that: \(^{490}\)

(a) Where an individual seeks genetic testing which would provide significant information about a genetic relative, the individual tested should be strongly encouraged to share relevant information with such relatives.

(b) Instances may arise where the individual refuses to share his or her genetic information with his or her genetic relatives, in which case such refusal should be respected unless, in very exceptional circumstances, not disclosing this information may put those relatives at risk of death or serious harm. In assessing whether a genetic relative will be


\(^{489}\) Above, n488: 71.

\(^{490}\) Above, n488: 71 - 73.
exposed to serious risk if he or she is not informed of his or her risk, the following factors should be considered:

(i) the severity of the potential genetic disorder;

(ii) the level of predictability of the information provided by testing;

(iii) what, if any, action the relatives could take to protect themselves or to make reproductive decisions if they were not informed of the risk.

The level of harm or benefit involved in disclosing or withholding the information should be carefully considered before any disclosure is made.

(c) If a doctor considers it necessary to proceed with disclosing an individual’s genetic information, without his or her consent, to at-risk genetic relatives (ie in the circumstances described in (b) above), such disclosure should be discussed with the patient before the information is divulged. Any reason given by the patient for refusing to share the information should be taken into account. It may sometimes be possible to avoid the need for non-consensual disclosure by counselling and providing general information to the person who may be at risk.

(d) As far as possible, where disclosure without the consent of the individual tested is necessary, genetic information which is given to genetic relatives should not identify that individual.

Thus, the BMA’s publication is based on the premise that an individual’s genetic information can be disclosed to at-risk relatives without that individual’s consent, but only in certain circumstances. Again, whether this position is reflected at law in the United Kingdom is discussed at paragraphs 3.3 and 3.4 below.

3.2.4. DH: Confidentiality: NHS Code of Practice

The DH’s role includes (among other things): (a) overseeing and improving the quality and convenience of health care provided by the NHS; and (b) setting national standards and shaping the direction of health care services.491

In 2003, the DH published *Confidentiality: NHS Code of Practice* (Code of Practice) after a major public consultation that took place in 2002/2003, involving patients, carers, citizens and the National Health Service (NHS), other health care providers, professional bodies and regulators.\(^{492}\)

The Code of Practice is a guideline for employees or contractors of the NHS on confidentiality and patients’ consent to the use of their health information. That is, the requirement to comply with the Code of Practice does not depend upon registration, as with the GMC.

The Code of Practice describes the concept of confidentiality, summarises the legal requirements in relation to confidentiality, and provides a decision support tool for sharing/disclosing information (including providing information disclosure scenarios).\(^{493}\)

Like the GMC Confidentiality Guideline, the Code of Practice does not specifically refer to genetic information, but is nevertheless applicable to it.

The UK Information Commissioner, GMC and BMA have all endorsed the Code of Practice.\(^{494}\) In particular:

(a) The Information Commissioner endorsed the Code of Practice as being consistent with the common law duty of confidence and data protection legislation.

(b) The President of the GMC noted that: (i) while some differences in detail and emphasis exist between the GMC Confidentiality Guideline and the Code of Practice, both are based on common principles and values; and (ii) if doctors follow the Code of Practice, they will also be satisfying the GMC Confidentiality Guideline.

(c) The Chairman of the Medical Ethics Committee of the BMA endorsed the Code of Practice as providing a useful guide as to how to strike the balance between protecting privacy and making information available when necessary.\(^{495}\)

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\(^{493}\) Above, n 492: 3.

\(^{494}\) Above, n 492: 2.

In light of the consistency of the Code of Practice with the other guidelines discussed in this paragraph 3.2, confidentiality and data protection laws (discussed at paragraphs 3.3 and 3.4 below), it is not necessary to discuss the requirements of the Code of Practice in detail. However, of particular relevance to this thesis, the Code of Practice:

(a) Acknowledges that ethical and legal standards are not always in step and that the law provides minimum standards of confidentiality, which are sometimes exceeded by ethical standards.⁴⁹⁶

(I note, however, that from my analysis of the law relating to the disclosure of genetic information so far, ethical standards seem to be more permissive of disclosure than the law, rather than vice versa, as indicated in the Code of Practice.)

(b) Provides a useful decision support tool, which provides guidance upon disclosing identifiable health information to third parties, together with examples, which I build upon in Chapter 7 in the context of the disclosure of genetic information under New Zealand law.⁴⁹⁷

3.2.5. HGC: Inside information – balancing interests in the use of personal genetic data

The HGC is a non-statutory advisory body which offers independent advice to the Department of Health and other organisations on: (a) how new developments in genetics will impact on people and on health care; and (b) the legal implications of current and potential developments in human genetics.⁴⁹⁸ The HGC’s advice is informative, rather than binding.⁴⁹⁹

In 2002, the HGC released a report Inside Information - Balancing Interests in the Use of Personal Genetic Data⁵⁰⁰ (Inside Information) in which it, among other matters, discussed

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⁴⁹⁶ Above, n492: 13.


⁵⁰⁰ Above, n473.
issues surrounding the disclosure (or not) of an individual’s genetic information to his or her genetic relatives. The HGC’s advice to the United Kingdom Government in that regard was as follows:

> disclosure of sensitive personal genetic information for the benefit of family members in certain circumstances may occasionally be justified. This would arise where a patient refuses to consent to such disclosure and the benefit of disclosure substantially outweighs the patient's claim to confidentiality.\(^{501}\)

Further to that advice, the HGC suggest that the following conditions should be satisfied when making any such disclosures:\(^{502}\)

1. that an attempt has been made to persuade the patient in question to consent to disclosure;
2. the benefit to those at risk is so considerable as to outweigh any distress which disclosure would cause the patient; and
3. the information is, as far as possible, anonymised and restricted to that which is strictly necessary for the communication of risk.

In short, the HGC’s advice is consistent with the guidance offered by the GMC, BMA, and DH.

### 3.2.6. Conclusion

Though having different functions, each of the GMC, BMA and DH have produced guidelines in relation to the privacy and confidentiality of heath information that are consistent with each other, with the recommendations made by the HGC, and (in the most part) with those issued by the NZMA and AMA. That is disclosure of health information is justified where:

1. the patient consents;
2. the law requires it; and/or
3. the public interest in disclosing confidential health information to third parties outweighs the public interest in maintaining confidentiality, which may for example

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\(^{501}\) Above, n473: 63.

\(^{502}\) Above, n473: 64.
arise where not disclosing the information puts another individual (such as a genetic relative) at risk of serious harm. Note, however, that whether the disclosure of genetic information in such circumstance is in the public interest will depend upon the facts of the case, and has not yet been tested by the Courts.

Notably, the exceptions to privacy/confidentiality under the United Kingdom guidelines/codes of practice do not require that the risk of serious harm to another individual be *imminent* or *immediate*, and are therefore broader than the exceptions under the NZMA or AMA codes of ethics. Thus, contrary to the position under the NZMA and AMA codes of ethics, disclosure of genetic information to genetic relative in the circumstances described above fits neatly within the exceptions to confidentiality, and is likely to be permitted under such guidelines/codes. Whether this more permissive regime is reflected at law in the United Kingdom is discussed next.

### 3.3. **Common Law Duty of Confidentiality**

#### 3.3.1. Scope of the Duty of Confidentiality and the Public Interest Exception

The existence of the health practitioner’s duty of confidentiality is clearly stated at English common law. In *W v Edgell*, 503 Scott J noted that the question is not whether the doctor owes a duty of confidentiality to the patient but what is its scope. The scope of the duty at English common law is consistent with that in New Zealand and Australia, and is set out in *AG v Guardian Newspapers (No 2)*. 504 In particular, Lord Goff states:

> I start with the broad general principle (which I do not intend in any way to be definitive) that a duty of confidence arises when confidential information comes to the knowledge of a person (the confidant) in circumstances where he has notice, or is held to have agreed, that the information is confidential, with the effect that it would be just in all the circumstances that he should be precluded from disclosing the information to others...

> [In addition to] this broad general principle, there are three limiting principles to which I wish to refer. The first limiting principle (which is rather an expression of the scope of the duty) is highly relevant to this appeal. It is that the principle of confidentiality only applies to information to the extent that it is confidential. In particular, once it has entered what is usually called the public domain (which means no more than that the information in

503 Above, n475: 1102.

question is so generally accessible that, in all the circumstances, it cannot be regarded as confidential) then, as a general rule, the principle of confidentiality can have no application to it...

The second limiting principle is that the duty of confidence applies neither to useless information, nor to trivia...

The third limiting principle is of far greater importance. It is that, although the basis of the law’s protection of confidence is that there is a public interest that confidences should be preserved and protected by the law, nevertheless that public interest may be outweighed by some other countervailing public interest which favours disclosure.505

Thus, like in New Zealand and Australia, the “public interest” can be used to justify both the existence of and a breach of medical confidentiality. As stated in the guidelines and codes of practice referred to in paragraph 3.2 above, preventing a risk of serious harm to others would justify a breach of the patient’s right to confidentiality under the public interest exception. Reviewing the Courts’ decision in relation to the public interest exception provides some insight into how serious such harm must be to justify disclosure.

First, in *W v Edgell*506 the claimant was detained in a secure hospital and appointed a psychiatrist to produce a report supporting his application to obtain a conditional discharge. The psychiatrist, however, opposed the transfer, after which the claimant withdrew his application. The Court held that the psychiatrist was justified in sending the report to the hospital after the psychiatrist learned that the application had been withdrawn and that the hospital had not received the report. In particular, Scott J held that a doctor’s duty to protect public health meant that doctors are required to disclose to the authorities the results of their examination if public safety so required regardless of the patient’s wishes. This decision was upheld in the Court of Appeal.507

Secondly, the Court followed Scott J’s decision in *W v Edgell* in *R v Crozier*.508 In *R v Crozier*, the appellant pleaded guilty to attempted murder of his sister following a dispute with her over the management of his deceased wife’s trust fund. The appellant appointed a psychiatrist to report on his mental condition for the purpose of the sentencing hearing. The

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505 Above, n504: 281-282.
506 Above, n475.
507 *W v Edgell* [1990] 1 All ER 835 (CA).
psychiatrist advised that the appellant should be put in a secure hospital for an unlimited period of time. The appellant did not disclose the report to the Court, and was sentenced to a nine year prison term. When the psychiatrist became aware that the Court had not seen his report, he disclosed it to the Judge, and the Judge amended his sentence, consistent with the advice in the report.

These decisions indicate that the risk which justifies a breach of confidence under the public interest exception: (a) must be a risk of physical harm to others; and (b) need not be imminent. Thus, it is likely that disclosure of genetic information to genetic relatives will be justified under the English common law public interest exception where the onset of genetic disease can be avoided or an effective treatment is available. It is not clear, however, that the public interest exception will justify the disclosure of genetic information to genetic relatives in the case of multifactorial genetic disorders, ie where the potential causes of a disorder are not solely genetic but also environmental, and risk can be minimised, but not necessarily prevented. Accordingly, in most cases, because very few genetic diseases have effective treatments, breach of an individual's right to confidentiality in his or her genetic information may not be justified.

3.3.2. Duty to warn?

As yet, the English Courts have not held that health practitioners owe a duty to disclose confidential medical or genetic information to persons at risk of serious harm. In the absence of any case law directly on point, in this section I discuss: (a) Roy Gilber's analysis in The Status of the Family in Law and Bioethics: The Genetic Context as to whether such a duty exists; and (b) the Court of Appeal's decision in Palmer v Tees Health Authority and Another in relation to whether a psychiatrist owed a duty of care to third parties where there was a risk his or her patient might harm various third parties.


511 Above, n510.

512 (1999) Lloyd's Medical Reports 151 (CA).
First, in his analysis of whether a duty to warn exists (or is likely to exist) under English common law, Gilbar comments as follows:

(a) The Californian Supreme Court in *Tarasoff v Regents of the University of California* held that a psychiatrist owed a duty to warn a victim that his patient threatened to kill her, on the basis that confidentiality ends "where public peril begins". In particular, Torbriner J held:

When a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger. The discharge of this duty may require the therapist to take one or more of various steps, depending on the nature of the case. Thus it may call for him to warn the intended victim or others likely to apprise the victim of the danger, to notify the police, or to take whatever other steps are reasonably necessary under the circumstances.

(b) In relation to whether doctors owe a duty to breach patient's right to confidentiality in order to warn genetic relatives of their risk of developing a genetic disease:

(i) In *Pate v Threlkel*, the Florida Supreme Court held that although doctors owe a duty of care to genetic relatives of their patients, they are not required to breach patients' rights to confidentiality. Rather, doctors should ask that their patients inform their genetic relatives of their potential risk of developing the same disease, and doctors are entitled to expect them to do so. The court emphasised that:

> to require the physician to seek out and warn various members of the patient’s family would often be difficult or impractical and would place too heavy a burden upon the physician.

513 *Tarasoff v Regents of the University of California* (1976) 551 P 2d 334 (Cal Sup Ct), 347. See also above, n510: 139.

514 Above, n513.

515 *Pate v Threlkel* (1995) 661 So.2d 278 (Fla Sup Ct), 282. Note, in *Pate and Threlkel*, a woman who suffered from a medullary thyroid carcinoma sued her mother's doctor on the grounds that: (a) he knew or should have been aware that her mother's previously diagnosed cancer was hereditary; (b) such knowledge gave rise to a duty to warn the mother that her relatives might be at risk and that they should be tested; and (c) had the plaintiff been tested, she would have taken preventative measures, and her condition would probably have been preventable.

516 Above, n515.
ii) In *Safer v The Estate of Pack*, a New Jersey appellate Court held that there might be circumstances where doctors are required to approach genetic relatives of patients directly when the patient refuses to inform them.\(^517\) In reaching its finding, the court applied the infectious disease model and noted that genetic risks are as foreseeable as infectious ones on the grounds that "the individual or group at risk is easily identified, and substantial future harm is easily identified or minimised by a timely and effective warning".\(^518\)

Thus, the position under tort law in America is not entirely consistent, but seems to be that a doctor is *generally* not obliged to breach his or her patients' right to confidentiality in order to inform his or her patients' genetic relatives of their risk of developing a genetic disease, but might have a duty to require his or her patients to inform their genetic relatives' of their potential risk.

(c) Given that the requirements of English tort law are stricter than those of American tort law, it is unlikely that the English courts will impose a positive duty on doctors to warn their patients' genetic relatives of their genetic risk without their patients' consent.\(^519\)

Secondly, in *Palmer* the court refused to hold that a duty of care was owed by a health authority to the mother of a child who was later abducted and murdered by a mental health

\(^{517}\) (1996) 677 A.2d 1188 (NJ Super A.D.), 1192-1193. See also above, n510: 140. Note, in *Safer v Pack* a woman sued her father's doctor for not warning her father that she should be tested for the same genetic condition on the basis that, if she had been warned on time, she could have taken preventive steps, and avoided developing a hereditary form of cancer.

\(^{518}\) Above, n517: 1192. Note, the decision in *Safer* has been criticised because it does not consider the practicalities or other negative consequences of imposing a duty to warn in relation to genetic disease. See Angela Liang, "Symposium: Testing and Telling?: Implications for Genetic Privacy, Family Disclosure and the Law: The Arguments Against a Physician's Duty to Warn for Genetic Diseases: The Conflicts Created by Safer v. Estate of Pack" (1998) 1 J. Health Care L. & Pol'y 437: 453.

\(^{519}\) Above, n510: 140. Note, the French law position in relation to the duty to warn is stricter still than under English law. In particular, the Ordre des Me'decins, the body responsible for maintaining the ethical and professional integrity of French physicians, stated in Article 4 of the Code of Medical Ethics (as revised in 1995): 'Professional confidentiality (le secret professionnel), instituted in patients' interest, is obligatory for every physician within the conditions established by law. Confidentiality applies to everything the physician learns in the exercise of his profession, that is to say not only what has been confided to him, but also what he has seen, heard or understood.'": see Conseil national de l'Ordre des Me'decins. *Code de de'ontologie me'dicale, Commentary by L. Rene* ': (Paris: Editions du Seuil, 1996). Notably, there is no exception to patient confidentiality for the purpose of protecting third parties. Consistently, Article 226-13 of the New Penal Code (2002) stated: "The revelation of confidential information (information a' caractere' re secret) by a person who possesses it either by profession or by reason of a function or of a temporary mission is punished by one year of prison and a fine of 15 000 Euros." – see *Code pe'nal 2002: nouveau code pe'nal, ancien code penal 99e me' edition*. Paris: Dalloz, 2002. Again, no exception to patient confidentiality exists under the Penal Code. See M Guedj, M T Mu'noz Sastre, E Mullet and P C Sorum, "Do French lay people and health professionals find it acceptable to breach confidentiality to protect a patient's wife from a sexually transmitted disease?" (2006) 32 J. Med. Ethics 414: 414.
patient of the authority, even though the patient had confessed to sexual feelings towards children and the child who he abducted lived within sight of his home, where the crimes were committed. The court held that there was insufficient proximity of relationship between the authority and the victim to found a duty of care, based on the knowledge that the authority had. In particular, the Court held that: (a) the authority had no knowledge of a specific and identifiable victim; and (b) knowledge of a general class of at-risk individuals, and geographical proximity of the parties was not sufficient to establish a relationship.\(^{520}\)

Arguably, the genetic relatives of a patient are both specific and identifiable. Thus, applying the reasoning in Palmer, there may be sufficient proximity of relationship between a doctor and his or her patients' genetic relatives in order to establish a duty of care owed by a doctor to those genetic relatives. In light of Gilbar's point at (c) above, however, it is unlikely that the English courts will translate this duty of care into a positive duty on doctors to warn their patients' genetic relatives of their genetic risk without their patients' consent.

3.3.3. Conclusion: disclosure justified under English common law in limited circumstances

Whether the exceptions to a patient's rights of privacy and confidentiality justify the disclosure of his or her genetic information to his or her genetic relatives, where that information can be used to avert harm, has not been specifically tested by the Courts in the United Kingdom. The above analysis of English common law, however, indicates that:

(a) It is likely that disclosure by a doctor of his or her patient's genetic information to that patient's genetic relatives will be justified under the public interest exception where the onset of genetic disease can be avoided or an effective treatment is available. Given the lack of available effective treatments available for genetic diseases, and the multifactorial nature of many genetic diseases, this exception will only ever apply in very limited circumstances.

(b) It is unlikely that English Courts will impose a positive duty on doctors to warn their patients' genetic relatives of their risk of genetic disease.

\(^{520}\) Above, n512.
3.4. United Kingdom data protection legislation

3.4.1. Data Protection Act 1998

3.4.1.1. Background

Data protection law in the United Kingdom derives originally from the *Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1981* (Data Protection Convention)\(^{521}\) which was itself: (a) drafted in tandem with the Organisation for Economic Co-operation and Development (OECD) *Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data*\(^{522}\) (OECD Privacy Recommendation); and (b) influenced by the Council of Europe *Convention for the Protection of Human Rights and Fundamental Freedoms 1950* (European Convention on Human Rights). (The European Convention on Human Rights provides for dual rights of respect for private and family life (Article 8) and freedom of expression (Article 10)).\(^{523}\)

In addition to the Data Protection Convention (which only applies to automated data processing), Directive 95/46/EC of the European Parliament and of the Council of the European Union of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (EU Data Protection Directive): (a) required Member States to implement legislation to protect the right of individuals to privacy with respect to the processing of personal data,\(^{524}\) and (b) therefore played a significant role in the development of the United Kingdom’s data protection

\(^{521}\) Note, however, that data protection law in the United Kingdom is only influenced to a very limited extent by the Data Protection Convention, which is aimed more at the protection of privacy life from government interference.


\(^{523}\) David Bainbridge, *Data Protection Law (second edition)* (xpl publishing, St Albans UK, 2005), 2.

\(^{524}\) Note, the main purpose of EU Data Protection Directive is set out in Article 1, and is as follows: (1) “In accordance with this Directive, Member States shall protect the fundamental rights and freedoms of natural persons, and in particular their right of privacy, with respect to the processing of personal data. (2) Member States shall neither restrict nor prohibit the free flow of personal data between Member States for reasons connected with the protection afforded under paragraph 1.” Note also, the Council of Europe and the European Union have different focuses. The Council of Europe has more of a human rights focus, whilst the European Union is more free trade oriented. For a discussion on the role and structure of the Council of Europe and European Union, see paragraph 4.2 below.
legislation. It is the EU Data Protection Directive which ultimately formed the basis of United Kingdom’s Data Protection Act 1998, which came into force on 1 March 2000.525

3.4.1.2 Relevant definitions

The Data Protection Act 1998 does not refer specifically to genetic information, but the broad definitions of “personal data” and “data” encompass it. In particular:

(a) The Data Protection Act 1998 only applies to personal data. According to section 1(1) of the Data Protection Act 1998, “personal data” means data which relate to a living individual who can be identified:

   (a) from those data; or

   (b) from those data and other information which is in the possession of, or likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

(a) “Data” means information526 which:

   (a) is being processed by means of equipment operating automatically in response to instructions given for that purpose;

   (b) is recorded with the intention that it should be processed by means of such equipment;

   (a) is recorded as part of a relevant filing system or with the intention that it should form part of a relevant filing system;

   (b) does not fall within paragraph (a), (b) or (c) but forms part of an accessible record as defined by section 68; or

   (c) is recorded information held by a public authority and does not fall in any of the paragraphs (a) to (d).527

525 Note, the United Kingdom’s previous data protection legislation (the Data Protection Act 1984) was a response to the Data Protection Convention. Like the Data Protection Convention, the Data Protection Act 1984 only applied to automatic, and not manual, processing of personal data.

526 Note, “information” is not defined in the Data Protection Act 1998, and therefore encompasses all information to the extent it is recorded in a way described in the definition of “data”.

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According to section 68(1) of the Data Protection Act 1998, an “accessible record” (as per clause (d) of the definition of “data”) includes a health record, being:

Any record which consists of information relating to the physical or mental health or condition of an individual and has been made by a health professional in connection with the care of that individual.  

Accordingly, clause (d) of the definition of “data” encompasses health and genetic information.

Further, section 2 of the Data Protection Act 1998 defines “sensitive personal data” as personal data consisting of information as to “his physical or mental health or condition”. Thus, health and genetic data fall within the definition of “sensitive personal data”.

The term “processing”, includes the collection, use and disclosure of data, among other operations.

