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THE PROTECTION OF GENETIC PRIVACY IN SOUTH AFRICA: TOWARDS A LEGISLATIVE RESPONSE BASED ON A CROSS-JURISDICTIONAL REVIEW OF LEGAL DEVELOPMENTS

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Thesis submitted in fulfilment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in the School of Law at the University of the Witwatersrand, Johannesburg

20 September 2012

DECLARATION

I, Sandra Govender, hereby declare that this thesis is my own unaided work. It is submitted in fulfilment of the requirements of the degree of Doctor of Philosophy (PhD) in the Faculty of Commerce, Law and Management at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

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ABSTRACT

The deciphering of the human genetic code in 2003 has been widely acknowledged as a major achievement in genetic science but it has given rise to a number of legal and ethical concerns, most notably that of the protection of genetic information. Universally, there are ongoing attempts to address this concern. This research proposes a suitable approach for South African law. It proceeds from the premise that the privacy paradigm, rather than the anti-discrimination paradigm, is better suited to the protection of genetic information, hence the discourse on genetic privacy. The unique challenges posed by genetic information are identified, with a focus on forensic DNA databases, genetic research databases, life insurance, employment, and genetic research involving human participants.

An in-depth analysis of the South African privacy protection framework is undertaken in order to determine its adequacy for the purpose of meeting the legal and ethical demands of genetic information. Aspects of the law of privacy, insurance, labour, evidence; medical law; philosophy and bioethics are accordingly traversed. A cross-jurisdictional review is undertaken with the aim of identifying lessons to be learnt from the experiences of the United Kingdom, Australia, Canada, the Netherlands, and the United States of America. Legislation, common law, codes of practice, court decisions, international conventions, legal literature, ethical guidelines, and industry developments pertaining to the selected jurisdictions, are studied with the aim of identifying strengths and weaknesses in the various approaches.

It is found that the current South African position is fragmented, complex, and in urgent need of reform. Another finding is that existing national and international ethical guidelines are not entirely adequate for the protection of genetic privacy. These findings, together with the lessons gleaned from the cross-jurisdictional review, lead to the conclusion that South Africa needs a specific genetic information protection statute for the protection of genetic privacy. This research culminates with recommendations regarding the content of the proposed statute.

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I am deeply indebted to my parents for where I find myself today. Sadly, though, my father passed away on 25 July 2012, as I awaited the results of the examination of this thesis. Even though I am unable to share this achievement with him personally, I hereby acknowledge the role that he played in my educational endeavours. I thank him for giving me the opportunity to start out on my educational journey and for the numerous sacrifices that he made over the years. May he rest in peace, knowing that his legacy lives on. I thank my mother for her continuous encouragement and support. At a tender age she taught me that education is the key to empowerment and independence. She instilled in me a desire to succeed in whatever I chose to do. This strong foundation enabled me to reach the pinnacle of my academic career.

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I dedicate this thesis to my beloved children, Trevaden (7) and Talia (4), who unknowingly paid the greatest price for this accomplishment. Thank you for your years of patience (and silence). Perhaps someday you will understand the extent of your sacrifice. Your unconditional love gave me the strength to complete this long, arduous journey to a truly rewarding destination. May you be inspired to explore unchartered territory and to strive for success in all facets of life!

SANDRA GOVENDER
Johannesburg
20 September 2012

To my children, Trevaden and Talia

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CHAPTER I

INTRODUCTION

1.1 BACKGROUND AND OBJECTIVES OF THE STUDY

> 'The advent of modern genetic science has generally been heralded as one of the greatest advances in human history. Unfortunately, it is also perceived as one of the biggest threats to individual interests in the contemporary private sphere.'[1]

> 'A great deal of the sociological and much of the legal literature on privacy is often both frustrating to read and futile to recount. This need not particularly concern the law reformer. Provided an identifiable wrong is shown to lack an adequate legal remedy, the necessity for which can be clearly demonstrated, the onus placed upon those who seek to change the law, is discharged.'[2]

The science of genetics emerged in the mid-nineteenth century when Gregor Mendel's experiments with peas led to the discovery of the basic mechanisms of heredity. It was then that the journey to deciphering the genetic code began. In 1953 James Watson and Francis Crick discovered the double-helix structure of deoxyribonucleicacid (DNA), a feat which earned them the Nobel Prize for Physiology or Medicine in 1962. The Human Genome Project was launched in 1990 and the first draft of the human genetic code was completed in June 2000. This code is considered to be the blueprint for human life, which in turn has led to theories of genetic determinism, genetic reductionism, and genetics exceptionalism.