3.4.1.3 Data protection principles

Like New Zealand’s Privacy Act 1993 and Australia’s Privacy Act 1988 (Cth), the data protection principles (set out at Schedule 1) are at the heart of the Data Protection Act 1998. The data protection principles originally derive from the Data Protection Convention.

The most relevant principles in relation to the disclosure of an individual’s genetic information to his or her at-risk genetic relatives are principles one and two. Dealing with each in turn:

Principle One

Principle One provides that:

Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless —

(a) at least one of the conditions in Schedule 2 is met, and

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527 Data Protection Act 1998, section 1(1) (emphasis added).
528 Data Protection Act 1998, section 68(2).
529 Data Protection Act 1998, section 1(1).
Thus, given that genetic information constitutes "sensitive personal data" (see paragraph 3.4.1.2 above), a health practitioner must meet the following requirements before using or disclosing his or her patient's genetic information to that patient's at-risk genetic relatives:

(i) The genetic information must be disclosed fairly.

(ii) The genetic information must be disclosed lawfully.

(iii) One of the conditions in Schedule Two must be met before the genetic information can be disclosed.

(iv) One of the conditions in Schedule Three must be met before the genetic information can be disclosed (which are generally restricted in scope than the conditions in Schedule Two).

As to the first requirement, the interpretation of Principle One set out in Schedule 2 Part II of the Data Protection Act 1998 states that information is deemed to have been processed fairly when the individual from whom the information is collected is informed at the time of collection, or as soon as practicable after collection as, of:

(i) the identity of the data controller (eg the General Practitioner's practice) and, if applicable, any representative nominated by the data controller for the purpose of the Data Protection Act 1998;

(ii) the purpose or purposes for which the data are intended to be processed; and

(iii) any further information which is necessary, having regard to the specific circumstances in which the data are or are to be processed, to enable processing in respect of the data subject to be fair.

The Data Protection Act 1998 does not provide any guidance as to what other information might be necessary to make the processing of data fair. The Information Commissioner's Office guidance on the application of the Data Protection Act 1998 in relation to the use and disclosure of health information (ICO Guideline), however, states that such information would include information as to whether any secondary uses of disclosures of data are optional (which will always be the case in relation to disclosing genetic information to at-risk
relatives on the basis that such disclosure is not essential for the treatment of the individual). 530

As to the second requirement, genetic information is disclosed lawfully if it is not contrary to any statutory prohibitions on the use or disclosure or the common law duty of confidence.

As to the third requirement, the conditions in Schedule Two that are most likely to be relevant to the use or disclosure of genetic information include:

(a) That the patient has consented (either expressly or impliedly) to the use or disclosure. 531

According to the ICO Guideline, where information has been collected fairly in accordance with Principle One, ie the patient: (i) has been given information as to whether his or her health information must be supplied or whether it is optional to do so; (ii) accepts treatment; and (iii) does not expressly object to any uses or disclosures of data, then the Information Commissioner will consider that valid consent to use or disclose that information has been given, albeit impliedly. 532 (See also paragraph 3.4.1.4 below in relation to the patient’s right to object to disclosure.)

(b) That the use or disclosure is necessary to protect the vital interests of the patient. 533

(c) That the use or disclosure is necessary for the exercise of a public function exercised in the public interest (for example, in a health context, medical research). 534

(d) That the use or disclosure is necessary for the purposes of the legitimate interests pursued by the medical practitioner, or those of a third party to whom the genetic information is disclosed, except where the use or disclosure is prejudicial to the rights and freedoms or legitimate interests of the patient. 535


532 Above, n530: 16.


535 Data Protection Act 1998, Schedule 2, Paragraph 6(1).
The upshot of this condition is that, under the Data Protection Act 1998: (i) an individual’s interest in maintaining privacy of his or her genetic information has primacy over the interest of his or her genetic relatives in knowing that genetic information; and therefore (ii) disclosure of a patient’s genetic information to at-risk genetic relatives where the patient does not consent, is unlikely to satisfy this condition.

Thus, the only circumstance under Schedule 2 in which a health practitioner can disclose his or her patient’s genetic information to that patient’s at-risk genetic relatives is where the patient consents (or does not object) to such disclosure (as per (a) above).

As to the fourth requirement, the most relevant conditions from Schedule Three of the Data Protection Act 1998 in relation to the disclosure of genetic information include:

(a) That the patient has given explicit consent to the use or disclosure of his or her genetic information.536

(b) That the use or disclosure of the genetic information is necessary to protect the vital interests (which are matters of life or death)537 of the patient or another person, where it is not possible to get consent.538

(c) That the use or disclosure of the genetic information is necessary in order to protect the vital interests of another person, in a case where consent by or on behalf of the patient has been unreasonably withheld.539

(d) That the use or disclosure is necessary for medical purposes and is undertaken by a health professional or a person owing a duty of confidentiality equivalent to that owed by a health professional.540

It seems, therefore, that there are two scenarios in which a health practitioner may be justified in disclosing a patient’s genetic information to his or her genetic relatives where the patient impliedly, but not expressly, consents to such disclosure. Examining each scenario in turn:

537 Above, n530: 8.
539 Data Protection Act 1998, Schedule 3, Paragraph 3(b).
First, where: (a) a health practitioner proposes to disclose a patient’s genetic information to his or her at-risk genetic relatives, and discusses this proposal with the patient prior to doing so (in accordance with “fair” processing under Principle 1); and (b) the patient explicitly objects to such disclosure, even though it might prevent the patient’s at-risk genetic relatives from developing a life threatening genetic disease (for example, cancer), it is arguable that the patient is *unreasonably withholding consent* for the purpose of Condition 3(b) of Schedule 3.

Secondly, a health practitioner may be entitled to disclose a patient’s genetic information to his or her at-risk relatives without the patient’s express consent where the health practitioner considers such disclosure to be necessary for “medical purposes” in accordance with condition eight of Schedule Three. This possible justification for disclosure arises on the basis that: (a) “medical purposes” include preventative medicine; and (b) condition 8 of Schedule 3 does not state that disclosure must be necessary for medical purposes associated only with the patient, ie as drafted, the condition would allow disclosure where it is necessary for medical purposes associated with the patient’s genetic relatives.

Further, as under New Zealand and Australian privacy laws, any such disclosure as per the above scenarios can only be made to the extent it is *necessary* to prevent harm to a genetic relative. That is, the health practitioner must be able to show that it would not be possible to prevent harm to his or her patient’s genetic relatives with a reasonable degree of ease without disclosing *personal* genetic information. (Note, as discussed in Chapter 5, paragraph 5.4.4.3, it is unlikely to be possible to de-identify genetic information in a family setting.)

*Principle Two*

Principle Two provides that:

> Personal data shall be obtained only for one or more specified and lawful purposes and shall not be further processed in any manner incompatible with that purpose or those purposes.

The ICO Guidelines state that the effect of Principle Two is to reinforce Principle One and to limit the range of cases where health information may be used or disclosed for purposes of which the patient was not informed to ones which are compatible with those for which the

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542 Above, n530: 4.
health information was originally obtained. Thus, a health practitioner is unlikely to be entitled to disclose his or her patient's genetic information to that patient's at-risk genetic relatives where the patient was not informed of the repercussions his or her genetic information might have for his or her genetic relatives prior to the health practitioner obtaining his or her genetic information. (Note, this is also a requirement for establishing implied consent to disclosure.)

3.4.1.4 The patient's right to object to disclosure

Whenever a health practitioner collects genetic information from a patient, and proposes to, if necessary, disclose that information to the patient's at-risk genetic relatives, the health practitioner should always inform the patient that such disclosure is not mandatory (on the basis that the disclosure is not essential in order to treat the patient), and he or she has the right to object to any such disclosure. Where the patient does not object to such disclosure, he or she will be deemed to have consented.

Further, a patient also has a general right to object at any time (by notice in writing) to the use or disclosure of his or her information under section 10 of the Data Protection Act 1998, regardless of whether the patient has been informed of his or her choice as to how such information will be used/disclosed, where:

(a) the processing of those data or their processing for that purpose or in that manner is causing or is likely to cause substantial damage or substantial distress to him or another; and

(b) that damage or distress is or would be insurmountable.

A patient cannot make such an objection, however, where he or she consented (impliedly or expressly) to the disclosure at the time the information was collected. Thus, this provision does not limit the circumstances discussed above where a health practitioner might be justified in disclosing his or her patient's genetic information.

If the distress caused to a patient by disclosing his or her genetic information to his or her at-risk genetic relatives is deemed to be sufficiently substantial to warrant an objection under

543 Above, n530: 12.
544 Data Protection Act 1998, s10(2).
section 10, however, this provision would give the patient an absolute right to determine what happens to his or her genetic information, provided he or she takes action prior to its collection.

3.4.2. Conclusion: United Kingdom data protection legislation allows disclosure of genetic information in limited circumstances

Like New Zealand and Australian privacy legislation, the Data Protection Act 1998 protects an individual's right to privacy and confidentiality in relation to his or her personal information (including genetic information). (Also, like New Zealand's privacy legislation, the Data Protection Act 1998 is not genetic specific.)

Whilst the rights protected under the Data Protection Act 1998 are not absolute, there are only very limited circumstances in which a health practitioner may be justified in disclosing a patient’s genetic information to that patient’s at-risk genetic relatives. Those circumstances do not extend the exceptions to privacy and confidentiality available under the common law.545

Thus, it is likely that a health practitioner will be entitled to disclose his or her patient’s genetic information to that patient’s genetic relatives where such disclosure enables the recipients of the information to: (a) avoid, or significantly reduce the risk of, developing a genetic disease; and/or (b) receive early and effective treatment for an undiagnosed existing genetic condition.

Whilst the circumstances in which disclosure of genetic information to genetic relatives are limited, the constraints on disclosure under the Data Protection Act 1998 are nevertheless less restrictive than the under New Zealand’s existing HIPC.

545 See paragraph 3.3 above.
4. **EUROPE**

4.1. Background

During the Second World War, Europe was, in essence, torn apart. By the end of it, Europe’s primary political objective was the reconciliation of its peoples. This led to the development of common political, legal and economic principles among the countries of Europe, through the establishment of common institutions. The two key institutions working towards European integration are the Council of Europe and the European Union.

This chapter examines the legal principles developed by the Council of Europe and the European Union that relate to the protection of genetic data. In particular, in this chapter I:

(a) Briefly explain the role and structure of the Council of Europe and European Union.
(b) Discuss relevant conventions, directives, laws and recommendations adopted and/or proposed by the Council of Europe and the European Union.

4.2. Role and structure of the Council of Europe and the European Union

4.2.1. Council of Europe

The Council of Europe was founded in 1949, and is the oldest organisation working for European integration. It is an intergovernmental organisation which, in accordance with its founding Statute, contributes to the harmonisation of Europe's legal systems, based primarily on common values, such as human rights and democracy.

The Council of Europe works mainly through conventions. By drafting conventions or international treaties, common legal standards are set for its 47 member states. The Council of Europe has drafted and adopted nearly 190 conventions (the most important convention

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being the European Convention on Human Rights of 1950) and agreements, as well as hundreds of recommendations dating back to the Council of Europe's establishment.\footnote{Note: Article 15.a of the Council of Europe Statute provides that the Committee of Ministers "shall consider the action require to further the aim of the Council of Europe, including the conclusion of conventions and agreements". Conventions are binding on the States which ratify them. Article 15.b of the Council of Europe Statute allows the Committee of Ministers to make recommendations to member states on matters for which it has agreed "a common policy". Such recommendations are not legally binding on member states, although their implementation is monitored by intergovernmental committees. \textit{Presentation of Activities of the Directorate General of Legal Affairs.} Online. Accessed 14 June 2004. Available on the Council of Europe website. http://www.coe.int/T/E/Legal_Affairs/About_us/Activities/Activities_DGI.asp.}

4.2.2. European Union

Like the Council of Europe, the European Union (EU) works for the integration of Europe. It consists of democratic European countries, committed to working together for peace and prosperity.\footnote{The EU at a glance: \textit{How is the EU Organised?} Online. Accessed 16 November 2007. Available on the European Union website. http://europa.eu/abc/panorama/in dex_en.htm.} The EU's member states are independent sovereign nations who have pooled together to set up common institutions to which they delegate some of their decision making powers so that decisions on specific matters of joint interest can be made democratically at the European level.

The EU is governed by a number of institutions, primarily the Council of the European Union (EU Council), the European Commission (EU Commission), and European Parliament (EU Parliament).

The EU Parliament forms half of the EU's legislative branch, and is directly elected by EU citizens every five years to represent their interests. The main job of the EU Parliament is to pass European laws.\footnote{Above, n549.}

The EU Council forms the other half of the EU's legislative branch, and consists of ministers from the national governments of all EU countries. The EU Council shares with the EU Parliament the responsibility for passing laws and taking policy decisions.\footnote{Above, n549.}

The EU Commission forms the executive arm of the EU, and consists of 27 representatives, one from each EU country. It represents and upholds the interests of Europe as a whole. The
EU is independent of national governments. It drafts proposals for new European laws (usually in the form of a regulation, a directly applicable act, or a directive, to be transposed into national law), which it presents to the EU Parliament and the EU Council. It is also responsible for the day-to-day business of the EU, implementing EU policies and spending EU funds. Further, the EU Commission ensures that everyone abides by the European treaties and laws. It can take rule-breakers to the Court of Justice if necessary.552

4.2.3. Interplay between Council of Europe and European Union?

While the Council of Europe is distinct from the 15 nation European Union, notably no country has ever joined the EU without first belonging to the Council of Europe.553 Thus, the principles behind the policies, recommendations and instruments established by the Council of Europe and the EU relating to the protection of genetic data are likely to be consistent.

4.3. Council of Europe: conventions and recommendations in relation to the protection of genetic data

The Council of Europe has issued a number of treaties and recommendations in relation to the way in which genetic and health information should be protected, which have subsequently been adopted by Governments of the Council of Europe member states. Examining these treaties and recommendations provides a useful guide to the principles upon which European countries base deal with the conflicts that arise as a consequence of the shared nature of genetic information at a national level. (I discuss each below, in chronological order.)

4.3.1. European Convention on Human Rights

The European Convention on Human Rights was adopted in 1950 in order to protect human rights and fundamental freedoms, including the right to privacy. In particular, Article 8 of the European Convention of Human Rights states that:

1. Everyone has the right to respect for his private and family life, his home and his correspondence.

552 Above, n549.

2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interest of national, security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Whilst it was unlikely to have been in the contemplation of the Council of Europe at the time the European Convention on Human Rights was adopted, arguably, to disclose an individual’s genetic information to his or her family members when that information has important consequences for such family members’ health and/or reproductive choices would be to act entirely in accordance with the “right to respect for family life”.

Consistently, and relevant to the privacy of health or genetic information, the European Court of Human Rights stated in Z v Finland\textsuperscript{54} that:

> The protection of personal data, not least medical data, is of fundamental importance to a person’s enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention ... Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and in the case of transmissible diseases, that of the community.

This suggests that the numerous other Council of Europe conventions and recommendations (discussed below) that have built upon this fundamental right might offer a more balanced approach in relation to the relationship between an individual’s right to privacy and confidentiality in his or her genetic information and the competing interests of his or her genetic relatives’ interest in knowing such information.

4.3.2. Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

The Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data extends the safeguards available under Article 8 of the European Convention on Human Rights, acknowledging the increase in the automatic processing of personal...

\textsuperscript{54} (1998) 25 EHRR 371.
As discussed at paragraph 3.4.1.1 above, this Convention forms the foundation for data protection law in the United Kingdom and Europe.

4.3.3. Recommendation No. R(92) 3 of the Committee of Ministers to Member States on Genetic Testing and Screening for Health Care Purposes

Recommendation R(92)3 on genetic testing and screening for health care purposes (Recommendation on Genetic Testing) sets out rules for good practice in genetic testing and screening. Some of these rules expressly recognise the benefits of genetic testing for both individuals and their genetic relatives.

First, principle five of the Recommendation on Genetic Testing provides that genetic testing for diagnostic purposes should only be permitted when it is necessary for an individual’s health or if the information that would result from such a test is necessary to diagnose the existence of a genetic disease in family members. The concept of testing an individual for the benefit of other family members is discussed in more detail in the Council of Europe’s recent Draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes and the Draft Explanatory Report to the draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (discussed at paragraph 4.3.6 below).

Secondly, principle nine of the Recommendation on Genetic Testing provides that anyone handling genetic information should comply with professional rules of conduct and relevant national legislation in relation to privacy and confidentiality. Principle nine provides that genetic information is to be protected on the same basis as other medical data, but that consideration should be given to informing an individual’s genetic relatives about matters relevant to their health or that or their future children where the results of an individual’s genetic test reveal a severe genetic risk for those genetic relatives. Any such disclosure must, however, be made in accordance with national legislation.


557 Above, n556: preamble.
Finally, principle eleven provides that where the results of a genetic test reveal unexpected findings, these can be communicated to genetic relatives if: (a) authorised by national law; and (b) the individual tested refuses expressly to inform them, even though their lives are in danger.

Thus, as early as 1992, the Council of Europe considered that the rights and interests of individuals and their genetic relatives in relation to genetic information should be recognised.

4.3.4. Recommendation No. R (97) 5 of the Committee of Ministers to Member States on the Protection of Medical Data.

The Council of Europe’s Recommendation on the Protection of Medical Data applies to the collection and automatic processing of personal medical data. It is an adaptation of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, giving the rules therein specific application to the protection of medical data.

“Medical Data” is defined in the Recommendation as personal data concerning the health of an individual. The definition expressly includes “genetic data”. The protection of privacy of medical data (and therefore genetic data) during its collection and processing is at the heart of the Recommendation on the Protection of Medical Data.

Because the Recommendation on the Protection of Medical Data applies to the automatic processing of medical data, it does not apply directly to the potential conflict between individual and familial rights to genetic information (where any disclosure of genetic information to genetic relatives is not likely to be automatic per se). Nevertheless, it provides express recognition of: (a) the shared nature of genetic information; and (b) the interests of the individual and relatives in the same “genetic line” as that individual.

558 Council of Europe, Committee of Ministers. Recommendation No. R (97) 5 of the Committee of Ministers to Member States on the Protection on Medical Data. (Council of Europe, 13 February 1997.): principle 2.1.

559 Above, n558: preamble.

560 Above, n558: principle 1.

561 Above, n558: principle 3.

562 Above, n558: principle 2.
First, principle four of the Recommendation on the Protection of Medical Data provides that medical data can be collected and processed, if permitted by law: (a) for preventive medical, diagnostic or therapeutic purposes with regard to the individual tested or his or her genetic relative; or (b) to safeguard the vital interests of the data subject or of a third person.

Secondly, principle seven of the Recommendation on the Protection of Medical Data deals with the communication of medical data and provides that medical data shall not be communicated, unless, for example it is permitted by law, and for the purpose of:

(a) the protection of the data subject or a relative in the genetic line, or
(b) safeguarding the vital interests of the data subject or of a third person.

Finally, principle 8.2(c) states that an individual's access to their medical data may be refused, limited or delayed if the law so provides, and if:

the information on the data subject also reveals information on third parties or if, with respect to genetic data, this information is likely to cause serious harm to consanguine or uterine kin or to a person who has a direct link with this genetic line. [Emphasis added.]

Similar limitations apply in relation to informing individuals of unexpected findings of genetic analysis. That is, the individual tested should be informed of such findings only where it is not likely to cause serious harm to that individual's health and/or serious harm to his or her genetic relatives or persons who have a direct link with the particular genetic line.

\[563\] Above, n558: principle 4.3(b)(i).
\[564\] Above, n558: principle 4.3(b)(ii).
\[565\] Above, n558: principle 7.3(b)(i).
\[566\] Above, n558: principle 7.3(b)(ii).
\[567\] Above, n558: principle 8.4(c)(i) and (ii). Note, the potential harm to the genetic relative need not be to his or her health to justify non-disclosure under this principle.

The Convention on Human Rights and Biomedicine and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No.164)\(^{568}\) (Convention on Human Rights and Biomedicine) is a legally binding international instrument designed to preserve human rights through a series of principles and prohibitions against the misuse of biological and medical advances.\(^{569}\) It provides a common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine. Developments in genetic medicine fall within its scope.\(^{570}\)

The Convention on Human Rights and Biomedicine was adopted by the EU Parliament on 19 November 1996, and was opened for signature on 4 April 1997.\(^{571}\) It has been ratified by 21, and signed by a further 13, European Countries.\(^{572}\)

An individual’s rights to private life and right to information are protected under chapter three, Article 10 of the Convention on Human Rights and Biomedicine, which states.\(^{573}\)

Article 10 – Private life and right to information

\(^{568}\) Council of Europe. 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 (Council of Europe, Oviedo, 4.IV.1997).


\(^{570}\) Note - the Human Genome is specifically referred to in Chapter IV (Articles 11 - 14) of the Convention on Human Rights and Biomedicine. Other articles within the Convention on Human Rights and Biomedicine relate to genetic information by virtue of their application to health information in general.


\(^{573}\) Above, n.568: Chapter III, Article 10, Paragraph 1.
1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

Thus, Article 10 reaffirms the principle in Article 8 of the European Convention on Human Rights, which was reiterated in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (discussed above).

Of particular note, paragraph two of Article 10 specifically endorses an individual’s right to know and right not to know his or her health information. The Council of Europe recognises, however, that limitations may be placed on such rights:

(a) In exceptional circumstances, where the law requires it (as per paragraph 3 of Article 10).

(b) To protect the rights of a third party or of society, as per Article 26.1 of the Convention on Human Rights and Biomedicine, which states that:

Article 26 – Restrictions on the exercise of the rights

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

The explanatory report to the Convention on Human Rights and Biomedicine (Explanatory Report) identifies some situations where it might be appropriate to override an individual’s right not to know, which have particular relevance to genetic conditions.

First, the Council of Europe acknowledges in the Explanatory Report that:

[I]t may be of vital importance for patients to know certain facts about their health, even though they have expressed the wish not to know them. For example, the
knowledge that they have a predisposition to a disease might be the only way to enable them to take potentially effective (preventive) measures.574

Secondly, the Council of Europe acknowledges that:

It could also be appropriate to inform an individual that he or she has a particular condition when there is a risk not only to that person but also to others.

Thirdly, the Council of Europe acknowledges that:

At the same time, certain facts concerning the health of a person who has expressed a wish not to be told about them may be of special interest to a third party, as in the case of a disease or a particular condition transmissible to others, for example.

In relation to each situation, the Council of Europe held that it is for domestic law, taking account of the social and cultural background, to indicate whether the doctor should override an individual’s right not to know.575 Further, specifically in relation to the third situation, the Council of Europe points out that the possibility for prevention of the risk to the third party might, on the basis of Article 26, warrant his or her right taking precedence over the patient’s right to privacy and right not to know. The Council did, however, recognise that the interests of the individual and the third party should be balanced by domestic law.576

The Council of Europe therefore acknowledges (indirectly) that situations exist where a genetic relative’s interest in knowing his or her genetic risk might outweigh an individual’s right to privacy. It does not, however, propose any mechanism for protecting such an interest. Rather, it leaves it up to domestic law to resolve the potential conflict that might arise between an individual’s right to privacy and his or her genetic relative’s right to know relevant genetic information.

4.3.6. Draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes

Article 31 of the Convention on Human Rights and Biomedicine states that:

574 Above, n571: paragraph 70.
575 Above, n571: paragraph 69-70.
576 Above, n571: paragraph 70.
Protocols may be concluded...with a view to developing, in specific fields, the principles contained in this Convention.577

The rapid developments in the area of human genetics prompted the Council of Europe to focus on the ethical and legal issues raised by applications of genetic technologies and to develop legal instruments to protect fundamental human rights in relation to such applications.578 In 1996, the Council of Europe Steering Committee on Bioethics (Steering Committee) established the Working Party on Human Genetics to begin the task of drafting a protocol to the Convention on Human Rights and Biomedicine in order to deal with such issues.

In February 2003, the Working Party on Human Genetics released the Working Document on the Application of Genetics for Health Purposes for comment from European non-governmental organisations, prior to the release of a draft additional protocol to the Convention on Human Rights and Biomedicine.579 In June 2007, the Steering Committee approved the Draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (Draft Protocol) and the Draft Explanatory Report to the draft Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (Draft Explanatory Report). In September 2007, the Draft Protocol and Draft Explanatory Report were presented to the Committee of Ministers of the Council of Europe (ie the decision making body of the Council of Europe). The Committee of Ministers will review the Draft Protocol and Draft Explanatory Report in light of an opinion which is to be provided by the Parliamentary Assembly of the Council of Europe (ie a representative body of national Parliaments of the 47 Council of Europe Member States), with a view to adopting the Draft Protocol and Draft Explanatory Report.580

577 Above, n568: Chapter XII, Article 31. Note: a protocol is a legal instrument which complements, amends, or modifies the main treaty or convention.


579 Council of Europe Working Party on Human Genetics (CDBI-CO-GT4). Working Document on the Applications of Genetics for Health Purposes: CDBI/INF (2003) 3. (Council of Europe, Stasbourg, 2003.) Note: the CDBI has not yet examined this document, but agreed to its publication. As such, the document does not necessarily reflect the views of the CBDI.

The Draft Protocol reaffirms the principles set out in the Convention on Human Rights and Biomedicine with a view to ensuring the protection of people in the field of genetic testing for health purposes. It also makes specific reference to: (a) the Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data; and (b) the work carried out by other intergovernmental organisations, and especially the United Nations’ Universal Declaration on Human Genome and Human Rights.

The Draft Protocol therefore has specific application to the potential conflict between: (a) an individual’s right to privacy in his or her genetic information; and (b) the interests of his or her genetic relatives in knowing such information. I discuss below the features of the Draft Protocol that are relevant to this conflict.

4.3.6.1 Relevant Articles of the Draft Protocol

First, in the preamble to the Draft Protocol, the Council of Europe acknowledges that the human genome is shared by all human beings, and stresses the particular bond that exists between genetic relatives as a result.

Secondly, Article One (in relation to the object and purpose of the Draft Protocol) states that:

Parties to this Protocol shall protect the dignity and integrity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other fundamental rights and freedoms with regard to the tests to which this Protocol applies in accordance with Article 2.

Thus, the protection of an individual’s right to privacy is at the heart of the Draft Protocol.

Thirdly, Article Eight (in relation to information and genetic counselling) states that the individual to be tested should be provided with prior appropriate information, especially in relation to the purpose and nature of the test, as well as the implications of the results, which include the implications of the test for the genetic relatives of that individual. Further, where a genetic test is predictive of a monogenic disease, susceptibility to genetic disease, or of carrier status, Article Eight mandates genetic counselling. It states that the form and extent of

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581 Above, n580: 9.
582 Above, n580: 2.
583 Above, n580: 2.
any such genetic counselling should be defined, among other factors, according to the results of the test and their significance for the person or members of his or her family. It therefore reiterates the importance of genetic counselling to support both the individual and his or her genetic relatives.

Fourthly, Chapter Four of the Draft Protocol relates to genetic tests conducted for the benefit of family members. While it relates primarily to informed consent in relation to conducting a genetic test as opposed to the privacy of the genetic information resulting from a genetic test, Articles 13 and 14 nevertheless shed light on where the balance lies between the rights of the individual and the rights and/or interests of his or her genetic relatives.

Article 13 provides that the law may allow a genetic test to be carried out for the benefit of family members on a person who does not have the capacity of consent if certain conditions are met, including where:

- the purpose of the genetic test is to allow the family members concerned to obtain a preventative, diagnostic or therapeutic benefit that has been independently evaluated as important for their health or to allow them to make an informed choice with respect to procreation;
- such a benefit cannot be obtained without the genetic test; and
- the expected benefit has been independently evaluated as substantially outweighing the risk for the private life of the individual tested that may arise from the communication of the results of the test (among other things).

The Protocol specifically acknowledges that this Article is contrary to Article Six, Paragraph One of the Convention on Human Rights and Biomedicine, and Article Ten of the Draft Protocol, indicating that the situations envisaged by the Draft Protocol are those in which an individual’s rights may be secondary to the interests of his or her genetic relatives.

The Explanatory Report sets out examples of when Article 13 might apply. These include cases where:

- An individual is suffering from cancer, is not in a position to consent, a test does not change the way in which that individual’s condition is treated, but where a test would
identify the relevant mutation and enable genetic relatives of the individual found to have the same mutation to regularly screen for cancer. 584

(b) A child is diagnosed with Cystic Fibrosis, and it is necessary to: (i) identify the existing mutation; (ii) identify whether the child’s parents carry that mutation; and (iii) determine whether the mutation was inherited or whether it was a newly occurring mutation in the child, so the parents can make future reproductive decisions. 585

(c) An individual is suffering from a disease for which the genetic mutation involved has not been identified, but where the transmission can be traced by studying genetic linkage, therefore multiple family members (affected and unaffected) need to be tested so as to ascertain an acceptable degree of diagnostic certainty. 586

Evidently, the potential benefits to an individual’s genetic relatives which might justify the application of Article 13 are broad, and encompass both health benefits and the ability to make informed reproductive choices. These benefits will only be deemed to outweigh the risks or burdens to the individual being tested where the risks and burdens to that individual are minimal, such as where the test involves a simple blood test. 587 Further, the principle of proportionality applies. That is, the anticipated benefit to the genetic relatives must significantly outweigh either the risk to the private life of, or the burden faced by, the individual being tested before Article 13 will apply. 588 (Note, the State, rather than an individual’s health practitioner, is charged with the task of weighing the benefit to genetic relatives against the potential risk or burden faced by the individual to be tested. 589)

Article 14 provides that tests on biological materials previously collected from an individual for another purpose may be tested for a genetic mutation without his or her consent for the benefit of his or her genetic relatives, in accordance with the principle of proportionality and where:

584 Above, n580: paragraph 106.
585 Above, n580: paragraph 107.
586 Above, n580: paragraph 108.
587 Above, n580: paragraph 111.
588 Above, n580: paragraph 121.
589 Above, n580: paragraph 109.
(a) reasonable efforts have been made, but it is not possible, to contact the individual concerned;

(b) the expected benefit cannot otherwise be obtained; and

(c) the genetic test cannot be deferred.

(Note, the Draft Protocol acknowledges that provision needs to be made where the individual concerned has expressly opposed any such use of his or her biological material, but does not discuss the matter any further.)

The situations contemplated by the Draft Protocol in which Article 14 might apply are discussed in the Explanatory Report. The situations are not as broad as those contemplated in Article 13, ie there must be serious consequences for the health of those genetic relatives whom the genetic test is intended to benefit before Article 14 applies (compared to, for example, seeking to make an informed reproductive decision). The example given in the Explanatory Report as to when Article 14 might apply is where: (a) there have been several cases of ovarian cancer in a family; (b) the genetic mutation involved has not been identified; and (c) the genetic test envisaged will contribute to a family study with a view to identifying that mutation. Identifying the mutation renders it unnecessary to remove the ovaries of female family members in whom the genetic mutation does not exist.

Thus, Articles 13 and 14 indirectly relate to the disclosure of an individual’s genetic information to his or her at-risk genetic relatives, without his or her consent.

Fifthly, Article 16 mirrors Article 10 of the Convention of Human Rights and Biomedicine, set out at paragraph 4.3.3 above. The key difference is that Article 16 of the Draft Protocol applies specifically to personal data derived from a genetic test.

The Draft Explanatory Report points out that to comply with Article 16, regard should be had to: (a) the wishes of the individual tested in relation to who can access the genetic information resulting from a test; and (b) any damage that such information might bring to the individual and/or his or her genetic relatives.590 Article 16 therefore recognises the interests of family members and, whilst regard must be had to the individual as to who can access such information, does not necessarily prevent disclosure of that information to family members.

590 Above, n580: paragraph 131.
The Explanatory Report also reiterates the importance of respecting an individual’s right not to know, especially, for example, where a test identifies the presence of a gene responsible for serious disease for which there is no treatment or cure.\(^{591}\)

Finally, and most relevantly for this thesis, Article 18 provides that:

> Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed.

This requirement reinforces the requirement in Article 8 of the Draft Protocol for health practitioners to advise an individual of all of the implications of a genetic test, including the implications for his or her family members. Informing an individual of such implications prior to testing is likely to reduce the number of conflicts that might arise between an individual's right to privacy and his or her genetic relatives’ interest in knowing important genetic information.

The Draft Explanatory Report also notes that the individual tested should be made aware of the importance of access to such information for his or her family members. The Draft Protocol leaves it to the State to decide how and when such information can be disclosed to that individual’s genetic relatives without his or her consent. In particular, the Draft Explanatory Report states:

> For the communication of this information to family members, appropriate provisions should be made, bearing in mind the rules on confidentiality and the protection of the private life of the various persons concerned (person on whom the test is performed and members of his or her family).\(^{592}\)

Nevertheless, the Draft Explanatory Report sets out some useful suggestions on how such information could be communicated to genetic relatives where the individual tested is unable or unwilling to directly inform his or her genetic relatives of the results of a genetic test. For example, the Explanatory Report suggests that:

(a) Where the individual tested does not want to inform his or her genetic relatives directly, he or she could be given appropriate material or leaflets to pass on to them.\(^{593}\)

\(^{591}\)Above, n580: paragraph 134.

\(^{592}\)Above, n580: paragraph 140.

\(^{593}\)Above, n580: paragraph 140.
(b) A mediating body could be established, which would be responsible for contacting family members of the individual concerned where the individual has requested that his or her genetic relatives be informed of the relevant information without the individual being identified as the source of the information.\textsuperscript{594}

(c) A competent body could be established to make a comparative assessment of the respective interests of the persons concerned on whether or not the genetic information in question must be communicated to an individual’s genetic relatives where the individual refuses to disclose relevant genetic information to his or her at-risk genetic relatives.\textsuperscript{595}

In cases where the genetic relatives of an individual tested are informed of the results of a genetic test, the Draft Explanatory Report advises that they be advised to consult a health practitioner and, where the genetic test is predictive, a genetic counsellor.\textsuperscript{596}

4.3.6.2 Conclusion: what does the Draft Protocol say about balance between the interests of individuals and genetic relatives?

An analysis of the provisions of the Draft Protocol and Draft Explanatory Report that are relevant to the potential conflict that arises between an individual’s right to privacy and his or her at-risk genetic relatives’ interest in knowing important genetic information suggests that:

(a) Both the rights of the individual and his or her genetic relatives should be recognised by law. (It is up to the individual Member States of the Council of Europe as to how the law provides such recognition.)

(b) Circumstances exist where the interests an individual’s genetic relatives will have primacy over that individual’s interests.

\textsuperscript{594} Above, n580: paragraph 140.

\textsuperscript{595} Above, n580: paragraph 140.

\textsuperscript{596} Above, n580: paragraph 141.
4.4. European Union

4.4.1. EU Treaty

The natural starting point for a discussion of the EU’s data protection laws and policies that relate to genetic data is its founding document which, in its most recent form, is the Draft Reform Treaty (a Treaty intended to consolidate the existing European treaties in a single text) (EU Treaty), and is due to come into force before June 2009.\textsuperscript{597}

The EU Treaty sets out the principles upon which the EU if founded, and provides, among other things, that the EU accedes to the European Convention for the Protection of Human Rights and Fundamental Freedoms, and that those fundamental rights will become general principles of EU law.

Thus, as provided in Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (discussed at paragraph 4.3.1 above), under EU law “everyone has the right to respect for his private and family life...” and:

\begin{quote}
There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.
\end{quote}

Such principles therefore form the basis of regulations and/or directives issued by the EU.


Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive) is the EU’s primary data protection instrument. The Data Protection Directive requires EU member states to:

\begin{quote}
Protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data.\textsuperscript{598}
\end{quote}


The Data Protection Directive, however, leaves the precise details of the legislative implementation of the protection of fundamental rights and freedoms to the national governments of the EU member states.

Given that the Data Protection Directive: (a) is the basis of the United Kingdom's Data Protection Act 1998, which is discussed in detail above; and (b) does not directly deal with genetic data, I do not consider it necessary to discuss its content in great detail. (I do acknowledge, however, that genetic information relating to an individual's health falls within the definition of "personal data" under Article 2(a), and is deemed to be personal data whose sensitivity requires a higher level of protection by virtue of it being "data concerning health" under Article 8(1), of the Data Protection Directive.)

Instead, I discuss below the genetic specific instruments developed by the Data Protection Working Party (which was established under Article 29 of the Data Protection Directive to, among other things, advise on specific issues in relation to safeguarding the rights and freedoms of individuals with regard to the processing of personal data) and the European Commission. I discuss the features of each instrument that touch on the potential conflict that exists between an individual's right to privacy and his or her genetic relatives' interest in knowing relevant information.

4.4.3. Data Protection Working Party: Genetic Specific Instruments

To date, in relation to the processing of genetic information, the Data Protection Working Party has adopted Opinion 6/2000 on the Human Genome and Privacy and a Working Document on Genetic Data.

4.4.3.1 Opinion 6/2000 on the Human Genome and Privacy


The Opinion is brief, and does no more than:


599 Above, n598: 48.
(a) Acknowledge that the genetic information can:

identify individuals, link them to others, and reveal complex data about the future health and developments of those individuals and other people to whom they are genetically related. 600

(b) Emphasise the importance of privacy as a fundamental right, and the need to adequately protect that right in light of developments in genetics. 601

4.4.3.2 Working Document on Genetic Data

The Working Document on Genetic Data (Working Document) provides more detail and was adopted by the Working Party on Data Protection on 17 March 2004. Its main purpose is to:

(a) identify areas of concern in relation to the processing of genetic data (from a data protection perspective); and

(b) contribute to a uniform approach to protection of genetic data in light of the natural measures adopted in the area under Data Protection Directive. 602

The proportionality principle underlies all of the suggestions made in the Working Document in relation to the processing of genetic data. That is, genetic data must be adequate, relevant and not excessive in relation to the purposes for which it is collected and further processed. 603

The proportionality principle therefore reiterates the importance of clearly determining the purpose for which genetic data is collected and processed at the outset of any genetic testing process.

It is important to acknowledge (and the Working Document acknowledges) that even if a health practitioner acts in accordance with the proportionality principle, the potential for a conflict to arise between an individual's and his or her genetic relatives' rights and interests in


601 Above, n600.


603 Above, 602: 6.
relation to privacy and access to genetic information still exists. Regardless of the clarity of
the information provided to an individual prior to testing, he or she may still object to his or
her genetic information to be passed on to at-risk genetic relatives. Accordingly, I discuss
below the points and suggestions made by the Working Party on Data Protection in the
Working Document in relation to possible ways of dealing with conflicting interests and
rights in genetic information.

First, whilst the Data Protection Directive indirectly acknowledges both the interests of
individuals and their genetic relatives, it does not provide a mechanism for resolving any
conflict that might arise between such interests. On the one hand, Article 10 provides that an
individual is entitled to receive information obtained directly from him or her. On the other
hand, Article 11 provides that an individual also has a right to information that relates to him
or her when the data has not been obtained from that individual.604

The Working Party on Data Protection notes in the Working Document that this raises:

(a) A dilemma for health practitioners, ie:

On the one hand [the health practitioner] might be bound by the obligation of
secrecy, while on the other hand, he [or she] could be obliged under Article 11 to
provide information to the data subject (e.g.: in the case where information is
extracted from genetic material received by relatives.605

(b) Questions as to what genetic information taken from an individual should be given to
genetic relatives of that individual, since such information may have serious
consequences for those genetic relatives.606

Secondly, the Working Party points out that particular regard needs to be had to access to
genetic information by “kindred members inside the relevant biological group” rather than
looking at genetic information from a traditional individualistic perspective.607 It notes that
one way of ensuring that the interests of genetic relatives are afforded sufficient recognition is
to consider any genetic data that has a familial dimension to be “shared information”, with

605 Above n602: 6.
606 Above n602: 8.
607 Above n602: 8.
genetic relatives having a right to access such information to the extent it might have implications for their future life or health.\textsuperscript{608}

The Working Party acknowledges, however, that the precise legal consequence of deeming genetic information to be shared information is not clear, but that there are two possible scenarios. That is, genetic relatives of individuals tested could either be:

(a) considered as data subjects, and have all of the rights associated with that status; or\textsuperscript{609}

(b) afforded a right to genetic information of a different type to the data subject, based on the fact that their personal interests might be directly affected.\textsuperscript{610}

I note, however, that there are inherent problems with deeming genetic information “shared information”, regardless of which formulation is adopted. If individuals \textit{and} genetic relatives are entitled to access particular genetic information (whether they are afforded the same or different rights), they might each have different views on who is to have access and how it is to be treated. Thus, treating genetic information as “shared information” does not resolve the conflicts from a practical or legal perspective. The Working Document suggests, therefore, that further consideration needs to be had in relation to such conflicts before adopting a new concept of “shared information”, and that until then, conflicts should be addressed on a case by case basis.

Finally, the Working Document also discusses the importance of addressing individuals’ and their genetic relatives’ right \textit{not} to know genetic information. In this regard, the Working Party on Data Protection adopts the position taken by France’s Commission nationale de l’informatique et des libertés (an administrative body whose purpose is to ensure compliance with data protection law), that it is not appropriate to systematically inform the genetic relatives of individuals who carry a gene of an incurable disease, thereby potentially generating permanent anxiety without a possible direct benefit for those genetic relatives, as no useful treatment would be available to them in the near future.\textsuperscript{611}

\textsuperscript{608} Above n602: 9.

\textsuperscript{609} Above n602: 9.

\textsuperscript{610} Above n602: 9.

\textsuperscript{611} Above n602: 9.
In summary, the main points that can be drawn from the Working Document in relation to the privacy of and access to genetic information are that:

(a) A new, legally relevant social group exists, ie the genetic family group (which would exclude family members such as one's spouse, but include gamete donors).

(b) Decisions in relation to potential conflicts that arise between an individual and the other members of the genetic family group, given the complexity of the issues involved, should be made on a case by case basis.

(c) Individuals' and their genetic relatives' right not to know genetic information should be upheld where there is no available prevention or treatment available in relation to the genetic disease in question.

4.4.4. European Commission: Report on Ethical, Legal and Social aspects of Genetic Testing

Alongside the Working Document, the European Commission established an independent expert group from various backgrounds to discuss the ethical, legal and social aspects of genetic testing and to make recommendations in relation to the issues surrounding the application of genetic testing to health care and other associated areas. The European Commission envisaged those recommendations being used as a broad platform for discussion by various stakeholders of the issues surrounding genetic testing. 612

The independent expert group formulated 25 recommendations. In relation to the potential conflict between an individual's right to privacy of, and his or her genetic relatives' interest in accessing, genetic information, the recommendations align with the suggestions made in the Working Document. The independent expert group recommends that:

(a) the relevance of genetic information to family members needs to be addressed; and

(b) the importance of a patient's right to know or not know be recognised and mechanisms incorporated into professional practice that respect this. In the context of genetic testing

(which encompasses information provision, counselling, informed consent procedures, and communication of test results) practices should be established to meet this need.613

Further, the independent expert group recommended that genetic information not be afforded “exceptional” status (ie it should receive the same level of protection as other comparably sensitive medical information), but that the public perception that genetic testing is different needs to be addressed.614

4.4.5. Summary of European Union position on competing interests in genetic information

Both the European Union’s Working Party on Data Protection and the European:

(a) Recognise that a potential conflict exists between an individual’s right to privacy and his or her genetic relatives’ interest in knowing genetic information.

(b) Acknowledge that the interests of the genetic family group in knowing genetic information about them but not derived directly from them are not adequately recognised under data protection law, but ought to be.

(c) Acknowledge that the rights of both individuals and their genetic relatives in knowing or not knowing genetic information must be protected.

5. OTHER INTERNATIONAL INSTRUMENTS RELATING TO THE PROTECTION OF GENETIC DATA

Regulatory and ethical issues that arise as a result of the rapid developments in human genetics have also received attention at an inter-governmental level. Both the United Nations Education, Scientific and Cultural Organisation (UNESCO) and the OECD have produced instruments in relation to genetics that have application to the potential conflict between an individual’s right to privacy and their genetic relatives’ interest in knowing genetic information. In addition, the World Health Organisation (WHO) requested that the Advisory Committee on Health Research prepare a report on the likely impact of genomics on global


614 Above, n613: 9 (Recommendation 3).

5.1. UNESCO

"since wars begin in the minds of men, it is in the minds of men that the defences of peace must be constructed"615

UNESCO was founded on 16 November 1945. It is a specialised United Nations agency which aims to set standards upon which to build universal agreements on emerging ethical issues.616 Its function is set out succinctly on its website as follows:

In short, UNESCO promotes international co-operation among its 193 Member States and six Associate Members in the fields of education, science, culture and communication.617

One of the mechanisms by which UNESCO sets such standards is by developing instruments on emerging ethical issues and submitting them to Member States for consideration and approval. Such instruments are generally produced in the form of international conventions (such as treaties or agreements), recommendations to Member States or declarations and charters.618

To date, UNESCO has produced three declarations619 in relation to human genetics, including:


617 Above, n616. Note, New Zealand, Australia and the United Kingdom are all member states of UNESCO.


619 Note, declarations are not subject to ratification, but set forth universal principles to which Member States of UNESCO wish to attribute the greatest possible authority and to afford the broadest possible support. "In United Nations practice, a "declaration" is a formal and solemn instrument, suitable for rare occasions when principles
(a) Universal Declaration on the Human Genome and Human Rights.