Genetic determinism refers to the belief that the future of an individual is decided solely by genetic makeup and nothing can be done to change that. Genetic reductionism is the theory that everything about human beings is determined by genes, without any regard to external factors. This includes health and behavioural traits. The influence of external factors is totally disregarded. Genetics exceptionalism is the theory that genetic information is unique and deserving of special protection. Privacy is said to have emerged as an important issue within a largely genetics exceptionalism discourse.[3] Fears of discrimination in areas of employment and

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1 Graeme Laurie *Genetic Privacy: A Challenge to Medico-Legal Norms* (2002) 20.
2 Raymond Wacks *The Protection of Privacy* (1980) 176.
3 Jennifer Molina *Genetic Privacy: Issues in Aotearoa/New Zealand* (2005) available at http://www.ssrc.canterbury.ac.nz/research/2004-5/Genetic%20Privacy.pdf accessed on 14 July 2007.

insurance have come to the fore. A fear of eugenics[4] has also emerged. Such anxiety may be attributed to the absence of regulation in this new but rapidly advancing field and a general fear of the unknown.

The realisation of the potential for diagnosis and prediction of genetic conditions began with the initiation of the Human Genome Project in 1990. This Project was an organised international scientific endeavour to determine the complete structure of the human DNA and to understand its function. The aims of the Human Genome Project were to -

(1) identify all the genes in human DNA;

(2) determine the sequences of the 3 billion chemical base pairs that make up human DNA;

(3) store this information in databases;

(4) improve tools for data analysis;

(5) transfer related technologies to the private sector; and

(6) address the ethical, legal, and social issues that may arise from the project.[5]

The completion of the human DNA sequence in 2003 coincided with the 50th anniversary of Watson and Crick's discovery of the fundamental structure of DNA. Although this achievement of the Human Genome Project has been hailed as a giant step in science, it has major consequences for the law. It has renewed the debates surrounding the issue of personal privacy and fears of discrimination as a consequential harm resulting from inadequate privacy protection. Since the completion of the human DNA sequence the issue of genetic privacy has gained attention in many countries. The potential uses[6] of genetic information give rise to privacy concerns. These concerns are wider than those that may be addressed by confidentiality. The protection afforded by confidentiality is not sufficient in the context of genetic information because genetic information is not limited to situations involving medical professionals and patients. Genetic information is generated in other settings such as research and it is therefore

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[4] The term was coined in 1883 by Francis Galton, a cousin of Charles Darwin. Galton defined the term as 'the science of improving inherited stock, not only by judicious matings, but by all the influences which give more suitable strains a better chance'. The forced sterilisation of mentally retarded individuals in the United States of America in the 1930's and the attempt to create a master-race by the mass killing of Jews in Germany are examples of eugenics. See David J. Galton & Clare J. Galton 'Francis Galton: and eugenics today' (1998) 24:2 *Journal of Medical Ethics* 99.

[5] Human Genome Project Information, available at http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml accessed on 2 July 2007.

[6] Genetic information is more commonly used for predicting and diagnosing medical conditions, assisting in reproductive decision-making, assessing suitability for employment, assessing insurance eligibility, identification in criminal cases, conducting medical research, and determining paternity. See Eugene Oscapella *Genetics, Privacy and Discrimination* Document Prepared for the Canadian Biotechnology Advisory Committee (2000) 8.

necessary to protect genetic information privacy instead of simply relying on confidentiality. Confidentiality can clearly not fully address the privacy concerns relating to genetic information due to its limited scope of application. Concerns around the use of genetic information in the context of insurance, employment, and databases have been most prominent in other countries. This is evident from the major inquiries[7] into the protection of genetic information as well as the results of empirical studies conducted in the United Kingdom[8] and in Australia.[9]

Genetic privacy protection is clearly an issue which will have to be addressed throughout the world in due course. For this reason it has to be considered and responded to in South Africa. The thrust of this study is accordingly to provide insight into the issues that must be considered when developing a South African response to the challenges posed by genetic privacy. In that sense it is proactive as it anticipates the challenges and makes recommendations. It focuses specifically on genetic information which is information about a person's inherited genetic make-up. Genetic information is obtained through genetic testing and disclosure of such information may lead to genetic discrimination. The focus does not extend to genomic information which is information gained from studies of the interaction between various genes as well as between genes and the environment. Such a study does not fall within the parameters of this research.

Genetic information privacy is not yet the subject of debate in South Africa but it needs attention for the following reasons:

(1) Genetic privacy is an issue that is inevitable in the wake of rapidly advancing technologies as is apparent from the ongoing debates in other countries.