(b) International Declaration on Human Genetic Data.

(c) Universal Declaration on Bioethics and Human Rights.

I discuss below the features of each declaration that relate to the potential conflict between an individual’s right to privacy and the rights/interests of genetic relatives in knowing important information that relates to them. (Note, common to each declaration is the requirement that genetic or health data be processed, used and stored only with the prior, free, informed and express consent of the individual, or in a manner prescribed by law. I confine my focus to other principles relevant to the conflict.)

5.1.1. Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights was adopted by UNESCO on 11 November 1997, and endorsed by the United Nations General Assembly on 9 December 1998.

The Universal Declaration on the Human Genome and Human Rights sets out broad principles in relation to the protection of fundamental rights and freedoms of individuals in relation to developments in genetic technology.

Relevant provisions include:

(a) Article 5(c) which states:

The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.

(b) Article 9, which states:

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

...
Like the conventions and recommendations adopted by the Council of Europe and the European Union, the Universal Declaration on the Human Genome and Human Rights leaves the development of any laws in relation to limitations on an individual’s rights to privacy (for example allowing the disclosure of genetic information to genetic relatives in certain circumstances) to the Members States, provided any such laws are consistent with international human rights law.

(c) Article 24, which encourages the further examination of issues raised by the applications of genetic technologies, with a view to developing further recommendations.

Thus, the Universal Declaration on the Human Genome and Human Rights recognises that individuals should have the right to know and not know genetic information about them, and provides that any limits on confidentiality should only be allowed for compelling reasons. It does not expressly recognise the relevance of genetic information to genetic relatives of an individual, and is framed from an individualistic perspective.

The International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights provide more detail in relation to, and apply more directly to, the conflict discussed in this thesis. Further, they show a less individualistic approach to the treatment of genetic information.

5.1.2. International Declaration on Human Genetic Data

The International Declaration on Human Genetic Data was adopted by UNESCO on 16 October 2003. It welcomed the broad worldwide public interest in the Universal Declaration on Human Genome and Human Rights, and further developed the principles therein.

The International Declaration on Human Genetic Data recognises that genetic information has a special status on account of its sensitive status, and notes that one of the reasons that such information has a special status is its familial nature. In particular, Article 4 provides that:

Article 4 – Special status

(a) Human genetic data have a special status because:

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they can be predictive of genetic predispositions concerning individuals;

(ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;

(iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;

(iv) they may have cultural significance for persons or groups.

(b) Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.

(Note, however, that the preamble to the International Declaration on Human Genetic Data recognises that all medical data should be treated with the same high standard of confidentiality, so despite Article 4, UNESCO does not necessarily support genetic exceptionalism.)

Further, the International Declaration on Human Genetic Data recognises that the right of an individual not to know the results of genetic research should extend to genetic relatives. Article 10 provides that:

**Article 10 – The right to decide whether or not to be informed about research results**

When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. *Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.*

[Emphasis added.]

Despite this, Article 14 of the International Declaration on Human Genetic Data provides that genetic data should not be disclosed to family members (among other third parties) without
the consent of the individual from whom it was obtained unless there are important public interest reasons for doing so:

**Article 14 – Privacy and confidentiality**

(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consistent with the international law of human rights.

(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights.....

[Emphasis added]

The International Declaration on Human Genetic Data does not specify what might constitute a public interest exception. It is possible that disclosing genetic information to protect the health of a family member, where the harm to the family member in not knowing the genetic information outweighs the harm to the individual from any such disclosure, might constitute “an important public interest reason”.

What is clear is that the focus of the International Declaration on Human Genetic Data is much more heavily weighted in favour of the rights of the individual than family members, in comparison to, for example, the Council of Europe’s Working Document on the Application of Genetics for Health Purposes (also adopted in 2003), which provides express recognition of the interests of genetic relatives in knowing relevant genetic information.

5.1.3. **Universal Declaration on Bioethics and Human Rights**

The Universal Declaration on Bioethics and Human Rights, adopted by UNESCO on 19 October 2005, relates to the ethical issues raised by the rapid advances in science generally, rather than genetic science in particular. The Universal Declaration on Bioethics and Human Rights is premised on the principle that:
It is necessary and timely for the international community to state universal principles that will provide a foundation for humanity’s response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment.621

Whilst it is not genetic specific, the following general principles are relevant to the conflict discussed in this thesis:

(a) Article 4 provides that, in applying and advancing medical practice (eg genetic testing), direct and indirect benefits to patients and other affected individuals should be maximised, and any possible harm to such individuals should be minimised.

This principle is consistent with disclosing genetic information to at-risk genetic relatives where doing so may benefit the health of those relatives. That is, the results of a genetic test can provide a direct benefit to the individual tested and an indirect benefit to his or her genetic relatives, both of which should be maximised to the extent that it outweighs any harm caused by the disclosure to the individual.

(b) Article 5 relates to autonomy and individual responsibility and provides that an individual’s autonomy to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected.

Arguably, where an individual decides to have a genetic test, this principle requires that the individual inform his or her genetic relatives of genetic information that may have relevance for them:

(i) Deciding to have a genetic test involves deciding to obtain information not only about oneself, but also about one’s genetic relatives. Thus, taking responsibility for the decision to have a genetic test might require disclosing genetic information to at-risk relatives in appropriate circumstances (ie where doing so can prevent harm to those relatives).

(ii) Respecting the autonomy of others might include arming them with relevant genetic information so that they are fully informed and therefore able to make autonomous decisions. (There are also arguments, however, that providing

genetic relatives with genetic information that they did not request might be not disrespectful of their autonomy.)

(c) Finally, Article 9 is a general provision on privacy and confidentiality and provides that an individual’s privacy and confidentiality is to be respected.

5.1.4. Resolutions on Genetic Privacy and Non-Discrimination

UNESCO adopted:


(c) On 21 July 2004, Resolution 2004/9 on Genetic Privacy and Non-Discrimination.

In confine my discussion to the most recent resolution (ie Resolution 2004/9) and the report produced by the Secretary General of UNESCO in 2007 as a result of a directive in that resolution.

5.1.4.1 Resolution 2004/9 on Genetic Privacy and Non-Discrimination

The principles adopted in Resolution 2004/9 on Genetic Privacy and Non-Discrimination ("Resolution 2004/9") are consistent with those adopted in the UNESCO Declarations in relation to genetics, discussed in this paragraph 5.1. In particular, Resolution 2004/9:

(a) Recognises that genetic data associated with an identifiable person can in some instances be relevant to other members of the individual’s family, and that the rights and interests of such persons must also be taken into account when handling such data.

(b) Leaves it up to Member States to develop appropriate standards in relation to the privacy of genetic information, but notes that any limitation to the principles of consent and confidentiality may be prescribed only by law, and for compelling reasons consistent with international law, including international human rights law.

Resolution 2004/9 also required the UNESCO Secretary General to bring Resolution 2004/9 to the attention of all governments, to collect and collate comments from those governments
in relation to Resolution 2004/9, and to submit a report to UNESCO at its substantive session in 2007.

5.1.4.2 Report of the Secretary on Genetic Privacy and Non Discrimination

This directive resulted in a Report of the Secretary on Genetic Privacy and Non Discrimination dated 2-27 July 2007. The Report includes information and comments received from UNESCO Member States in response to Resolution 2004/9. The responses submitted to the Secretary General were limited. The comments that were submitted discuss, at a very high level, initiatives undertaken by particular States in relation to the protection of genetic information. None of them refer directly to the issues discussed in this thesis, so the report does not require further discussion.

5.1.5. Conclusion: principles proposed by UNESCO in relation to genetic information

In short, the broad principles put forward by UNESCO in its declarations, resolutions and reports in relation to the protection of genetic information are as follows:

(a) Genetic information is sensitive information, but should be treated consistently with other, equally sensitive, medical data.

(b) Genetic information can only be collected, used, processed and stored with the prior, free, informed and express consent of the individual from whom it is being collected.

(c) The rights and interests of individuals and their genetic relatives in relation to genetic information ought to be recognised.

(d) Rules in relation to confidentiality and privacy of genetic information should only be limited if there is a compelling reason to do so. Such rules are to be developed by Member States, and should be consistent with international law.

Thus, whilst UNESCO does not discuss the matter directly in its declarations, resolutions or reports, the disclosure of an individual’s genetic information to his or her at-risk genetic relative for the purpose of protecting the life or health of that genetic relative is not contrary to

the broad principle put forward by UNESCO in relation to the protection of genetic information.

5.2. OECD

The OECD is a forum in which governments of member countries work together to address the economic, social and environmental challenges. It provides a mechanism for governments to compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.623

In disseminating the results of its work, the OECD produces decisions, standards, recommendations and guidelines on various issues. Two of the OECD’s recommendations have particular relevance to the issues examined in this thesis.624 These are the:

(a) Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data.

(b) Recommendation of the Council on Quality Assurance in Molecular Genetic Testing.

5.2.1. OECD Privacy Recommendation

The OECD Privacy Recommendation is the basis upon which New Zealand’s Privacy Act 1993 was drafted. In particular, the Information Privacy Principles in the Privacy Act 1993 conform to the OECD Privacy Recommendation.625

Given the extensive discussion of New Zealand’s privacy / health information privacy regime in Chapter 5, and the compliance of that regime with the OECD Privacy Recommendation, I do not consider it necessary to discuss it here, other than to note that it sought to propose common privacy protection principles so as to align privacy laws among member states.


624 Note, while an OECD recommendation is not a legally binding document, it represents an important political commitment on the part of the Member States. See above n623: 6.

625 Privacy Act 1993. Long Title
5.2.2. Recommendation of the Council on Quality Assurance in Molecular Genetic Testing.

The Recommendation of the Council on Quality Assurance in Molecular Genetic Testing (OECD Molecular Genetic Testing Recommendation) was adopted by the OCED on 10 May 2007.\textsuperscript{626} It sets out a number of principles and best practices relevant to molecular genetic testing. It was developed by the OECD: (a) due to the steady growth in the use and availability of molecular genetic testing; and (b) because regulatory and oversight procedures in relation to quality assurance in genetic testing are either not established, or inconsistent, among OECD countries.\textsuperscript{627}

The OECD Molecular Genetic Testing Recommendation reiterates the importance of offering genetic testing services within a quality assurance framework that retains the confidence of the public, given than genetic tests are highly predictive of the future health of the individual \textit{and the implications of such tests for relatives of the person tested}.\textsuperscript{628} Whilst it sets out principles and best practices that take into account the familial nature of genetic information, for example:

\begin{itemize}
\item \textbf{A. General principles and best practices for molecular genetic testing}
\item A5. Pre and post test counselling should be available. It should be proportionate and appropriate the characteristics of the test, the test limitations, the potential harm, and the relevance of the test results to individuals \textit{and their relatives}. \textsuperscript{629}
\end{itemize}

\begin{itemize}
\item \textbf{D. Quality of result reporting}
\item D vii. Where appropriate, the test report should include the following information:
\end{itemize}

\begin{itemize}
\item 2. Implications for other family members.\textsuperscript{629}
\end{itemize}

\textsuperscript{626} Above n623.

\textsuperscript{627} Above n623: 6.

\textsuperscript{628} Above n623: 7.

\textsuperscript{629} Above n623: 13, 18.
the OECD Molecular Genetic Testing Recommendation does not expressly contemplate the conflict that might arise between individuals and their family members in relation to privacy of and access to the genetic information of the individual tested.

The OECD Molecular Genetic Testing Recommendation does, however, offer important recognition of the familial nature of genetic information, and of the need to acknowledge the importance of genetic information to individuals and their families when dealing with genetic information (whether in a clinical or laboratory context).

5.3. WHO

The WHO, established on 7 April 1948, is a specialist agency of the UN, which acts as the directing and coordinating authority on world health. Any member of the UN can become a member of the WHO by accepting its constitution. To date, the WHO has 193 member countries.

The WHO’s key objective is set out at Article 1 of its constitution, ie "the attainment by all peoples of the highest possible level of health." Accordingly, genetic information and its impact on the health of individuals and their relatives falls within the remit of the WHO’s focus.

In 2002, in light of the complex scientific, social and ethical concerns that have arisen as a consequence of the rapid advances in genetics, the WHO commissioned a report, Genomics and World Health (WHO Report), which contains specific recommendations in relation to the appropriate treatment of genetic information.

One of the concerns discussed in the WHO Report which is particularly relevant to this thesis included whether the prospect of the increase in genetic information available through the advent of modern genetics raised new ethical issues in relation to confidentiality for health


care systems in which such information exists, which it considered to be a relevant concern to every society.634

The WHO identified what it considered to be the four key grounds for maintaining the confidential information of health information (including genetic information), being that:635

(a) It prevents potential harm to the patient, such as discrimination in employment and insurance.

(b) Since health information is obtained only with the patient’s consent and cooperation, the patient should control who has access to it.

(c) Since health information is about the patient, the patient has the greatest interest in it and who has access to it.

(d) The medical profession in most countries promises patients that their health information will be kept confidential.

The WHO pointed out that, in relation to genetic information with important consequences for family members’ health and/or reproductive choices, only the second of the above grounds would justify not disclosing that information to a patient’s family members without the patient’s consent. It considered that confidentiality need not be promised to patients in such circumstances, especially because: (i) disclosing genetic information with important consequences for family members’ health to those family members would typically not harm the patient; and (ii) such information is equally about those family members who therefore have a comparable interest in obtaining it.

On that premise, the WHO recommended that health organisations should (except in special circumstances) adopt a limit on confidentiality to emphasise the fact that genetic information is characteristically about families, and not only individuals.636 The WHO noted that there could be special circumstances, either individual or cultural, which might justify maintaining confidentiality, even where a patient’s genetic information had important consequences for his or her family members’ health and/or reproductive choices. An example put forward by the WHO was where disclosure would likely lead to harm or violence to the individual.

634 Above, n633: 155.
635 Above, n633: 156.
Accordingly, the WHO further recommended that an institutionalised process be established to evaluate individual cases of limiting patient confidentiality without the patient's consent in order to information potentially affected relatives.\textsuperscript{637}

Thus, the WHO directly acknowledges the potential conflict between an individual's right to privacy and their genetic relatives' interest in knowing genetic information, and proposes to resolve this conflict by making the disclosure of genetic information to family members the rule rather than the exception.

6. CONCLUSION

An examination of the approaches taken in Australia, England, Europe and at an intergovernmental level in dealing with the challenges raised by the familial nature of genetic information, and in particular the potential conflict that can arise between an individual's right to privacy and his or her genetic relatives' interests and rights in knowing relevant genetic information about them, revealed the following:

\textbf{Australia}

(a) As under the NZMA Code of Ethics, there are no exceptions in the AMA Code of Ethics which would likely justify a health practitioner disclosing a patient's genetic information to his or her genetic relatives without his or her consent.

(b) Under Australian common law, health practitioners likely owe a duty of care to their patients' genetic relatives to warn their patients of the implications a genetic test could have for genetic relatives, and of the importance of providing them with relative information.

(c) Despite the apparent uncertainty surrounding, and perhaps lack of recognition of, the rights of genetic relatives under the AMA Code of Ethics and Australian common law, Australia's \textit{Privacy Act 1988 (Cth)} has been amended to deal directly with issues that arise in relation to genetic information. In particular:

(i) The definition of "health information" has been amended to include "genetic information".

\textsuperscript{637} Above, n633: 157.
(ii) Health practitioners are now given a discretionary right to disclose a patient's genetic information to that patient's genetic relatives where such disclosure is necessary to prevent a serious threat to an individual's life, health or safety, even where the threat is not imminent.

(iii) The legislation provides scope for the development, by legislative instrument, of guidelines for health professionals in relation to disclosing genetic information to genetic information which are to:

(aa) address the circumstances in which disclosure to genetic relatives is ethically justified or required and the need for patients to be counselled about the disclosure of information in these circumstances;

(bb) include advice to health practitioners in dealing with requests for access to genetic information by genetic relatives of patients.

(d) Australian privacy legislation does not acknowledge that an individual's and/or his or her family member's right not to know genetic information.

**United Kingdom**

(e) A multitude of relevant ethical guidelines exist in the United Kingdom in relation to the treatment of genetic information. An analysis of these guidelines revealed that a health practitioner would likely be justified in disclosing a patient's genetic information to that patient's genetic relatives where doing so could prevent serious harm to those relatives, and the benefits of disclosure substantially outweigh the patient's claim to confidentiality (ie any harm likely to be suffered as a result of a breach of privacy/confidentiality). In comparison to the New Zealand and Australian ethical guidelines, the United Kingdom guidelines do not require that the harm to be prevented be imminent before disclosure is justified.

(f) Under United Kingdom common law, a health practitioner is justified in disclosing a patient's genetic information to that patient's genetic relatives where doing so is in the public interest. An analysis of the United Kingdom common law on this point indicates that disclosure is likely to be justified on this ground where it can prevent the onset of genetic disease or can enable effective treatment to be pursued by the genetic relative. It is unlikely that the public interest exception can be relied upon to justify disclosure in
many circumstances, however, given the multifactorial nature of, and the lack of effective treatment available for, many genetic diseases.

(g) As in New Zealand and Australia, there is no positive duty on a health practitioner under United Kingdom common law to disclose genetic information to genetic relatives, even where doing so would prevent/reduce risk/harm to those relatives.

(h) United Kingdom’s privacy legislation is not genetic specific, but nevertheless is likely to justify the disclosure by a health practitioner of a patient’s genetic information to genetic relatives in order to enable those relatives to avoid/significantly reduce the risk of developing a genetic condition, or seek treatment for an undiagnosed genetic condition. Thus, it is less restrictive than New Zealand’s non-genetic specific Privacy Act 1993, and produces much the same result as Australia’s recently amended genetic-specific Privacy Act 1988 (Cth).

(i) Like in New Zealand and Australia, privacy legislation in the United Kingdom does not expressly deal with an individual’s, or his or her genetic relatives’, right not to know genetic information.

Europe

(j) European intergovernmental organisations (ie the Council of Europe and the EU) have produced a number of conventions and recommendations in relation to the conflict examined in this thesis. These recommendations and conditions set out the principles upon which European countries are to base their laws (ie as opposed to providing a direct legislative solution to the issues discussed in the recommendations).

(k) Relevant points and principles that can be taken from the Council of Europe and EU recommendations and conventions are as follows:

(i) The rights and interests of individuals and their genetic relatives should be expressly recognised.

(ii) Circumstances exist (explained above) where genetic relatives’ interests in knowing genetic risk outweigh an individual’s right to privacy.

(iii) Circumstances exist (explained above) where a genetic test should be carried out on an individual’s biological material without his or her consent for the benefit of family members.
(iv) An individual, and his or her genetic relatives, have the right to know *and* not to know genetic information about them.

(v) Any limitations to the right not to know can only be justified where:

(aa) where the law requires it; and/or

(bb) where such limitation is necessary to protect the rights and freedoms or others.

(vi) Genetic information should be used in accordance with the principle of proportionality.

(l) On the basis of (k) above, the principles proposed by European intergovernmental organisations: (i) justify the disclosure of an individual’s genetic information to his or her at-risk relatives where doing so would prevent harm to those relatives, and such benefit outweighs any harm caused as a result of the breach on an individual’s privacy/confidentiality; and (ii) suggest that, in certain (limited) circumstances, the rights of the genetic individual are paramount.

**International intergovernmental organisations**

(m) UNESCO and the OECD have also produced guidelines and recommendations that apply to the conflict. Such guidelines are less permissive and on point than those proposed by the Council of Europe and the EU. Nevertheless, disclosure of an individual’s genetic information to his or her genetic relatives in order to prevent harm to those relatives would not be contrary to most UNESCO and OECD guidelines.

(n) In contrast to the less permissive approach seen in the UNESCO and the OECD guidelines, the WHO proposes that the conflict be resolved in favour of genetic relatives by making disclosure of genetic information with important consequences for genetic relatives’ health or reproductive choices the rule rather than the exception. It did, however, acknowledge that in special circumstances, the confidentiality of an individual’s genetic information should not be limited for the purpose of making such a disclosure.

The above analysis provides a useful point of comparison against which to the position under New Zealand’s privacy regime in relation to the conflict between an individual’s right to privacy and his or her genetic relatives’ interest in knowing relevant genetic information.
With the above positions and principles in mind, in the next chapter, I assess the effectiveness of New Zealand's current privacy regime, and discuss possible options for reform.
CHAPTER 7

CONCLUSION: RECOMMENDATIONS FOR REFORM

1. INTRODUCTION

Two things are certain after discussing the nature of genetic information and reviewing the existing health information privacy law in New Zealand and overseas in relation to the potential conflicts between: (a) an individual’s right to privacy and his or her genetic relatives’ rights or interest in knowing important genetic information; and (b) a patient’s desire to share information and his or her genetic relatives’ interest in not knowing it. First, the interests of the individual and his or her genetic relatives’ in knowing or not knowing genetic information deserve legal recognition. Secondly, New Zealand’s health information privacy law does not adequately achieve a balance between the competing interests and rights at stake.

In this chapter, I:

(a) Discuss the Privacy Commissioner’s recent proposal to amend the HIPC in relation to the ability to disclose genetic information to genetic relatives to avert serious harm, and whether those amendments will achieve an appropriate balance between the competing interests of individuals and their genetic relatives.

(b) Discuss the submissions made by various New Zealand stakeholders in relation to the Privacy Commissioner’s proposed amendments to the HIPC.

(c) Drawing from the above, and from the recommendations made and/or approaches taken overseas, formulate an alternative proposal for reforming New Zealand’s privacy regime as it applies to genetic information, and in particular the rights and interests of individuals and their genetic relatives in relation to that information.

2. PROPOSED AMENDMENTS TO THE HEALTH INFORMATION PRIVACY CODE

In April 2007, the Privacy Commissioner released Proposed Amendment No 6 to the Health Information Privacy Code 1994 (HIPC Amendment). Item 8 of the HIPC Amendment
proposed to amend Rule 11 of the HIPC and therefore has particular relevance to this thesis. I set out below the Privacy Commissioner’s proposed amendment to Rule 11 of the HIPC, and the reasoning behind that amendment.

2.1. Proposed amendment to Rule 11 of the HIPC

2.1.1. New Rule 11(2)(l) – disclosure of genetic information to genetic relatives

The HIPC Amendment proposed to amend Rule 11 of the HIPC to allow health practitioners to disclose genetic information to genetic relatives of the individual tested in certain circumstances. In particular, the Privacy Commissioner proposed that a new exception to the general prohibition on disclosure of personal health information in rule 11 of the HIPC be inserted at rule 11(2)(l), as follows:

Rule 11

Limits on the disclosure of health information

(2) Compliance with paragraph 1(b) is not necessary if the health agency believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the individual concerned, and:

(1) that the information is genetic information obtained in the course of providing a health or disability service to the individual concerned, and is disclosed by a health practitioner to a genetic relative of the individual concerned, and the disclosure is necessary to prevent or lessen a serious threat to the life or health of the individual to whom the disclosure is made.638

In essence, the new Rule 11(2)(l) removes the “imminent” requirement from the “serious and imminent” test under the existing Rule 11(2)(d) when applied to genetic information. That is, it does not require that the threat to the genetic relative to be imminent for disclosure to that genetic relative to be justified.

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The Privacy Commissioner acknowledged that, while it was preferable to rely on the other exceptions to privacy under the HIPC, ie:

(a) obtaining consent of the individual concerned (see Rule 11(1)(b)); or

(b) ensuring that the patient is aware, and proceeds with a genetic test on the basis, that disclosure to avert harm to genetic relatives is one of the purposes for which his or her genetic information is being obtained (see Rule 11(1)(c)),

adding Rule 11(2)(l) is necessary because it is inevitable that, in some circumstances an individual would refuse to consent to the disclosure of his or her genetic information to genetic relatives, or would not be made aware that disclosure to avert harm to his or her genetic relatives is one of the purposes of collection. In such circumstances it is still important that an individual’s genetic information is disclosed to his or her genetic relatives where doing so could prevent serious health consequences for them by allowing the early detection and/or treatment of genetic diseases.

The Privacy Commissioner also noted that, because Rule 11(2) only allows the disclosure of as much information as is necessary to carry out the purpose, disclosure of an individual’s genetic information to his or her genetic relatives would only ever be permissible where some action could be taken by the genetic relative to prevent or lessen the threat to his or her life or health (and the other requirements under Rule 11(2) are met, as set out in Chapter Five, paragraph 5.4.4.3).

2.1.2. Definition of genetic relative

In light of the proposed new Rule 11(2)(d), the Privacy Commissioner proposed to insert a definition of "genetic relative" as follows:

**[G]enetic relative of an individual (the first individual) means another 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.**

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639 Above, n638: 11.

640 Above, n638: 10.

641 Above, n638: 13.
2.1.3. Further amendments considered but not adopted

In addition to the new Rule 11(2)(l), the Privacy Commissioner considered, but rejected, a number of other potential amendments to the HIPC in relation to the disclosure of genetic information to genetic relatives.

First, the Privacy Commissioner considered relaxing the “serious and imminent” test in Rule 11(2)(d) in relation to all health information, rather than only genetic information. This was rejected on the basis that it would mean that health information would attract less privacy protection than other personal information in some instances, and therefore amounted to “an unacceptable weakening of the confidentiality of personal health information”.642

Secondly, the Privacy Commissioner considered adopting a parallel provision in the HIPC to s95AA(1) of Australia’s Privacy Act (Cth) 1988, which gives the Australian Federal Privacy Commissioner the ability to approve guidelines for the ethical use of genetic information, to be issued by the National Health and Medical Research Council.643 The Privacy Commissioner chose not to adopt this provision because the HIPC deals with privacy matters only, and “does not aim to dictate the ethical standards to which health professionals have to conform”. She noted, however, that she would expect to be consulted on privacy aspects of any ethical guidelines relating to the disclosure of genetic information to genetic relatives.644

2.1.4. Does the proposed amendment to Rule 11(2) achieve an appropriate balance between individuals’ and genetic relatives’ rights and interests in genetic information?

2.1.4.1 Proposed amendment achieves a prima facie balance between competing interests

The proposed amendment to Rule 11(2) and the associated insertion of the definition of “genetic relative” (Proposed Amendment) achieves a prima facie balance between: (a) an individual’s right to privacy and his or her genetic relatives’ right to know important genetic information; and (b) an individual’s desire to share his or her genetic information, and his or her genetic relatives’ right not to know.

642 Above, n638: 11.
643 See also Chapter 5, paragraph 2.4.3.1.
644 Above, n638: 12.
First, the Proposed Amendment recognises:

(a) A genetic relatives’ right to know important genetic information, in that it expressly allows the disclosure of genetic information in some circumstances.

(b) An individual’s right to privacy, in that it only permits such disclosure where it is necessary to prevent or lessen a serious threat to the life or health of the genetic relative (ie consistent with the principle of proportionality).

Secondly, the Proposed Amendment goes some way towards recognising a genetic relatives’ right not to know their risk of developing a genetic condition. In particular, it indirectly recognises a genetic relative’s right not to know in most instances (eg where no available treatment exists for the genetic disease in question), because disclosure under the Proposed Amendment would only ever be permitted where some action could be taken by the genetic relative to prevent or lessen the threat to his or her life or health. Whilst this is somewhat paternalistic, and makes the assumption that people would want to be avoid suffering wherever possible, it nevertheless provides a practical solution to an issue that is nearly impossible to legislate.

The inherent difficulty in properly protecting the right not to know is that the genetic relative cannot exercise such a right in relation to genetic information when they do not know that the genetic information is available. Thus, any legal recognition of the right not to know will necessarily require a third party (such as a health practitioner) to determine whether an individual might want to uphold his or her right. Thus, only allowing the health practitioner to disclose genetic information to a genetic relative where intervention is available indirectly (and broadly) assumes that an individual will seek to enforce his or her right not to know where no treatment is available.

2.1.4.2 Problems inherent with the Proposed Amendment

Despite the prima facie balance achieved under the Proposed Amendment between the rights and interests of individuals and their genetic relatives, I consider that there are some inherent problems with the Proposed Amendment.

First, for the Proposed Amendment to operate effectively and appropriately (ie without unnecessarily encroaching on an individual’s right to privacy), it essentially requires that all health practitioners have a sufficient degree of training in clinical genetics, ie so that they can
properly exercise their discretion under the new Rule 11(2)(l). However, as noted by the New Zealand Organisation for Rare Disorders (see paragraph 2.2.1.2 below), and as concluded in a survey of New Zealand General Practitioner’s general knowledge and current practice in relation to genetic testing, there is a clear gap in the training of some health practitioners in relation to this rapidly developing area. In particular, at present there are too few clinical geneticists and associates (counsellors) in New Zealand by international standards. Accordingly, general practitioners are playing a critical role in meeting the increased demand for genetic tests. The aforementioned survey illustrated, however, that some medical practitioners do not have sufficient knowledge in relation to ordering genetic tests, interpreting the results of genetic tests, or providing or facilitating the provision of genetic counseling for patients.

Secondly, and related to the first issue, the Proposed Amendment could cause innumerable problems if it stands alone (ie without further guidance on good practice) in that it can only generally define when it is permissible to disclose genetic information. It is essential that the Proposed Amendment be accompanied by a revised commentary to the HIPC, appropriate guidelines, and/or a referral protocol, each of which would recognise the complex nature of genetic information and the rapid developments in genetic science, and aim to provide guidance to the health practitioner on when it is and is not appropriate to disclose an individual’s genetic information to his or her genetic relatives.

Thirdly, and as referred to above, the Proposed Amendment only indirectly protects a genetic relative’s right not to know. I propose that to provide more complete recognition of the right not to know, the Proposed Amendment needs to expressly acknowledge a genetic relative’s right not to know, and expressly require the health practitioner to undertake a balancing exercise between the competing interests.

Finally (and related to the comment in the preceding paragraph), the Proposed Amendment does not expressly require the health practitioner to undertake any balancing exercise between the potential harm suffered by the individual as a result of disclosing his or her sensitive

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646 Sonia White and Deborah McLeod. *Genetic Testing: A Survey of New Zealand General Practitioner’s General Knowledge and Current Practice – Prepared for the National Health Committee.* (Department of General Practice, Wellington School of Medicine and Health Sciences, University of Otago, Wellington, 2003): 34. See also Interview with Joanne Dixon, Clinical Geneticist (Central Regional Genetic Services, Wellington, 8 March 2004).
information, and the potential harm suffered by the genetic relatives in not being made aware of important, relevant genetic information. Rather, it assumes that the “serious threat” to the genetic relative will always outweigh the potential harm suffered by “interfering” with an individual’s privacy. Whilst this will be the case in most situations (ie the potential serious harm suffered by the genetic relative will outweigh any other possible harm), it is nevertheless essential that the HIPC recognises and requires an assessment of both interests at stake. Before disclosure is justified under Rule 11(2)(l), the health practitioner should reasonably believe that the benefit for the genetic relative substantially outweigh the potential burden faced by the individual.

I discuss potential solutions to these issues below, after first reviewing and discussing the issues raised in the submissions received by the Privacy Commissioner in relation to the Proposed Amendment.

2.2. Public submissions on proposed amendment to Rule 11 of the HIPC

The Privacy Commissioner sought public submissions on the Proposed Amendment No 6 to the HIPC. Of the submissions she received, fourteen related to the Proposed Amendment (ie in relation to genetic information).

Whilst one stakeholder saw the Proposed Amendment as unnecessary, and another considered that it resulted in an inappropriate reduction in the level of health information privacy protection, most stakeholders were supportive of the Proposed Amendment in principle but had various concerns and/or suggestions in relation to some features of it. I discuss first the suggestions made by proponents of the Proposed Amendment, then the concerns raised by those stakeholders considered the Proposed Amendment unnecessary and/or inappropriate.

647 Above, n638: 21.

648 Catherine Miller. Submission to Privacy Commissioner in relation to Health Information Privacy Code 1994 Amendment No.6. (Written communication, 31 May 2007). Note, Catherine Miller is a government lawyer for Counties Manukau District Health Board. Her submission to the Privacy Commissioner was not made on behalf of, nor was it representative of the views of, Counties Manukau District Health Board.

2.2.1. Suggestions made by stakeholders who “agree in principle” with the Proposed Amendment

The proposal to allow health practitioners to disclose an individual’s genetic information to that individual’s genetic relatives, where doing so could avert harm, was generally supported by organisations who made submissions to the Privacy Commissioner, and was noted as being consistent with New Zealand’s current health care environment. Many stakeholders, however, raised concerns and/or suggestions in relation to the operation of the Proposed Amendment. These concerns/suggestions generally fell into in one of more of the following categories:

2.2.1.1 Further public consultation and consideration of the issues required

A concern raised by a number of stakeholders was that there was insufficient consultation and consideration of the issues in relation to the Amendment, and that further consultation and consideration should take place before any amendment in relation to the disclosure of genetic information to genetic relatives was adopted. In particular:

(a) The Federation of Women’s Health Councils Aotearoa was disappointed that the Proposed Amendment was released without further publicity from the Office of the Privacy Commissioner to draw the public’s attention to it.

(b) The Health and Disability Commissioner:

(i) was very concerned that the Proposed Amendment had not received further public consultation or publicity;

650 In particular, the New Zealand Medical Council, Federation of Women’s Health Council, Ministry of Health, Health and Disability Commissioner, Auckland Women’s Health Council, Women’s Health Action Trust, Plunket, Human Rights Commission, Pinnacle Life, Whanganui District Health Board and the New Zealand Organisation for Rare Disorders, all supported the proposed Amendment in principle.

651 Whanganui District Health Health Board. Submission to Privacy Commissioner in relation to Health Information Privacy Code 1994 Amendment No.6. (Written communication, 28 May 2007.)


653 Health and Disability Commissioner. Extract of submission to Privacy Commissioner in relation to Health Information Privacy Code 1994 Amendment No.6. (Written communication, 23 May 2007.) 1
(ii) noted that the Proposed Amendment involved complex ethical and privacy issues that have not yet been fully explored; and

(iii) suggested that further debate with the wider public and relevant consumers take place before the Proposed Amendment (or any other amendment) is adopted.

(c) The Ministry of Health considered that it was necessary to engage in a more comprehensive consideration of the issues before any amendment was implemented.

(d) Catherine Miller stated generally that there needs to be wider consideration of how genetic information should be managed, and that the Proposed Amendment was potentially unnecessary.

Related to the suggested need for wider consultation and further consideration of the issues, the Ministry of Health and the Women’s Health Action Trust noted that any amendment to Rule 11(2) in relation to the disclosure of genetic information needs to be made in a New Zealand specific context, rather than relying too heavily on the consultation and research conducted by the Australian Law Reform Commission and Australian Health Ethics Committee, reported in Essentially Yours: The Protection of Human Genetic Information in Australia - Report 96.

As to the “myriad of issues” that has not been addressed in the Proposed Amendment, stakeholders commented as follows:

(a) Whilst the Proposed Amendment squarely addresses the “right to know”, the Ministry of Health and the Family Planning Association noted that it does not recognise the rights of a genetic relative “not to know” information about themselves.

(b) Catherine Miller pointed out that:

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654 Above, n653.

655 Above, n653.


657 Above, n648.

(i) Even though the purpose of the Proposed Amendment is to prevent harm to genetic relatives, there are social, psychological and financial implications that can result from the type of disclosure anticipated under the Proposed Amendment. She acknowledges that whilst individuals having a genetic test would usually have genetic counselling, such testing would not have been provided to genetic relatives, ie they would not have the opportunity to choose whether to undergo the test or receive the resulting information.

This point is valid, and a proposed solution to it is proposed as part of recommendation 4 below.

(ii) The information a health practitioner can give to a genetic relative is not certain, it can only ever be that the genetic relative might have inherited a gene that might lead to genetic disease.

Whilst valid, I do not consider that this point renders redundant the need to amend the HIPC to recognise the rights and interests of both individuals and their genetic relatives.

(iii) There are numerous practical issues that may arise as a result of the Proposed Amendment, for example issues surrounding: (aa) a health practitioner providing very sensitive information to individuals with whom he or she has had no previous contact; and (bb) ascertaining who might be affected by the genetic information, and therefore who needs to be warned (let alone how to contact them).

In this regard, the Family Planning Association also questions the practicality of health practitioners being able to identify who is or is not a genetic relative of an individual without a DNA test. It points out that with the increasing use of Human Assisted Reproductive Technologies, and today's increasingly diverse family relationships, will create significant barriers to the correct identification of an individual's genetic relatives.

I note that this is an important consideration when adopting any amendment to the HIPC, but again, does not render the Proposed Amendment redundant. Further, the Proposed Amendment does not place a duty on health practitioners to disclose genetic information, but rather gives them a discretionary right to do so in certain circumstances. Where a genetic relative cannot be identified or contacted,
disclosure will not be possible. This does not, however, mean that disclosure should not take place where a genetic relative can be contacted.

2.2.1.2 Further clarification required

A significant number of the submissions made to the Privacy Commissioner stressed that aspects of the Amendment required further clarification. Again, there were common themes to the clarifications sought, as set out below.

Clarification as to what steps need to be taken before a health practitioner can rely on the exception in Rule 11(2)(l)

The Ministry of Health and the Federation of Women’s Health Council both suggested that the Amendment be clarified by explaining that: (a) the exception to the Rule 11 prohibition on disclosure is discretionary, and that any disclosure made under the exceptions in Rule 11(2) be made only where a health practitioner has attempted to obtain the consent of the individual concerned, or has a good reason why it is unable to do so; and (b) that any disclosure made under Rule 11(2)(l) is only permitted to the extent that it is necessary for the purpose, ie averting serious harm to the genetic relatives to whom the information is disclosed.659 (Note, neither the Ministry of Health nor the Federation of Women’s Health Council suggested how such clarifications be made, but I propose that the logical place for any such clarification would be in the commentary to the HIPC and/or any guidelines issued in relation to the Proposed Amendment.)

Similarly, the Women’s Health Action Trust submitted that clear guidelines should be implemented to explain what constitutes a “reasonable basis for believing it is not desirable or practicable” to obtain permission to make a disclosure under Rule 11(2) of the HIPC (ie the pre-requisite for relying on the exception in Rule 11(2)(l)).660

659 Above, n656: 6 and n652: 3.

660 See Women’s Health Action Trust. Extract of submission to Privacy Commissioner in relation to Health Information Privacy Code 1994 Amendment No.6. (Written communication, extract undated.) 3. Note, as discussed at paragraph 5.4.4.3 of Chapter 5, the Privacy Commissioner’s Case Notes provide some guidance as to what constitutes a “reasonable ground” for believing it is not desirable or practicable to obtain authorisation for the disclosure of health/genetic information, but such guidance is very much dependent upon the facts of the particular case. None of the Case Notes to date have considered the disclosure of genetic information, nor does the existing commentary to the HIPC discuss this requirement of the HIPC. Thus, clear guidelines would be beneficial.
The New Zealand Organisation for Rare Diseases submitted that the exception in Rule 11(2)(l) should only be relied upon in exceptional circumstances, and expressed its concern that such disclosures do not become routine practice. I note that, if implemented, the suggestions made by the Ministry of Health, Federation of Women’s Health Council and the Women’s Health Action Trust would ensure that this should not happen.

Finally, the Ministry of Health suggested that:

(a) Health practitioners be made aware that, in accordance with Rule 3 of the HIPC, they should advise individuals who are about to have a genetic test of the possibility of the disclosure of the resulting information to their genetic relatives, where such disclosure would avert harm.\(^{661}\)

As discussed in Chapter 5, complying with Rule 3 of the HIPC may eliminate the need to rely on the exceptions to the general prohibition on disclosure under Rule 11. As explained further below, however, I do not consider that the existence of Rule 3 alone is sufficient to provide adequate recognition of the rights and interests of genetic relatives.

(b) Where a disclosure is made under Rule 11(2)(l), that the health practitioner should be required to inform the individual concerned in advance of the fact that disclosure will occur, where practicable.\(^{662}\)

*Clarification as to what constitutes a “serious threat” to the life or health of a genetic relative*

The Ministry of Health, the Federation of Women’s Health Councils Aotearoa and the Women’s Health Action Trust all suggested that a clear explanation of what constitutes a “significant condition”, or a “serious threat” to the life of health of a genetic relative, is necessary.

The Ministry of Health further submitted that any explanation of the new Rule 11(2)(l) in the commentary to the HIPC include examples of where (and where not) a threat to the life or health of a genetic relative is serious enough to justify a disclosure under the rule.

*Written guidelines to Rule 11(2)(l) to be developed?*

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\(^{661}\) Above, n656: 6.

\(^{662}\) Above, n656: 6
The Women’s Health Action Trust and the Human Rights Commission both welcomed the development of guidelines on the use of genetic information in light of the Amendment. The Women’s Health Action Trust reiterated that such guidelines should be freely accessible, and the availability of them well publicised. The Human Rights Commission’s submission was directed at the development of guidelines about the ethical use of genetic information, which it suggested should have a human rights approach. The Human Rights Commission made express reference to UNESCO’s Universal Declaration on Human Genome and Human Rights and the International Declaration on Human Genetic Data.663

The extent to which clear guidelines in relation to the Proposed Amendment are required is reiterated in some of the comments made by, for example, the Royal New Zealand College of General Practitioners (Royal College). The Royal College noted that more clarification was required around the legal responsibilities of general practitioners in relation to genetic testing, and queried the extent to which a general practitioner had a duty to warn genetic relatives of their potential risk. Whilst it is clear after reviewing the Proposed Amendment from a legal perspective that it does not impose a duty to warn (on the basis that the exception in Rule 11(2)(l) is discretionary), this needs to be expressly stated in any commentary to the HIPC or in any written guidelines, so that relevant stakeholders have practical guidance at hand as to the legal requirements imposed by the HIPC.

Finally, and perhaps most illustrative of the need for clear guidance in relation to the Proposed Amendment, the New Zealand Organisation for Rare Disorders (NZORD) raised concerns in relation to the lack of detailed knowledge of genetics among many health practitioners, who do not have specialist training in the topic. It notes that:

It is our view that the average GP, nurse or other community-based health practitioner, for example, would not have sufficiently detailed knowledge of matters such as inheritance patterns and penetrance, to make a well informed judgement about the risks to their patient’s genetic relative.664

NZORD suggested that it is likely that only those practising as specialist medical geneticists, or other secondary level specialists such as cardiac physicians, who are likely to have the requisite level of knowledge and training to make an appropriate assessments of, and to


664 New Zealand Organisation for Rare Disorders. Submission to Privacy Commissioner in relation to Health Information Privacy Code 1994 Amendment No.6. (Written communication, 18 June 2007.)
provide advice in relation to, the potential risk of developing a genetic disease faced by genetic relatives, that is contemplated by the Amendment. 665

As a practical solution to overcome the issues that might arise in light of the varying competencies of health practitioners in relation to genetic testing, NZORD suggested that any disclosure under Rule 11(2)(1) should only occur after the health practitioner has consulted an appropriately qualified colleague with appropriate post graduate training in genetics (unless of course, the health practitioner already has that level of qualification). Relevantly, as pointed out by NZORD, the National Health Committee suggested in its report Molecular Genetic Testing in New Zealand 666 that developing protocols for health practitioners to assist them in relation to the use of genetic tests (and in this case, for example, the use of the resulting information) is preferable to regulation.

2.2.1.3 Definitions of genetic information and genetic relative

A number of stakeholders raised issues with the proposed definition of “genetic relative”, and also suggested that a definition of “genetic information” was required. In relation to the definition of “genetic relative”:

(a) The Ministry of Health acknowledged that a definition was necessary, but suggested that it required clarification. (It did not elaborate on what aspects of it should be clarified.)

(b) The Health and Disability Commissioner suggested that a broad definition of genetic relative could be problematic. It noted that the definition as drafted potentially allows the disclosure of genetic information to a very large pool of people, many of whom may have no real connection to the individual from whom the information was obtained.