(2) South Africa currently has disease registries which are not covered by legislation regarding disease notification and which were initiated as a result of scientific interest. Cancer registries and the birth defects registry are prime examples.[10] This is of concern especially in the case of breast cancer which has been attributed to the BRCA-1 and BRCA-2 genes. BRCA1 is a

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[7] Australian Law Reform Commission (Project 26) *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003); Human Genetics Commission *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002).

[8] Lawrence Low, Suzanne King & Tom Wilkie 'Genetic discrimination in life insurance: Empirical evidence from a cross-sectional survey of genetic support groups in the United Kingdom' (1998) 317 *British Medical Journal* 1632.

[9] Margaret F Otlowski, Sandra D Taylor & Kristine K Barlow-Stewart 'Australian empirical study into genetic discrimination' (2002) 12 *Eubios Journal of Asian and International Bioethics* 164.

[10] Nokuzola Mqoqi , Freddy Sitas and Jane Halkett *South African Health Review* (2002) ch 20, available at http://www.hst.org.za/uploads/files/chapter20.pdf, accessed on12 June 2007.

breast cancer susceptibility gene that was first identified in 1994. People carrying a mutation in this gene are at an increased risk of breast or ovarian cancer. BRCA-2 was identified in 1995 and is also a cancer causing gene when mutated. The data in cancer registries are used by researchers and insurers, amongst others.[11] Unregulated or insufficiently regulated access to this information is cause for concern because hereditary breast cancer is caused by a mutant gene passed from parents to children and also because breast cancer is more prevalent in certain ethnic groups such as Ashkenazi Jews.

(3) The third concern relates to the facilitation of international collaborative medical research which may involve the transborder flow of data. This requires that South Africa develop privacy protection mechanisms which are found to be adequate by international roleplayers in research. A case in point is the European Data Protection Directive,[12] in terms of which all countries trading with European Union member states are required to have data protection regimes which conform to the adequacy standards laid down in the Directive.[13] The Directive provides that member states shall only transfer data to countries which provide an adequate level of protection to personal data.

(4) The National Health Act 61 of 2003 provides for the prevention of unauthorised access to health records but does not define a health record.[14] It is therefore uncertain whether genetic information will be afforded such protection from disclosure under this legislation.

(5) The Department of Health has published policy guidelines for the management and prevention of genetic disorders, birth defects and disabilities.[15] One of the goals set down in these guidelines is to establish a national monitoring and evaluation system for genetic disorders and birth defects.[16] Item 5.6 refers to data collection by the department under a National Genetic Information System. The guidelines do provide that individual privacy should be protected from institutional third parties such as employers, insurers, schools, commercial entities, and government agencies.[17] The department's goal is to integrate genetic services into the primary

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11 Ibid 398.

12 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.

13 Ibid art. 25.

14 Section 17.

15 Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth Defects and Disabilities (2001).

16 Ibid 11.

17 Ibid 49.

health care system and it recognises that protection of privacy is important when dealing with genetic information. The question which arises is how privacy is to be protected.

(6) Guidelines issued by the Medical Research Council draw attention to the long-term storage of information resulting from genetic screening and which may form the basis of a genetic register.[18] The Council acknowledges that 'confidentiality of all medical information is essential, and this is particularly the case with genetic registers, which may contain highly sensitive and potentially identifiable data on large numbers of individuals with, or at risk of, serious genetic disorders. Computer-based genetic registers are subject to the Promotion of Access to Information Act 2 of 2000, but there is a need for additional safeguards for all genetic registers, including secure storage of information, limitation of access to those specifically responsible for a register, and the removal of identifying information when data are used for research purposes. This is an important area of concern. The Department of Health, in consultation with health authorities and appropriate professional bodies, should devise effective arrangements for the preservation of confidentiality, particularly in relation to genetic registers, and should provide the necessary guidance.'[19] The nature of genetic registers clearly indicates a need for privacy protection. The Department of Health has issued regulations[20] dealing with these issues this issue but the adequacy of these regulations is open to debate. It is important to note that the promotion of Access to Information Act applies only in the context of requests for access to information. Information is only protected from disclosure in the case of a request for access.

(7) There is no legislation in South Africa for the regulation of human genetic databases as is apparent from the regulations[21] mentioned above.

(8) Data protection measures are very limited in South Africa. Neethling observes that 'South African commentators are unanimous that the creation of such measures through legislation is a matter of great urgency.'[22] The call for urgent legislative intervention is due to the threat posed to the privacy of individuals by the collection of personal data. As far as genetic information is concerned, the threat arises in the context of the creation of forensic DNA

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18 South African Medical Research Council *Guidelines on Ethics in Reproductive Biology and Genetic Research* (2000).