I note, however, that under the Proposed Amendment, genetic information can only be disclosed in order to avert harm, so if a genetic relative is too far removed to allow any reasonable assessment of the risk of developing a genetic disease that he or she faces, disclosure would not be permitted. Thus, whilst the pool of people to whom genetic

665 Above, n664.

666 National Advisory Committee on Health and Disability. Molecular Genetic Testing in New Zealand. (National Advisory Committee on Health and Disability, Wellington, 2003.)
information can be disclosed may be large, only those people who might benefit from knowing the genetic information (and who therefore have a legitimate interest in knowing the information) will be eligible recipients.

(c) Miller aptly notes that the scope of “genetic relative” is not entirely clear, given that the definition includes but is not limited to siblings, parents or descendants. As discussed at (b) above, I consider that the definition is necessarily broad, and that an individual’s genetic information may also have bearing on an individual’s aunts or uncles etc. Miller’s point does, however, reiterate the need for clear guidelines in relation to when genetic information should be disclosed to whom.

In relation to the need for a definition of “genetic information”:

(a) The Ministry of Health, Health and Disability Commissioner, Women’s Health Action Trust and Pinnacle Life Insurance all considered that, if Rule 11(2)(l) was adopted, it was necessary to insert a definition of “genetic information”.

(b) Pinnacle Life Insurance considers that a definition is required because there is clear evidence that some conditions which may have a genetic component may also be influenced by non-genetic factors, eg premature heart disease or sporadic breast cancer, which might create interpretive difficulties when applying the HIPC.

The difficulties in defining “genetic information” are discussed in Chapter 4. Despite the comments above, and provided the recommendations discussed below are implemented, I do not consider it necessary to insert a definition of “genetic information” in the circumstances. I explain this further in the recommendations table below.

2.2.1.4 Should the amendment apply to all health information?

The New Zealand Medical Council was the only stakeholder to suggest that the Proposed Amendment be extended to apply to all health information. It noted that it was difficult to see a difference in the imminence of a threat posed by a genetic condition and the imminence posed by some disease states. The example put forward by the New Zealand Medical Council was that HIV is a contagious disease that puts others at serious risk, but which is not imminent. As discussed in chapter 5 (paragraph 5.2.4.1) however, specific notification requirements exist under the section 74 of the Health Act 1956 where an individual’s condition represents an infection risk to others. Thus, whilst valid, I do not consider that the New
Zealand Medical Council's example provides a sufficient justification for limiting the scope of privacy protection under the HIPC. Further, as noted above, relaxing the requirement of Rule 11(2)(d) would mean that health information would attract less privacy protection than other, non-sensitive, personal information.

2.2.2. Concerns raised by stakeholders who do not support the amendment

Two stakeholders did not support the implementation of the Proposed Amendment. In particular, Miller considers that the Proposed Amendment is unnecessary in light of Rule 3 of the HIPC, and the Family Planning Association considers that the Proposed Amendment inappropriately diminishes the level of privacy protection available for genetic and health information in general.

2.2.2.1 Amendment is unnecessary

Miller notes that, if a doctor is testing an individual for a genetic disease which is treatable, then before proceeding with that test, he or she should advise the individual: (a) of the consequences of the test for that individual’s genetic relatives; and (b) that any information derived from the genetic test may be disclosed to that individual’s genetic relatives. Complying with this procedure would enable the health practitioner to then disclose and individual’s genetic information to his or her genetic relatives on the basis that doing so is one of the purposes for which the information was obtained, and the genetic relatives are intended recipients of the information.667

Whilst Miller raises an important point,668 which should be reiterated in any revised commentary to the HIPC and/or guidelines developed in relation to the Proposed Amendment, Rule 3 does not deal with the real possibility that: (a) a health practitioner fails to have the requisite discussion with a patient prior to genetic testing; or (b) an individual refuses to consent to the genetic test if the resulting information will be disclosed to genetic relatives, and the health practitioner proceeds with the test on that basis. In such circumstances, any disclosure of the individual’s genetic information to genetic relatives would be prohibited (ie none of the exceptions in the existing Rule 11(2) would apply), and under the existing HIPC,

667 Above, n648

668 Note, this point is noted in Chapter 5, paragraph 5.4.4.1.
the rights and interests of genetic relatives would not be adequately recognised or protected. Thus, whilst Rule 3 should be complied with/relied upon at the outset, the Proposed Amendment is nevertheless necessary to adequately recognise the rights and interests of genetic relatives in all circumstances, rather than only where a health practitioner has acted prudently.

2.2.2.2 Amendment is inappropriate

The Family Planning Association expressed serious concerns in relation to the Proposed Amendment, and considered that it “undermines the Privacy Act”, and “does not contribute to the codes goal of ensuring protection of individual privacy” [sic].669

The Family Planning Association’s considered that the Proposed Amendment:

(a) Opens doors to the release of other health information relating to non-genetic conditions that could be considered important in relation to early detection, treatment and mitigation of risk, for example, a person’s HIV status.

(b) May result in patients avoiding being tested. In this regard, the Family Planning Association noted that fear of disclosure of sensitive health information is a common concern that has been put forward in research in relation to barriers to accessing appropriate health services.

As an alternative to the Proposed Amendment, the Family Planning Association strongly supported health practitioners working with patients in order to obtain informed consent to the disclosure of health information where such disclosure may prevent, mitigate, or enable early detection and/or treatment of disease in third parties who may or may not be genetically related to the patient.670

Again, whilst the Family Planning Association raises legitimate concerns in relation to the Proposed Amendment, I consider that maintaining status quo in relation to the position on disclosure of genetic information under the HIPC fails to adequately recognise the rights and interests of genetic relatives at law. Thus, alongside the Family Planning Association’s suggestion (ie working with patients to encourage informed consent), I consider that an

amendment (whether by way of the Proposed Amendment or otherwise) to the HIPC is necessary.

2.3. Proposal for reform

Having concluded that:

(a) the nature of genetic information results in conflicts of interest between:

(i) an individual's right to privacy and his or her genetic relatives' right to know relevant genetic information; or

(ii) an individual's desire to share his or her genetic information, and the rights of his or her genetic relatives' in not knowing that information;

(b) New Zealand’s current health information privacy law does not adequately address these conflicts, and accordingly an imbalance exists in relation to the protection of rights and interest of individuals and genetic relatives, with greater protection afforded to the former; and

(c) the Proposed Amendment is a good starting point for achieving a balance between the rights and interests of individuals and genetic relatives, but is requires clarification and amendment before it adequately addresses both conflicts,

I set out in Table One below my proposed recommendations for amending the HIPC so that it achieves the requisite balance. As a starting point, I suggest that the Proposed Amendment be retained, but amended as set out in Table One.

I note that the solutions proposed below are drawn from my analysis of: (i) the nature of genetic information; (ii) the approaches taken in Australia, the United Kingdom and Europe (at an intergovernmental level), and by other international, intergovernmental organisations; and (iii) the Proposed Amendment and the submissions made to the Privacy Commissioner in that regard.
### Table One: proposed recommendations

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<tr>
<th>Issue</th>
<th>Proposed solution</th>
<th>Basis of proposed solution</th>
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<tr>
<td>1</td>
<td>Lack of specialist genetic knowledge by health practitioners.</td>
<td>Establish a competent body of four experts, comprising: (a) a health practitioner with postgraduate training in genetics; and (b) a representative from either Northern or Central and Southern Region Genetics Services; (c) an ethics advisor; and (d) a privacy officer, (together the Advisory Committee), to operate in accordance with a terms of reference, to be developed in consultation with the Privacy Commissioner and other relevant stakeholders. Amend the proposed Rule 11(2)(I) by requiring that any anticipated disclosure under that Rule be referred to and approved by the Advisory Committee.</td>
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Having such a referral protocol in place:

(a) Resolves the difficulty in:

(i) legislating in an area that is constantly changing, and therefore where the circumstances in which disclosure should be permissible are not easily defined and vary depending upon the type of genetic condition involved (ie depending on the penetrance and expression of the disease, and prevention and treatment options);

(ii) identifying in any guidelines the genetic conditions that are sufficiently serious to warrant a disclosure under the Proposed Amendment;

(iii) advising on a general basis an appropriate approach to disclosure for multifactorial disorders, where there is an complex interplay between genetic and non-genetic causes.

(b) Resolves the issues that arise in light of the limited number of health practitioners with specialist training in genetics.

(c) Eliminates the need to provide a general definition of “genetic information” under the HIPC, because the Advisory Committee would determine what information to take into account during their assessment, and in turn what information to disclose to the genetic relative.
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<th>Issue</th>
<th>Proposed solution</th>
<th>Basis of proposed solution</th>
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<td>(d)</td>
<td>Reinforces the recognition of and mitigates any unwarranted interference with a genetic relative’s right not to know, i.e., the Advisory Committee would (consistent with the requirements of the Proposed Amendment) ensure that disclosure is only ever made where adequate treatment and/or screening/prevention options exist (i.e., where disclosure could lessen or prevent serious harm).</td>
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<td>(e)</td>
<td>Goes some way towards providing a practical solution that addresses the Privacy Commissioner’s concern in relation to developing statutory guidelines that are outside the scope of the functions of the Office of the Privacy Commissioner, and stakeholders’ concerns in relation to the lack of clear guidelines in place in relation to Rule 11(2)(1).</td>
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2 No requirement to conduct a cost-benefit analysis in relation to the potential harm/benefit to the rights and interests of individuals and genetic relatives.

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<tr>
<th>Proposed solution</th>
<th>Basis of proposed solution</th>
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<td>Amend the Proposed Rule 11(2)(d) to expressly require health practitioners to consider an individual’s reasons for refusing the consent to disclose his or her genetic information. Further to recommendation 1 above, require the Advisory Committee to conduct a cost-benefit analysis of the benefit/harm likely to be experienced by each party as a consequence of disclosure or non-disclosure. The Advisory Committee and the relevant health practitioner should reasonably believe that the benefit for the genetic relative substantially outweighs the potential burden faced by the individual before any disclosure is made under Rule 11(2)(1).</td>
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Expressly requiring that health practitioners conduct a cost-benefit analysis between the rights and interests of individuals and genetic relatives:

(a) Avoids any assumption that the “serious threat” to the genetic relative will always outweigh the potential harm suffered by “interfering” with an individual’s privacy.

(b) Ensures that the proposed amended HIPIC, whilst recognising the rights of genetic relatives in knowing genetic information, does not inappropriately limit an individual’s right to privacy.

3 Lack of practical guidelines

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<th>Basis of proposed solution</th>
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<td>Amend the existing commentary to the HIPIC in light of, and release it for public consultation alongside, the revised Proposed Amendment. Any revised commentary should:</td>
<td>Department of Health Code of Practice (UK)</td>
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The purpose of the HIPC Decision Support Tool (together with associated commentary and guidelines) is to assist health practitioners to: (a) act in accordance with the HIPC; and (b) make preliminary decisions in relation to the disclosure of a patient’s genetic information to his or her genetic relatives, before referring the case to the Advisory Committee for a final decision on whether or not to proceed with any such disclosure. It provides clear, high level guidance to ensure that all appropriate factors are taken into account at an early stage in the potential disclosure process. Among other matters, it ensures that:

(a) Health practitioners rely on Rule 11(2)(l) as a last resort, and should first work with the patient to obtain consent.

(b) The recipient of any genetic information received as a result of a disclosure under the HIPC has appropriate genetic counselling during and after the disclosure. (Such disclosure should be arranged either by: (i) the health practitioner (if the patient consents to disclosure), as per step 3(a) and (b) in the HIPC Decision Support Tool; or (ii) the Advisory Committee (if the patient refuses to consent to disclosure, and the Advisory Committee considers that genetic counselling is appropriate).)

(c) Disclosure can only be made under Rule 11(2)(l) where appropriate treatment is available (thus reinforcing the recognition of the “right not to know”).

At Appendix Three to this thesis I have applied the HIPC Decision Support Tool to each of the hypothetical clinical scenarios set out at Appendix One in order to illustrate how it would work in practice. In light of the different fact matrixes involved in each scenario, the application of the tool helps...
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<th><strong>Issue</strong></th>
<th><strong>Proposed solution</strong></th>
<th><strong>Basis of proposed solution</strong></th>
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<tr>
<td>Lack of ethical guidelines</td>
<td>Direct that an appropriate body (such as the New Zealand Medical Association, the Medical Council of New Zealand, Genetics Services, or a combination of all three) in consultation with relevant stakeholders (including, for example, the Human Rights Commission) and the Privacy Commissioner, develop detailed guidelines in relation to the ethical use of genetic information, to supplement the HIPC Decision Support Tool. Such guidelines should explain in detail the circumstances in which, and provide examples of when, disclosure of an individual’s genetic information to his or her genetic relatives is ethically justified.</td>
<td>Australian Law Reform Commission / Privacy Act (Cth) 1988</td>
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Such guidelines:

(a) Whilst not having legal status, should become a statement of best practice, and should be regularly reviewed in light of national and international developments in genetic science and ethics.

(b) Would further assist health practitioners (ie in addition to the practical guidelines referred to at 3 above) in making decisions in relation to the collection, use and disclosure of genetic information.

(c) Would allay any concerns had by the Privacy Commissioner in relation to the HIPC remaining a legal rather than an ethical instrument in relation to health information privacy protection.

### 2.4. Conclusion

Consistent with the analyses and conclusions drawn throughout this thesis, the above recommendations for reform:

(a) Recognise that genetic information reveals important information about individuals and their genetic relatives. (See chapters two and three.)
(b) Adopt an integrated (rather than exceptionalist) approach to protecting genetic information. That is, the recommendations recognise that:

(i) genetic information is a component of health information, and should be treated as such under health information privacy law; but

(ii) the nature of genetic information creates a (limited) set of circumstances in which the privacy of health information should be restricted (ie in order to prevent or lessen serious threats to the life or health of genetic relatives), in addition to those circumstances already contemplated in the context of traditional medical information (eg in order to prevent or lessen a serious and imminent threat to the life or health of a third party); and

(iii) genetic medicine is developing rapidly and the line between traditional medicine and genetic medicine is becoming (and will continue to become) increasingly blurred, requiring corresponding developments in legal and ethical guidelines in relation to the use of genetic information.

(See chapter four.)

(c) Adopt a permissive approach to disclosing genetic information (rather than imposing a duty), which provides an effective balance between familial and individual ethical claims to genetic information. (See chapter four.)

(d) Ensure that, in relation to genetic information, New Zealand’s health information privacy law moves away from a previously strictly individualistic approach, and instead recognises the rights of both individuals and genetic relatives in knowing (or not knowing) genetic information. This aligns health information privacy with ethical approaches to health information, and assists in providing an effective balance between familial and individual legal claims to genetic information. (See chapters four, five and six.)

(e) Are consistent with legislation, recommendations, conventions and guidelines adopted overseas that specifically deal with the conflict between individual and familial rights and interests in genetic information. That is, the recommendations justify the disclosure of an individual’s genetic information to his or her at-risk relatives where doing so would prevent harm to those relatives, and such benefit outweighs any harm caused as a result of the breach on an individual’s privacy/confidentiality. (See chapter six.)
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ANNEXURE ONE

HYPOTHETICAL CLINICAL SCENARIOS

1. INTRODUCTION

The hypothetical clinical scenarios set out below illustrate the potential conflicts that arise between: (a) an individual's privacy interest in his or her genetic information, and a genetic relative's interest in knowing or accessing such information where it can be used to avert harm; and (b) an individual’s desire to share his or her genetic information, and a genetic relative’s right not to know.

The scenarios are placed along on a continuum, with scenario one illustrating a situation where disclosing the information to a genetic relative may save his or her life, and scenario four illustrating a situation where disclosing the information has little benefit and may cause more harm than good.

2. SCENARIO ONE: FAMILIAL ADENOMATOUS POLYPOSIS

John was 10 when his father died of colon cancer. John’s parents knew that the cancer was caused by familial adenomatous polyposis (FAP) (a disease caused by mutations on the APC gene), but did not discuss it with John. Instead, the cause of John’s father’s cancer was “swept under the carpet” and not mentioned after he died even though there was a 50 percent chance that John may have inherited the gene mutation associated with FAP.

At age 20, John was diagnosed with FAP and advanced colon cancer. He faces limited prospects of survival.671

John’s cancer could have been prevented if he had been aware of his risk and had had preventative surgery, or cured if diagnosed early enough.

671 Scenario based on a case reported in The Age newspaper. See Noble, T. “Let us warn patients of cancer mutation, say doctors” The Age (Melbourne, 6 August 2002), Health.
3. **SCENARIO TWO: BREAST CANCER**

Susan, who is 40, discovers during an exploration of her family history that her mother’s sisters and some of her cousins had been diagnosed with breast cancer (some at an early age). Susan had known that her mother had been diagnosed with the disease at about the same age as she is now. Concerned with her own risk, she was informed by her doctor that, because a BRCA gene had been identified in her mother (who had consented to the disclosure of her genetic information to her genetic relatives at the appropriate time), a genetic test was available for Susan.

Before having the test, Susan agreed that she and other relatives, including her daughter could be informed of the outcome, so that her unaffected relatives could be tested. Susan undertook the genetic test and was told that she had the BRCA gene and therefore had around a 60% chance of developing breast cancer. Upon receiving the result she revoked permission for this information to be disclosed to her relatives.

Two years later, Susan’s older sister was shocked to be diagnosed with advanced breast cancer, being otherwise unaware of her risk.

4. **SCENARIO THREE: COMPLETE TESTICULAR FEMINISATION**

Mary has a daughter with primary amenorrhoea. Tests indicate her daughter has complete testicular feminisation (that is, she is genetically male and cannot reproduce).

This disease follows an X-linked recessive pattern of inheritance. Therefore, Mary is likely to be a carrier of the gene. There is a 50% chance that her daughters and sisters without the syndrome are also carriers with a 25% chance of having an afflicted child.

Due to the social stigma of the syndrome, Mary refuses to inform her sisters and/or their daughters of the risk, even though intervention may prevent potential malignancies.\(^{672}\)

5. **SCENARIO FOUR: HUNTINGTON'S DISEASE**

Anna’s grandmother developed Huntington’s Disease (HD) when she was 45, and later died, aged 55. There is a 50 percent chance that Anna’s mother has inherited the disease, and

therefore a 25 percent chance that Anna has too. People who have the HD gene invariably
develop the disease.

Anna has lived with the knowledge that she might develop HD since she was in her teens, and
now wants to have a predictive genetic test to determine whether or not she has inherited the
HD gene, before deciding whether to start a family. Anna’s mother is adamant that she does
not want to know. If Anna’s test results reveal that she has inherited the HD gene, it means
her mother must also have the gene. If Anna’s test results reveal that she has not inherited the
HD gene, this does not rule out her mother’s risk of having inherited it (seeing as there is only
a 50 percent chance of passing the gene on to one’s children).
ANNEXURE TWO:

HIPC DECISION SUPPORT TOOL

The purpose of the HIPC Decision Support Tool is to provide guidance to health practitioners in relation to steps to be taken and factors to be considered when proposing to disclose a patient's genetic information to his or her genetic relatives for health care purpose.

1. Was the patient informed prior to the genetic test of the purpose and nature of the test, including the implications of the results of the genetic test on genetic relatives (in accordance with Rule 3 of the HIPC)?

   Yes ➔ 1(a). Go to 3

   No ➔

   2. Since obtaining the genetic test results, have you explained to the patient the significance of the genetic test results for his or her genetic relatives?

      No ➔ 2(a). Explain to the patient the significance of the genetic test results for his or her genetic relatives and go to 3.

      Yes ➔

      3. Has the patient consented to the disclosure of his or her genetic information to his or her genetic relatives?

         Yes ➔ 3(a). Advise the patient that you intend to disclose the genetic information to his or her genetic relatives in order to provide a medical benefit to those relatives.

            3(b). Engage a genetic counsellor to contact, and arrange disclosure (after appropriate genetic counselling) to the genetic relatives.

         No ➔
4. Have you made reasonable efforts to obtain the patient’s consent to disclose his or her genetic information to his or her genetic relatives, but with no success?

Yes

5. Will disclosing the genetic information potentially lessen a serious risk to the life or health of a genetic relative (i.e., by enabling appropriate screening and/or preventive measures)?

Yes

6. Can the anticipated benefit by disclosing the genetic information to the genetic relative be obtained in any other way?

No

7. Does the anticipated benefit by disclosing the genetic information to the genetic relative significantly outweigh the risk to the patient’s life by disclosing the genetic information?

No

8. Refer the case to the Advisory Committee to obtain final approval to disclose the patient’s genetic information to his or her genetic relatives.

4(a) If appropriate, reiterate to the patient the relevance and importance of the genetic information to the life and/or health of his or her genetic relatives. Go to 5.

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy and the genetic relatives’ right not to know should be upheld.

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to the genetic relative should be utilised.

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.
ANNEXURE THREE:

APPLICATION OF THE HIPC DECISION SUPPORT TOOL TO HYPOTHETICAL CLINICAL SCENARIOS

1. INTRODUCTION

The purpose of this section is to illustrate how the HIPC Decision Support Tool could work in practice. I have applied the tool to each of the hypothetical clinical scenarios set out in Appendix One to:

(a) Illustrate how the tool can operate as a step-by-step tool to guide a health practitioner through the steps to be taken and factors to be considered when proposing to disclose a patient’s genetic information to his or her genetic relatives.

(b) Demonstrate the variety of considerations that need to be made, and the variety of decision paths that might be available (depending on the particular fact matrix involved in each case), when assessing whether or not the disclosure of a patient’s genetic information to his or her genetic relatives is appropriate in the circumstances.

2. APPLICATION OF HIPC DECISION SUPPORT TOOL TO SCENARIO ONE

In applying the HIPC Decision Support Tool to Hypothetical Clinical Scenario One, I have assumed that:

(a) When John’s father’s health practitioner communicated the results of his genetic test, he informed John’s father of the inheritance pattern of FAP and that John had a 50% risk of also developing FAP and colon cancer (see steps one and two below).

(b) John’s father’s health practitioner tried to obtain his consent to disclose his genetic information to John (and other genetic relatives that could also have been affected) (see step four below), but John’s father refused to consent to the disclosure (see steps three and four).

(c) John would have wanted to be informed of his risk of developing FAP and colon cancer (ie he would not have wanted to uphold his right not to know).
1. Was John’s father informed prior to the genetic test (ie the test for the gene mutation associated with FAP) of the purpose and nature of the test (ie to diagnose the cause of his cancer), including the implications of the results of the genetic test on genetic relatives (ie the risk that his genetic relatives, including John, faced of also having the same gene mutation and of developing the same form of cancer) (in accordance with Rule 3 of the HIPC)?

Yes

1(a). Go to 3

No

2. Since obtaining the genetic test results, did you explain to John’s father the significance of the genetic test results for his genetic relatives (ie including his son, John)?

Yes

2(a). Explain to the patient the significance of the genetic test results for his or her genetic relatives and go to 3.

No

3. Has John’s father consented to the disclosure of his genetic information to his or her genetic relatives?

Yes

3(a). Advise the patient that you intend to disclose the genetic information to his or her genetic relatives in order to provide a medical benefit to those relatives.

3(b). Engage a genetic counsellor to contact, and arrange disclosure (after appropriate genetic counselling) to, the genetic relatives.

No

4. Have you made reasonable efforts to obtain John’s father’s consent to disclose his genetic information to his or her genetic relatives, but with no success?

Yes

4(a) If appropriate, reiterate to the patient the relevance and importance of the genetic information to the life and/or health of his or her genetic relatives. Go to 5.

No
5. Will disclosing the genetic information (ie that John’s father had the gene mutation associated with FAP) potentially lessen a serious risk to the life or health of a genetic relative (ie by enabling appropriate screening for and early treatment of cancer, or preventative surgery)?

Yes -> It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy and the genetic relatives’ right not to know should be upheld.

No -> It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to the genetic relative should be utilised.

6. Can the anticipated benefit by disclosing the genetic information to the genetic relative be obtained in any other way?

Yes -> It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to the genetic relative should be utilised.

No -> It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.

7. Does the anticipated benefit by disclosing the genetic information to the genetic relative significantly outweigh the risk to the patient’s life by disclosing the genetic information?

Yes -> (Cancer can be prevented or cured where individuals who are known to have FAP have preventative surgery, or regular screening and early treatment.)

No -> It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.

8. Refer the case to the Advisory Committee to obtain final approval to disclose the John’s father’s genetic information to his genetic relatives.
On the basis of the above, if John's father's health practitioner had followed the steps recommended in the HIPC Decision Support tool, the tool would have guided him or her to refer the case to the Advisory Committee to make a determination under the HIPC as to whether it was appropriate in the circumstances to disclose John's father's genetic information (ie that John's father has the gene mutation associated with FAP) to his genetic relatives. If the proposed amendment to Rule 11(2) is adopted, it is likely that the Advisory Committee would have allowed the disclosure to John (and other genetic relatives, as applicable) on the basis that:

(a) It was not practicable to obtain authorisation from John's father (on the basis that he had refused to consent to disclosure, even after his health practitioner had explained to him the likelihood of his genetic relatives also developing FAP and ultimately colon cancer). (See proposed amendment to Rule 11(2) of the HIPC, set out at paragraph 2.1.1 of Chapter 7.)

(b) The information to be disclosed was genetic information, to be disclosed by a health practitioner to John (being a genetic relative of his father). (See proposed amendment to Rule 11(2)(l) of the HIPC, set out at paragraph 2.1.1 of Chapter 7.)

(c) The disclosure to John is necessary to prevent or lessen a threat to his life and health. (See proposed amendment to Rule 11(2)(l) of the HIPC, set out at paragraph 2.1.1 of Chapter 7.)

3. APPLICATION OF HIPC DECISION SUPPORT TOOL TO SCENARIO TWO

In applying the HIPC Decision Support Tool to Hypothetical Clinical Scenario Two, I assumed that:

(a) Susan was informed of the inheritance pattern of the BRCA gene and of the fact that individuals who have the BRCA gene face a significantly higher risk of developing breast cancer (see steps one and two below).

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673 See paragraph 5.4.4.3(ii) of Chapter 5 for a discussion on what might constitute a reasonable ground for believing it is not desirable or practicable to obtain consent. As discussed in that paragraph, refusal to provide consent could constitute a reasonable ground for believing that it is not practicable to obtain consent, but this would always depend on the particular circumstances of the case, and upon any further guidance issued in accordance with the proposed recommendations made in Chapter 7.

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(b) Susan’s sisters would want to be informed of their risk of having inherited the BRCA gene and developing breast cancer in order to have the best chance (ie they would not have wanted to uphold their right not to know).

(c) Susan’s daughter was 6 years old, and therefore Susan’s health practitioner was not yet considering whether to disclose Susan’s genetic information to her (on the basis that disclosing such information would not yet reduce any risk to her daughter’s life or health).

1. Was the Susan informed prior to the test for the BRCA gene of the purpose and nature of the test, including the implications of the results of the genetic test on her genetic relatives (in accordance with Rule 3 of the HIPC)?

   Yes → 1(a). Go to 3

   No → 2

2. Since obtaining Susan’s genetic test results, have you explained to her the significance of the genetic test results for her genetic relatives, including her daughter and sisters?

   Yes → 3

   No → 2(a). Explain to the patient the significance of the genetic test results for his or her genetic relatives and go to 3.

3. Has Susan consented to the disclosure of her genetic information (ie that she carries the BRCA gene) to his or her genetic relatives?

   Yes → 3(a). Advise the patient that you intend to disclose the genetic information to his or her genetic relatives in order to provide a medical benefit to those relatives.

   No → 3(b). Engage a genetic counsellor to contact, and arrange disclosure (after appropriate genetic counselling) to, the genetic relatives.
4. Have you made reasonable efforts to obtain Susan’s consent to disclose her genetic information to her sisters, but with no success?

Yes → 4(a) If appropriate, reiterate to the patient the relevance and importance of the genetic information to the life and/or health of his or her genetic relatives. Go to 5.

No

5. Will disclosing Susan’s genetic information (ie that she has the BRCA gene) potentially lessen a serious risk to the life or health of a genetic relative, including her sisters (ie by alerting her sisters to the need to seek appropriate screening for breast cancer and/or have preventive surgery)?

Yes

No → It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy and the genetic relatives’ right not to know should be upheld.

6. Can the anticipated benefit by disclosing Susan’s genetic information to the genetic relatives be obtained in any other way?

Yes → (Disclose Susan’s mother’s genetic information instead.)

No → It is not appropriate to disclose Susan’s genetic information to her genetic relatives. Susan’s right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to Susan’s genetic relatives should be utilised.

7. Does the anticipated benefit by disclosing the genetic information to the genetic relative significantly outweigh the risk to the patient’s life by disclosing the genetic information?

Yes

No → It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.

8. Refer the case to the Advisory Committee to obtain final approval to disclose the patient’s genetic information to his or her genetic relatives.
On the basis of the above, if Susan’s health practitioner had followed the steps recommended in the HIPC Decision Support tool, the tool would have guided her to the decision that it was inappropriate to disclose Susan’s genetic information to her sisters because the anticipated benefit by making such a disclosure could be achieved by disclosing Susan’s mother’s genetic information (who had consented to such disclosure before her death) instead. Thus, Susan’s health practitioner could (or Susan’s mother’s health practitioner should, if possible) have disclosed her mother’s genetic information to her sisters, rather than disclosing Susan’s genetic information, in order to alert her sisters of the need to have: (a) a test tested for the BRCA gene themselves; (b) preventive surgery; and/or (b) regular screening for breast cancer.

4. **APPLICATION OF HIPC DECISION SUPPORT TOOL TO SCENARIO THREE**

In applying the HIPC Decision Support Tool to hypothetical clinical scenario three, I made the assumptions that:

(a) Mary’s mother was informed of the inheritance pattern of the complete testicular feminisation prior to her daughter being tested (see steps one and two below).

(b) Complete testicular feminisation does not present any risks to an individual’s life or health.

1. Was Mary’s mother informed prior to her daughter’s test of the purpose and nature of the test, including the implications of the results of the genetic test on genetic relatives (in accordance with Rule 3 of the HIPC)?

   - **Yes**
   - **No**

   1(a). Go to 3

2. Since obtaining the genetic test results, have you explained to Mary’s mother the significance of Mary’s genetic test results for her genetic relatives?

   - **Yes**
   - **No**

   2(a). Explain to the patient the significance of the genetic test results for his or her genetic relatives and go to 3.
3. Has the patient consented to the disclosure of his or her genetic information to his or her genetic relatives?

Yes

No

4. Have you made reasonable efforts to obtain Mary's mother's consent to disclose Mary's genetic information to her genetic relatives, but with no success?

Yes

No

5. Will disclosing Mary's genetic information potentially lessen a serious risk to the life or health of a genetic relative (i.e., by enabling appropriate screening and/or preventive measures)?

Yes

No

6. Can the anticipated benefit by disclosing the genetic information to the genetic relative be obtained in any other way?

Yes

No

3(a). Advise the patient that you intend to disclose the genetic information to his or her genetic relatives in order to provide a medical benefit to those relatives.

3(b). Engage a genetic counsellor to contact, and arrange disclosure (after appropriate genetic counselling) to the genetic relatives.

4(a) If appropriate, reiterate to the patient the relevance and importance of the genetic information to the life and/or health of his or her genetic relatives. Go to 5.

It is not appropriate to disclose the patient's genetic information to his or her genetic relatives. The patient's right to privacy and the genetic relatives' right not to know should be upheld.

It is not appropriate to disclose the patient's genetic information to his or her genetic relatives. The patient's right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to the genetic relative should be utilised.
7. Does the anticipated benefit by disclosing the genetic information to the genetic relative significantly outweigh the risk to the patient’s life by disclosing the genetic information? 

Yes \(\Rightarrow\) 

No \(\Rightarrow\)  

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.

8. Refer the case to the Advisory Committee to obtain final approval to disclose the patient’s genetic information to his or her genetic relatives.

On the basis of the above, if Mary’s health practitioner had followed the steps recommended in the HIPC Decision Support tool, the tool would have guided him or her to the decision that it was inappropriate to disclose Mary’s genetic information to her genetic relatives because, whilst disclosing the genetic information might influence Mary’s genetic relatives’ reproductive decisions, it would not necessarily lessen a serious risk to their lives.

5. APPLICATION OF HIPC DECISION SUPPORT TOOL TO SCENARIO FOUR

In applying the HIPC Decision Support Tool to hypothetical clinical scenario four, I made the assumption that Anna was informed of the inheritance pattern of HD prior to being tested (see steps one and two below).

1. Was Anna informed prior to her genetic test (ie to see if she has inherited the HD gene) of the purpose and nature of the test, including the implications of the results of the genetic test on genetic relatives, including her mother (in accordance with Rule 3 of the HIPC)?

Yes \(\Rightarrow\)  

1(a). Go to 3

No \(\Rightarrow\)  

2. Since obtaining the genetic test results, have you explained to Anna the significance of her genetic test results for her genetic relatives?

Yes \(\Rightarrow\)  

2(a). Explain to the patient the significance of the genetic test results for his or her genetic relatives and go to 3.

No \(\Rightarrow\)
3. Has Anna consented to the disclosure of her genetic information to her genetic relatives?

Yes

3(a). Advise the patient that you intend to disclose the genetic information to his or her genetic relatives in order to provide a medical benefit to those relatives.

3(b). Engage a genetic counsellor to contact, and arrange disclosure (after appropriate genetic counselling) to the genetic relatives.

No

4. Have you made reasonable efforts to obtain Anna’s consent to disclose her genetic information to her genetic relatives, but with no success?

Yes

4(a) If appropriate, reiterate to the patient the relevance and importance of the genetic information to the life and/or health of his or her genetic relatives. Go to 5.

No

5. Will disclosing Anna’s genetic information potentially lessen a serious risk to the life or health of a genetic relative (ie by enabling appropriate screening and/or preventive measures)?

Yes

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy and the genetic relatives’ right not to know should be upheld.

No

6. Can the anticipated benefit by disclosing the genetic information to the genetic relative be obtained in any other way?

Yes

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld. Instead, the alternative mechanism available to provide the anticipated benefit to the genetic relative should be utilised.

No
7. Does the anticipated benefit by disclosing the genetic information to the genetic relative significantly outweigh the risk to the patient’s life by disclosing the genetic information?

Yes

No

It is not appropriate to disclose the patient’s genetic information to his or her genetic relatives. The patient’s right to privacy should be upheld.

8. Refer the case to the Advisory Committee to obtain final approval to disclose the patient’s genetic information to his or her genetic relatives.

On the basis of the above, like in Scenario Three, if Anna’s health practitioner had followed the steps recommended in the HIPC Decision Support tool, the tool would have guided him or her to the decision that it was inappropriate to disclose Anna’s genetic information to her genetic relatives because doing so would not lessen a serious risk to the life or health of her genetic relatives. In fact, in this scenario, disclosing the results of Anna’s test for the HD gene could give rise to psychological harm to Anna’s genetic relatives, rather than preventing harm, in the event that they did not want to know whether or not they had inherited the HD gene.
ANNEXURE FOUR:

SELECTED PROVISIONS FROM RELEVANT NEW ZEALAND LEGISLATION

1. PRIVACY ACT 1993

*Long title*

An Act to promote and protect individual privacy in general accordance with the Recommendation of the Council of the Organisation for Economic Cooperation and Development Concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data, and, in particular,—

(a) To establish certain principles with respect to—
   (i) The collection, use, and disclosure, by public and private sector agencies, of information relating to individuals; and
   (ii) Access by each individual to information relating to that individual and held by public and private sector agencies; and

(b) To provide for the appointment of a Privacy Commissioner to investigate complaints about interferences with individual privacy; and

(c) To provide for matters incidental thereto.

......

*46 Codes of practice*

(1) The Commissioner may from time to time issue a code of practice.

(2) A code of practice may—
   (a) Modify the application of any one or more of the information privacy principles by—
      (i) Prescribing standards that are more stringent or less stringent than the standards that are prescribed by any such principle:
      (ii) Exempting any action from any such principle, either unconditionally or subject to such conditions as are prescribed in the code:
      (aa) Apply any one or more of the information privacy principles (but not all of those principles) without modification:
   (b) Prescribe how any one or more of the information privacy principles are to be applied, or are to be complied with.

(3) A code of practice may apply in relation to any one or more of the following:
(a) Any specified information or class or classes of information:
(b) Any specified agency or class or classes of agencies:
(c) Any specified activity or class or classes of activities:
(d) Any specified industry, profession, or calling or class or classes of industries, professions, or callings.

(4) A code of practice may also—
(a) Impose, in relation to any agency that is not a public sector agency, controls in relation to the comparison (whether manually or by means of any electronic or other device) of personal information with other personal information for the purpose of producing or verifying information about an identifiable individual:
(b) In relation to charging under section 35 of this Act,—
   (i) Set guidelines to be followed by agencies in determining charges:
   (ii) Prescribe circumstances in which no charge may be imposed:
(c) Prescribe procedures for dealing with complaints alleging a breach of the code, but no such provisions may limit or restrict any provision of Part 8 or Part 9 of this Act:
(d) Provide for the review of the code by the Commissioner:
(e) Provide for the expiry of the code.

(5) A code of practice may not limit or restrict the circumstances in which an individual is entitled,—
(a) Under subclause (1)(a) of principle 6, to obtain confirmation of whether or not a public sector agency holds personal information; or
(b) Under subclause (1)(b) of principle 6, to have access to personal information held by a public sector agency; or
(c) Under principle 7,—
   (i) To request the correction of personal information held by a public sector agency; or
   (ii) To request that there be attached to any such information a statement of any correction sought but not made.

(6) Notwithstanding the definition of the term {individual in section 2(1) of this Act,—
(a) For the purposes of the issuing under this section of any code of practice relating to {health information (whether or not any such code also relates to any other information), principle 11 shall be read as if it applies in respect of health information about any individual, whether living or deceased; and
(b) Any code of practice so issued shall have effect under section 53 of this Act as if
principle 11 so applied, and the provisions of this Act shall apply accordingly.

(7) For the purposes of subsection (6) of this section, the term health information has the
same meaning as it has in section 22B of the Health Act 1956.

53 Effect of code
Where a code of practice issued under section 46 of this Act is in force,—

(a) The doing of any action that would otherwise be a breach of an information privacy
principle shall, for the purposes of Part 8 of this Act, be deemed not to be a breach of
that principle if the action is done in compliance with the code:

(b) Failure to comply with the code, even though that failure is not otherwise a breach of
any information privacy principle, shall, for the purposes of Part 8 of this Act, be
deemed to be a breach of an information privacy principle.

54 Commissioner may authorise collection, use, or disclosure of personal information

(1) The Commissioner may authorise an agency to collect, use, or disclose personal
information, even though that collection, use, or disclosure would otherwise be in
breach of principle 2 or principle 10 or principle 11, if the Commissioner is satisfied
that, in the special circumstances of the case,—

(a) The public interest in that collection or, as the case requires, that use or that
disclosure outweighs, to a substantial degree, any interference with the privacy of
the individual that could result from that collection or, as the case requires, that
use or that disclosure; or

(b) That collection or, as the case requires, that use or that disclosure involves a clear
benefit to the individual concerned that outweighs any interference with the
privacy of the individual that could result from that collection or, as the case
requires, that use or that disclosure.

(2) The Commissioner may impose in respect of any authority granted under subsection (1)
of this section such conditions as the Commissioner thinks fit.

(3) The Commissioner shall not grant an authority under subsection (1) of this section in
respect of the collection, use, or disclosure of any personal information for any purpose
if the individual concerned has refused to authorise the collection or, as the case
requires, the use or disclosure of the information for that purpose.
Interference with privacy

(1) For the purposes of this Part of this Act, an action is an interference with the privacy of an individual if, and only if,—

(a) In relation to that individual,—

(i) The action breaches an information privacy principle; or

(ii) The action breaches a code of practice issued under section 63 of this Act (which relates to public registers); or

(iii) The provisions of Part 10 of this Act (which relates to information matching) have not been complied with; and

(b) In the opinion of the Commissioner or, as the case may be, the Tribunal, the action—

(i) Has caused, or may cause, loss, detriment, damage, or injury to that individual; or

(ii) Has adversely affected, or may adversely affect, the rights, benefits, privileges, obligations, or interests of that individual; or

(iii) Has resulted in, or may result in, significant humiliation, significant loss of dignity, or significant injury to the feelings of that individual.

(2) Without limiting subsection (1) of this section, an action is an interference with the privacy of an individual if, in relation to an information privacy request made by the individual,—

(a) The action consists of a decision made under Part 4 or Part 5 of this Act in relation to the request, including—

(i) A refusal to make information available in response to the request; or

(ii) A decision by which an agency decides, in accordance with section 42 or section 43 of this Act, in what manner or, in accordance with section 40 of this Act, for what charge the request is to be granted; or

(iii) A decision by which an agency imposes conditions on the use, communication, or publication of information made available pursuant to the request; or

(iv) A decision by which an agency gives a notice under section 32 of this Act; or

(v) A decision by which an agency extends any time limit under section 41 of this Act; or

(vi) A refusal to correct personal information; and
(b) The Commissioner or, as the case may be, the Tribunal is of the opinion that there is no proper basis for that decision.

(3) If, in relation to any information privacy request, any agency fails within the time limit fixed by section 40(1) of this Act (or, where that time limit has been extended under this Act, within that time limit as so extended) to comply with paragraph (a) or paragraph (b) of section 40(1) of this Act, that failure shall be deemed, for the purposes of subsection (2)(a)(i) of this section, to be a refusal to make available the information to which the request relates.

(4) Undue delay in making information available in response to an information privacy request for that information shall be deemed, for the purposes of subsection (2)(a)(i) of this section, to be a refusal to make that information available.

67 Complaints

(1) Any person may make a complaint to the Commissioner alleging that any action is or appears to be an interference with the privacy of an individual.

(2) A complaint under this Part of this Act may be lodged with the Commissioner or an Ombudsman.

(3) On receiving a complaint under this Part of this Act, an Ombudsman shall forward the complaint to the Commissioner as soon as practicable.

......

69 Investigation of interference with privacy of individual

(1) The functions of the Commissioner under this Part of this Act shall be—

   (a) To investigate any action that is or appears to be an interference with the privacy of an individual:

   (b) To act as conciliator in relation to any such action:

   (c) To take such further action as is contemplated by this Part of this Act.

(2) The Commissioner may commence an investigation under subsection (1)(a) of this section either on complaint made to the Commissioner or on the Commissioner’s own initiative.

70 Action on receipt of complaint

(1) On receiving a complaint under this Part of this Act, the Commissioner may—

   (a) Investigate the complaint; or

   (b) Decide, in accordance with section 71 of this Act, to take no action on the complaint.
(2) The Commissioner shall, as soon as practicable, advise the complainant and the person to whom the complaint relates of the procedure that the Commissioner proposes to adopt under subsection (1) of this section.

71 Commissioner may decide to take no action on complaint

(1) The Commissioner may in his or her discretion decide to take no action or, as the case may require, no further action, on any complaint if, in the Commissioner's opinion,—

(a) The length of time that has elapsed between the date when the subjectmatter of the complaint arose and the date when the complaint was made is such that an investigation of the complaint is no longer practicable or desirable; or

(b) The subjectmatter of the complaint is trivial; or

(c) The complaint is frivolous or vexatious or is not made in good faith; or

(d) The individual alleged to be aggrieved does not desire that action be taken or, as the case may be, continued; or

(e) The complainant does not have a sufficient personal interest in the subjectmatter of the complaint; or

(f) Where—

(i) The complaint relates to a matter in respect of which a code of practice issued under section 46 of this Act is in force; and

(ii) The code of practice makes provision for a complaints procedure,— the complainant has failed to pursue, or to pursue fully, an avenue of redress available under that complaints procedure that it would be reasonable for the complainant to pursue; or

(g) There is in all the circumstances an adequate remedy or right of appeal, other than the right to petition the House of Representatives or to make a complaint to an Ombudsman, that it would be reasonable for the individual alleged to be aggrieved to exercise.

(2) Notwithstanding anything in subsection (1) of this section, the Commissioner may in his or her discretion decide not to take any further action on a complaint if, in the course of the investigation of the complaint, it appears to the Commissioner that, having regard to all the circumstances of the case, any further action is unnecessary or inappropriate.

(3) In any case where the Commissioner decides to take no action, or no further action, on a complaint, the Commissioner shall inform the complainant of that decision and the reasons for it.
73 **Proceedings of Commissioner**

Before proceeding to investigate any matter under this Part of this Act, the Commissioner—

(a) Shall inform the complainant (if any), the person to whom the investigation relates, and any individual alleged to be aggrieved (if not the complainant), of the Commissioner’s intention to make the investigation; and

(b) Shall inform the person to whom the investigation relates of—

(i) The details of the complaint (if any) or, as the case may be, the subjectmatter of the investigation; and

(ii) The right of that person to submit to the Commissioner, within a reasonable time, a written response in relation to the complaint or, as the case may be, the subjectmatter of the investigation.