19 Ibid para 3.3.4.1.4.

20 Regulations relating to the use of human biological material GN R.177 *GG* 35099 of 2 March 2012.

21 Ibid.

22 J Neethling, J M Potgieter & P J Visser *Neethling's Law of Personality* 2ed (2005) 271.

databases. The individual's right to privacy has to be balanced against the interest of the state in solving crime.

(9) In South Africa the doctrine of privilege does not apply to the confidential relationship between doctor and patient. Genetic information gained in the course of such a relationship is therefore protected by the rules of confidentiality but is not subject to any privilege. A concept of 'genetic privilege' as a statutory privilege is therefore worth investigating. This privilege may be based on the nature of the relationship within which the information has been imparted or come into existence or on the nature of the information sought to be protected from disclosure. Alternatively, a judicial discretion to excuse a witness from giving evidence in breach of a social or ethical value may be considered. A statutory basis for such discretion would ensure that the discretion is exercised in a consistent and reasonably predictable manner.

All of the abovementioned issues support the argument that the issue of genetic privacy requires prompt attention from legal scholars, policymakers, and legislators in South Africa. Privacy is a constitutionally entrenched right and is therefore important enough to warrant this investigation, especially when other countries have already debated the issue and have developed appropriate strategies to deal with genetic privacy. Even though this area is evolving rapidly, it has to be regulated to prevent harm which could jeopardise the realisation of the constitutionally-entrenched right to privacy in South Africa. Failure to take action is likely to result in unnecessary uncertainty and otherwise avoidable litigation.

The main objective of this research is accordingly to demonstrate a need for genetic privacy legislation in South Africa, based on the identification of gaps, inconsistencies, and overlaps in the current regulatory framework as well as the advances that have been made in the selected overseas jurisdictions. This entails striking a balance between the privacy rights of the individual and the rights of third parties who may seek access to the genetic information. In order to strike the correct balance, it is essential to consider the debates that have informed such decisions in other countries. This research is therefore very important for South Africa because it will position policymakers and legislators to respond to the challenges posed by genetic information privacy in an informed manner.

1.2 THE DEFINITION OF GENETIC INFORMATION

Literature on the nature of genetic information is characterised by polarised views on genetics exceptionalism and the genetic inclusivist approach (sometimes referred to in the literature as genetic anti-exceptionalism). Genetics exceptionalism has been defined as 'the societal practice of treating genetic data as different from other types of health data for the purposes of assessing privacy and security protections.'[23] The leading proponents of genetics exceptionalism are Annas, Glantz and Roche who are of the view that genetic information is unique because it -

(1) can predict an individual's likely medical future for a variety of conditions;

(2) divulges personal information about parents, siblings, and children; and

(3) has historically been used to stigmatise and victimise individuals.[24]

They refer to the information contained in DNA as an individual's 'coded probabilistic future diary'.[25] They take the view that genetic information is uniquely powerful, uniquely personal, and thus merits unique privacy protection.[26]

The Human Genetics Commission in the United Kingdom identified the following as possible reasons for the special consideration of genetic information:

(1) it is uniquely identifying information;

(2) it can be obtained from a small sample and even without the knowledge of the individual from whom it is obtained;

(3) it is predictive;

(4) it may be of interest to third parties such as insurance companies and employers;

(5) it has potential commercial value;

(6) it has value for pharmacogenomics; and

(7) it may be collected for one purpose and subsequently be used for another purpose.[27]

Proponents of the genetic inclusivist approach contend that genetic information is just another form of medical information and it therefore does not warrant special protection. Gostin, Hodge, and Murray are opposed to the idea of genetics exceptionalism. Gostin and Hodge argue that genetics exceptionalism is flawed for the following two reasons:

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[23] Gostin LO & Hodge JG 'Genetic privacy and the law: An end to genetics exceptionalism' (1999) 40 *Jurimetrics* 21 at 31.

[24] George J Annas , Leonard H Glantz & Patricia A Roche 'Drafting the Genetic Privacy Act: Science, policy and practical considerations' (1995) 23:4 *Journal of Law, Medicine and Ethics* 360.

[25] Ibid.

[26] Ibid 365.

[27] Human Genetics Commission Discussion Document *Whose Hands on Your Genes* (2000) at 6.