74 **Settlement of complaints**

Where it appears from a complaint, or any written response made in relation to a complaint under section 73(b)(ii) of this Act, that it may be possible to secure a settlement between any of the parties concerned and, if appropriate, a satisfactory assurance against the repetition of any action that is the subjectmatter of the complaint or the doing of further actions of a similar kind by the person concerned, the Commissioner may, without investigating the complaint or, as the case may be, investigating the complaint further, use his or her best endeavours to secure such a settlement and assurance.

77 **Procedure after investigation**

(1) Where the Commissioner, after making any investigation under this Part of this Act, is of the opinion,—

(a) In the case of a complaint, that the complaint has substance, the Commissioner shall use his or her best endeavours to secure a settlement between any parties concerned and, if the Commissioner considers it appropriate, a satisfactory assurance against the repetition of any action that was the subjectmatter of the investigation or the doing of further actions of a similar kind by the person concerned; or

(b) In any other case, that the matter ought to be proceeded with, the Commissioner shall use his or her best endeavours to secure such an assurance as is referred to in paragraph (a) of this subsection.

(2) If,—
(a) In the circumstances referred to in section 74 of this Act, the Commissioner is unable to secure such a settlement and assurance as is referred to in that section; or

(b) In the circumstances referred to in paragraph (a) or paragraph (b) of subsection (1) of this section, the Commissioner is unable to secure such a settlement and assurance or, as the case may be, such an assurance as is referred to in either of those paragraphs; or

(c) In any case to which section 74 of this Act or subsection (1) of this section applies, it appears that the action that was the subject matter of the complaint or, as the case may be, the investigation was done in contravention of such an assurance as is referred to in that section or that subsection, given on a previous occasion, or that any term of such a settlement as is referred to in that section or that subsection, reached on a previous occasion, has not been complied with,— the Commissioner may refer the matter to the Director of Human Rights Proceedings for the purpose of deciding whether proceedings under section 82 of this Act should be instituted against the person against whom the complaint was made or in respect of whom the investigation was conducted.

(3) Where a matter is referred to the Director of Human Rights Proceedings under subsection (2) of this section, it shall, subject to section 82(3) of this Act, be for the Director of Human Rights Proceedings to determine, in his or her discretion, both whether a matter justifies the institution of proceedings under section 82 of this Act and whether proceedings should be instituted under section 82 of this Act in respect of that matter.

82 Proceedings before Human Rights Review Tribunal

(1) This section applies to any person—

(a) In respect of whom an investigation has been conducted under this Part of this Act in relation to any action alleged to be an interference with the privacy of an individual; or

(b) In respect of whom a complaint has been made in relation to any such action, where conciliation under section 74 of this Act has not resulted in a settlement.

(2) Subject to subsection (3) of this section, civil proceedings before the Human Rights Review Tribunal shall lie at the suit of the Director of Human Rights Proceedings
against any person to whom this section applies in respect of any action of that person that is an interference with the privacy of an individual.

(3) The Director of Human Rights Proceedings shall not take proceedings under subsection (2) of this section against any person to whom this section applies unless the Director of Human Rights Proceedings has given that person an opportunity to be heard.

(4) The Director of Human Rights Proceedings may, under subsection (2) of this section, bring proceedings on behalf of a class of individuals, and may seek on behalf of individuals who belong to the class any of the remedies described in section 85 of this Act, where the Director of Human Rights Proceedings considers that a person to whom this section applies is carrying on a practice which affects that class and which is an interference with the privacy of an individual.

(5) Where proceedings are commenced by the Director of Human Rights Proceedings under subsection (2) of this section, the aggrieved individual (if any) shall not be an original party to, or, unless the Tribunal otherwise orders, join or be joined in, any such proceedings.

83 *Aggrieved individual may bring proceedings before Human Rights Review Tribunal*

Notwithstanding section 82(2) of this Act, the aggrieved individual (if any) may himself or herself bring proceedings before the Human Rights Review Tribunal against a person to whom section 82 of this Act applies if the aggrieved individual wishes to do so, and—

(a) The Commissioner or the Director of Human Rights Proceedings is of the opinion that the complaint does not have substance or that the matter ought not to be proceeded with; or

(b) In a case where the Director of Human Rights Proceedings would be entitled to bring proceedings, the Director of Human Rights Proceedings—

   (i) Agrees to the aggrieved individual bringing proceedings; or

   (ii) Declines to take proceedings.

84 *Remedies that may be sought*

In any proceedings before the Human Rights Review Tribunal, the Director of Human Rights Proceedings or the aggrieved individual (as the case may be) may seek such of the remedies described in section 85 of this Act as he or she thinks fit.

85 *Powers of Human Rights Review Tribunal*
If, in any proceedings under section 82 or section 83 of this Act, the Tribunal is satisfied on the balance of probabilities that any action of the defendant is an interference with the privacy of an individual, it may grant one or more of the following remedies:

(a) A declaration that the action of the defendant is an interference with the privacy of an individual:

(b) An order restraining the defendant from continuing or repeating the interference, or from engaging in, or causing or permitting others to engage in, conduct of the same kind as that constituting the interference, or conduct of any similar kind specified in the order:

(c) Damages in accordance with section 88 of this Act:

(d) An order that the defendant perform any acts specified in the order with a view to remedying the interference, or redressing any loss or damage suffered by the aggrieved individual as a result of the interference, or both:

(e) Such other relief as the Tribunal thinks fit.

In any proceedings under section 82 or section 83 of this Act, the Tribunal may award such costs against the defendant as the Tribunal thinks fit, whether or not the Tribunal makes any other order, or may award costs against the plaintiff, or may decline to award costs against either party.

Where the Director of Human Rights Proceedings is the plaintiff, any costs awarded against him or her shall be paid by the Privacy Commissioner, and the Privacy Commissioner shall not be entitled to be indemnified by the aggrieved individual (if any).

It shall not be a defence to proceedings under section 82 or section 83 of this Act that the interference was unintentional or without negligence on the part of the defendant, but the Tribunal shall take the conduct of the defendant into account in deciding what, if any, remedy to grant.

2. HEALTH INFORMATION PRIVACY CODE 1994

4 Application of code

(1) This code applies to the following information or classes of information about an identifiable individual:

(a) information about the health of that individual, including his or her medical history;
(b) information about any disabilities that individual has, or has had;
(c) information about any health services or disability services that are being provided, or have been provided, to that individual;
(d) information provided by that individual in connection with the donation, by that individual, of any body part or any bodily substance of that individual or derived from the testing or examination of any body part, or any bodily substance of that individual; or
(e) information about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.

5 Health information privacy rules

The information privacy principles are modified in accordance with the Act by the following rules which apply to health information and health agencies:

Rule 3

Collection of Health Information from Individual

(1) Where a health agency collects health information directly from the individual concerned, or from the individual's representative, the health agency must take such steps as are, in the circumstances, reasonable to ensure that the individual concerned (and the representative if collection is from the representative) is aware of:

(a) the fact that the information is being collected;
(b) the purpose for which the information is being collected;
(c) the intended recipients of the information;
(d) the name and address of:
   (i) the health agency that is collecting the information; and
   (ii) the agency that will hold the information;
(e) whether or not the supply of the information is voluntary or mandatory and if mandatory the particular law under which it is required;
(f) the consequences (if any) for that individual if all or any part of the requested information is not provided; and
(g) the rights of access to, and correction of, health information provided by rules 6 and 7.

(2) The steps referred to in subrule (1) must be taken before the information is collected or, if that is not practicable, as soon as practicable after it is collected.
(3) A health agency is not required to take the steps referred to in subrule (1) in relation to the collection of information from an individual, or the individual's representative, if that agency has taken those steps in relation to the collection, from that individual or that representative, of the same information or information of the same kind for the same or a related purpose, on a recent previous occasion.

(4) It is not necessary for a health agency to comply with subrule (1) if the agency believes on reasonable grounds:

(a) [revoked]

(b) that compliance would:
   (i) prejudice the interests of the individual concerned; or
   (ii) prejudice the purposes of collection;

(c) that compliance is not reasonably practicable in the circumstances of the particular case; or

(d) that non-compliance is necessary to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution, and punishment of offences.

Rule 10
Limits on Use of Health Information

(1) A health agency that holds health information obtained in connection with one purpose must not use the information for any other purpose unless the health agency believes on reasonable grounds:

(a) that the use of the information for that other purpose is authorised by:
   (i) the individual concerned; or
   (ii) the individual's representative where the individual is unable to give his or her authority under this rule;

(b) that the purpose for which the information is used is directly related to the purpose in connection with which the information was obtained;

(c) that the source of the information is a publicly available publication;

(d) that the use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to:
   (i) public health or public safety; or
   (ii) the life or health of the individual concerned or another individual;

(e) that the information:
(i) is used in a form in which the individual concerned is not identified;
(ii) is used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or
(iii) is used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned;

(f) that non-compliance is necessary:

(i) to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution, and punishment of offences; or
(ii) for the conduct of proceedings before any court or tribunal (being proceedings that have been commenced or are reasonably in contemplation);

(g) that the use of the information is in accordance with an authority granted under section 54 of the Act.

(2) This rule does not apply to health information obtained before [1 July 1993].

Rule 11
Limits on Disclosure of Health Information

(1) A health agency that holds health information must not disclose the information unless the agency believes, on reasonable grounds:

(a) that the disclosure is to:

(i) the individual concerned; or
(ii) the individual’s representative where the individual is dead or is unable to exercise his or her rights under these rules;

(b) that the disclosure is authorised by:

(i) the individual concerned; or
(ii) the individual’s representative where the individual is dead or is unable to give his or her authority under this rule;

(c) that the disclosure of the information is one of the purposes in connection with which the information was obtained;

(d) that the source of the information is a publicly available publication;

(e) that the information is information in general terms concerning the presence, location, and condition and progress of the patient in a hospital, on the day on which the information is disclosed, and the disclosure is not contrary to the express request of the individual or his or her representative;
(f) that the information to be disclosed concerns only the fact of death and the disclosure is by a [health practitioner], or by a person authorised by a health agency, to a person nominated by the individual concerned, or the individual’s representative, partner, spouse, principal caregiver, next of kin, whanau, close relative or other person whom it is reasonable in the circumstances to inform [; or]

(g) the information to be disclosed concerns only the fact that an individual is to be, or has been, released from compulsory status under the Mental Health (Compulsory Assessment and Treatment) Act 1992 and the disclosure is to the individual’s principal caregiver.

(2) Compliance with paragraph (1)(b) is not necessary if the health agency believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the individual concerned and:

(a) that the disclosure of the information is directly related to one of the purposes in connection with which the information was obtained;

(b) that the information is disclosed by a [health practitioner] to a person nominated by the individual concerned or to the principal caregiver or a near relative of the individual concerned in accordance with recognised professional practice and the disclosure is not contrary to the express request of the individual or his or her representative;

(c) that the information:

(i) is to be used in a form in which the individual concerned is not identified;

(ii) is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(iii) is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form which could reasonably be expected to identify the individual concerned;

(d) that the disclosure of the information is necessary to prevent or lessen a serious and imminent threat to:

(i) public health or public safety; or

(ii) the life or health of the individual concerned or another individual;

(e) that the disclosure of the information is essential to facilitate the sale or other disposition of a business as a going concern;

(f) that the information to be disclosed briefly describes only the nature of injuries of an individual sustained in an accident and that individual’s identity and the disclosure is:
(i) by a person authorised by the person in charge of a hospital;
(ii) to a person authorised by the person in charge of a news medium; for the purpose of publication or broadcast in connection with the news activities of that news medium and the disclosure is not contrary to the express request of the individual concerned or his or her representative;

(g) that the disclosure of the information:
(i) is required for the purposes of identifying whether an individual is suitable to be involved in health education and so that individuals so identified may be able to be contacted to seek their authority in accordance with paragraph (1)(b); and
(ii) is by a person authorised by the health agency to a person authorised by a health training institution;

(h) that the disclosure of the information:
(i) is required for the purpose of a professionally recognised accreditation of a health or disability service;
(ii) is required for a professionally recognised external quality assurance programme; or
(iii) is required for risk management assessment and the disclosure is solely to a person engaged by the agency for the purpose of assessing the agency's risk; and the information will not be published in a form which could reasonably be expected to identify any individual nor disclosed by the accreditation or quality assurance or risk management organisation to third parties except as required by law;

(i) that non-compliance is necessary:
(i) to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution and punishment of offences; or
(ii) for the conduct of proceedings before any court or tribunal (being proceedings that have been commenced or are reasonably in contemplation);

(j) that the individual concerned is or is likely to become dependent upon a controlled drug, prescription medicine or restricted medicine and the disclosure is by a [health practitioner] to a Medical Officer of Health for the purposes of section 20 of the Misuse of Drugs Act 1975 or section 49A of the Medicines Act 1981;

(k) that the disclosure of the information is in accordance with an authority granted under section 54 of the Act.

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Disclosure under subrule (2) is permitted only to the extent necessary for the particular purpose.

Where under section 22F(1) of the Health Act 1956, the individual concerned or a representative of that individual requests the disclosure of health information to that individual or representative, a health agency:

(a) must treat any request by that individual as if it were a health information privacy request made under rule 6; and

(b) may refuse to disclose information to the representative if:

(i) the disclosure of the information would be contrary to the individual’s interests;

(ii) the agency has reasonable grounds for believing that the individual does not or would not wish the information to be disclosed; or

(iii) there would be good grounds for withholding the information under Part 4 of the Act if the request had been made by the individual concerned.

This rule applies to health information about living or deceased persons obtained before or after the commencement of this code.

[Despite subrule (5), a health agency is exempted from compliance with this rule in respect of health information about an identifiable deceased person who has been dead for not less than 20 years.]

Note: Except as provided in rule 11(4) nothing in this rule derogates from any provision in an enactment which authorises or requires information to be made available, prohibits or restricts the availability of health information or regulates the manner in which health information may be obtained or made available - Privacy Act, section 7. Note also that rule 11, unlike the other rules, applies not only to information about living individuals, but also about deceased persons - Privacy Act, section 46(6).

3. **HEALTH ACT 1956**

22B **Interpretation**

In this section and sections 22C to 22H of this Act, unless the context otherwise requires,—

**Health information**, in relation to an identifiable individual, means—

(a) Information about the health of that individual, including that individual's medical history:
(b) Information about any disabilities that individual has, or has had:
(c) Information about any services that are being provided, or have been provided, to that individual:
(d) Information provided by that individual in connection with the donation, by that individual, of any body part, or any bodily substance, of that individual:
(e) For the purposes of section 22E of this Act and for that purpose only, information—
   (i) Derived from the testing or examination of any body part, or any bodily substance, donated by an individual; or
   (ii) Otherwise relating to any part or substance so donated, or relating to the donor and relevant (whether directly or indirectly) to the donation:

**Individual** means a natural person, and includes a deceased natural person

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22C **Disclosure of health information**

(1) Any person (being an agency that provides services or arranges the provision of services) may disclose health information—
   (a) If that information—
      (i) Is required by any person specified in subsection (2) of this section; and
      (ii) Is required (or, in the case of the purpose set out in paragraph (j) of that subsection, is essential) for the purpose set out in that subsection in relation to the person so specified; or
   (b) If that disclosure is permitted—
      (i) By or under a code of practice issued under section 46 of the Privacy Act 1993; or
      (ii) If no such code of practice applies in relation to the information, by any of the information privacy principles set out in section 6 of that Act.

(2) The persons and purposes referred to in subsection (1)(a) of this section are as follows:
   (a) Any medical officer of a prison within the meaning of the Corrections Act 2004, for the purposes of exercising or performing any of that person's powers, duties, or functions under that Act:
   (b) Any probation officer within the meaning of the Corrections Act 2004, for the purposes of exercising or performing any of that person's powers, duties, or functions under any enactment:
(c) A Social Worker or a Care and Protection Co-ordinator within the meaning of the Children, Young Persons, and Their Families Act 1989, for the purposes of exercising or performing any of that person's powers, duties, or functions under that Act:

(d) Any employee of the department for the time being responsible for the administration of the Social Security Act 1964, for the purposes of administering section 75 of the Social Security Act 1964:

(e) Any member of the New Zealand Defence Force, for the purposes of administering the Armed Forces Discipline Act 1971 or the Defence Act 1990:

(f) Any member of the Police, for the purposes of exercising or performing any of that person's powers, duties, or functions:

(g) Any employee of the Ministry of Health, for the purposes of—
   (i) Administering this Act or the Hospitals Act 1957; or
   (ii) Compiling statistics for health purposes:

(h) Any employee of the Ministry of Agriculture and Forestry authorised by the chief executive of that Ministry to receive the information, for the purposes of administering the Meat Act 1981 or the Animal Products Act 1999:

(i) Any employee of the New Zealand Transport Agency, for statistical or research purposes in relation to road safety or the environment:

(j) any employee of a district health board, for the purposes of exercising or performing any of that board's powers, duties, or functions under the New Zealand Public Health and Disability Act 2000.

(3) For the purposes of principle 11(d) of the Privacy Act 1993, the disclosure of health information about an individual may be authorised—

(a) By that individual personally, if he or she has attained the age of 16 years; or

(b) By a representative of that individual.

22F Communication of information for diagnostic and other purposes

(1) Every person who holds health information of any kind shall, at the request of the individual about whom the information is held, or a representative of that individual, or any other person that is providing, or is to provide, services to that individual, disclose that information to that individual or, as the case requires, to that representative or to that other person.
(2) A person that holds health information may refuse to disclose that information under this section if—

(a) That person has a lawful excuse for not disclosing that information; or

(b) Where the information is requested by someone other than the individual about whom it is held (not being a representative of that individual), the holder of the information has reasonable grounds for believing that that individual does not wish the information to be disclosed; or

(c) Refusal is authorised by a code of practice issued under section 46 of the Privacy Act 1993.

(3) For the purposes of subsection (2)(a) of this section, neither—

(a) The fact that any payment due to the holder of any information or to any other person has not been made; nor

(b) The need to avoid prejudice to the commercial position of the holder of any information or of any other person; nor

(c) The fact that disclosure is not permitted under any of the information privacy principles set out in section 6 of the Privacy Act 1993 — shall constitute a lawful excuse for not disclosing information under this section.

(4) Where any person refuses to disclose health information in response to a request made under this section, the person whose request is refused may make a complaint to the Privacy Commissioner under Part 8 of the Privacy Act 1993, and that Part of that Act, so far as applicable and with all necessary modifications, shall apply in relation to that complaint as if the refusal to which the complaint relates were a refusal to make information available in response to an information privacy request within the meaning of that Act.

(5) Nothing in subsection (4) of this section limits any other remedy that is available to any person who is aggrieved by any refusal to disclose information under this section.

22H Anonymous health information
Notwithstanding any enactment, rule of law, or other obligation, any person may supply to any other person health information that does not enable the identification of the individual to whom the information relates.
4. OFFICIAL INFORMATION ACT 1982

Long title
An Act to make official information more freely available, to provide for proper access by each person to official information relating to that person, to protect official information to the extent consistent with the public interest and the preservation of personal privacy, to establish procedures for the achievement of those purposes, and to repeal the Official Secrets Act 1951.

Interpretation
(1) In this Act, unless the context otherwise requires,—

Official information—
(a) Means any information held by—
(i) A Department; or
(ii) A Minister of the Crown in his official capacity; or
(iii) An organisation....

4 Purposes
The purposes of this Act are, consistently with the principle of the Executive Government's responsibility to Parliament,—

(a) To increase progressively the availability of official information to the people of New Zealand in order—
(i) To enable their more effective participation in the making and administration of laws and policies; and
(ii) To promote the accountability of Ministers of the Crown and officials,—
and thereby to enhance respect for the law and to promote the good government of New Zealand:
(b) To provide for proper access by each person to official information relating to that person:
(c) To protect official information to the extent consistent with the public interest and the preservation of personal privacy.

5 Principle of availability
The question whether any official information is to be made available, where that question arises under this Act, shall be determined, except where this Act otherwise expressly requires,
in accordance with the purposes of this Act and the principle that the information shall be made available unless there is good reason for withholding it.

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9 Other reasons for withholding official information

(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

(2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to—

(a) Protect the privacy of natural persons, including that of deceased natural persons; or

(b) Protect information where the making available of the information—

(i) Would disclose a trade secret; or

(ii) Would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or

(ba) Protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information—

(i) Would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or

(ii) Would be likely otherwise to damage the public interest; or

(c) Avoid prejudice to measures protecting the health or safety of members of the public; or

(d) Avoid prejudice to the substantial economic interests of New Zealand; or

(e) Avoid prejudice to measures that prevent or mitigate material loss to members of the public; or

(f) Maintain the constitutional conventions for the time being which protect—

(i) The confidentiality of communications by or with the Sovereign or her representative;

(ii) Collective and individual ministerial responsibility;

(iii) The political neutrality of officials;
(iv) The confidentiality of advice tendered by Ministers of the Crown and officials; or

(g) Maintain the effective conduct of public affairs through—

(i) The free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or

(ii) The protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or

(h) Maintain legal professional privilege; or

(i) Enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or

(j) Enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or

(k) Prevent the disclosure or use of official information for improper gain or improper advantage.

29B Consultation with Privacy Commissioner

Where an Ombudsman investigates a complaint made under section 28 of this Act in relation to a refusal to make official information available in reliance on section 9(2)(a) of this Act, the Ombudsman shall, before forming a final opinion under section 30 of this Act in relation to the merits of refusing that request on that ground, consult with the Privacy Commissioner under the Privacy Act 1993.

48 Protection against certain actions

(1) Where any official information is made available in good faith pursuant to this Act,—

(a) No proceedings, civil or criminal, shall lie against the Crown or any other person in respect of the making available of that information, or for any consequences that follow from the making available of that information; and

(b) No proceedings, civil or criminal, in respect of any publication involved in, or resulting from, the making available of that information shall lie against the author of the information or any other person by reason of that author or other person
having supplied the information to a Department or Minister of the Crown or organisation.

(2) The making available of, or the giving of access to, any official information in consequence of a request made under this Act shall not be taken, for the purposes of the law relating to defamation or breach of confidence or infringement of copyright, to constitute an authorisation or approval of the publication of the document or of its contents by the person to whom the information is made available or the access is given.