(1) Strict protections of autonomy, privacy and equal treatment of persons with genetic conditions threaten the accomplishment of public goods; and

(2) there is no clear demarcation separating genetic data from other health data.'[28]

Murray argues that there is no good moral justification for treating genetic information differently from other medical information.[29] He points out that many other types of medical information also provide 'probabilistic peeks' into future health risks and may give rise to discrimination.[30] He accordingly finds it difficult to justify the different treatment of genetic information.

Rothstein argues that the reasons for regarding genetic information as different from other medical health information are social rather than scientific.[31] O'Neill also rejects the genetics exceptionalism theory and draws a distinction between the use of genetic data and the data itself. She believes that there are good reasons for regarding certain uses of data as distinctive.[32] Genetic data becomes distinctive because of the way it may be used by third parties. Tavani agrees with O'Neill's argument only insofar as it relates to the use of genetic data being distinctive as opposed to the intrinsic nature of the data itself. He goes a step further and asks what exactly makes the use of genetic data distinctive and his answer lies in the advanced data processing technology that is now available.[33]

Tavani correctly argues that genetics exceptionalists focus too strongly on the differences between genetic and non-genetic personal information whilst anti-exceptionalists underestimate critical differences.[34] A few commentators have suggested a middle ground in relation to the classification of genetic information. Lemmens and Austin adopt a particularly robust approach to genetic information.[35] They convincingly argue that genetic information shares many of the characteristics of traditional health information and that it does not raise new legal or ethical questions. This argument is qualified by the acknowledgement that there is still a need for a

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[28] Op cit note 23 at 21.

[29] T Murray 'Genetic Exceptionalism and Future Diaries: Is Genetic Information Different from Other Medical Information?' in Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 71.

[30] Ibid 64.

[31] Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 459.

[32] Onora O'Neill *Autonomy and Trust in Bioethics* (2002) 105.

[33] Herman T Tavani 'Genomic research and data–mining technology: Implications for personal privacy and informed consent' (2004) 6 *Ethics and Information Technology* 15 at 21.

[34] Ibid 20.

[35] Trudo Lemmens & Lisa Austin *Of volume, death and speed: The challenges of genetic information* Report for the Canadian Biotechnology Advisory Committee (2001).

reassessment of existing regimes and consideration of the development of new regulatory responses. They argue that the following factors should be reasons for reassessing current regulatory approaches:

(1) exacerbation of existing ethical and social problems relating to general health information;

(2) elevation of existing social and ethical issues beyond the level of the individual, to family and community levels;

(3) the volume of information that can be extracted from one sample which can be kept indefinitely;

(4) speed of testing; and

(5) the link between genetics and computer technology.[36]

Lemmens and Austin conclude that 'the concerns raised by the advent of genetic testing are related more to what one can call an amplification of existing concerns about the use of health information than to the specificity of genetics. It is a matter of degree, or depth, more than a matter of newness.'[37]

Kosseim et al[38] have identified four general approaches to the protection of human genetic information:

(1) The personal information approach in terms of which genetic information is encompassed by the broad definition of personal data. Canada, France and New Zealand adopt this approach.

(2) The sensitive information approach which requires genetic information to be classified as sensitive data in order to be protected. This approached is followed by the European Parliament, Austria, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

(3) The medical information approach which recognises genetic information as medical information. The World Medical Association, Australia, Council of Europe, and the United States of America follow this approach.

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[36] Ibid 23.
[37] Ibid 2.
[38] Patricia Kosseim, Martin Letendre & Bartha Maria Knoppers 'Protecting genetic information: A comparison of normative approaches' (2004) 2:1 *GenEdit* 1 at 3-4.

(4) The genetic information approach which requires genetic-specific rules. UNESCO, the United Nations, and Israel follow this approach.[39]

Kosseim et al[40] adopt a similar view to that taken by Lemmens and Austin. They argue that the issues raised by genetic information are not new but a more acute form of those relating to other personal information. They do not support the idea of a separate legal regime to regulate genetic data. Instead, they recommend that existing frameworks governing personal information should be reassessed in light of the 'new' issues raised by genetics. These commentators favour the personal information regime because it focuses on the purpose for which personal information may be collected, used and disclosed rather than on the type of information sought to be protected.

It follows from the discussion above that it cannot be assumed that existing regulatory regimes will address the heightened challenges posed by genetic information. The first step in the assessment process would be to adopt an appropriate definition of genetic information and thereafter to determine the extent to which existing regulatory mechanisms protect such information. The definition or classification of genetic information will have a significant impact on the methods employed to protect it. From a legal perspective the definition of genetic information is crucial to the determination of the appropriate privacy protection model. It is important to determine whether genetic information should be treated as personal information, as sensitive information within the ambit of general data protection legislation, or whether it warrants separate attention. It is necessary to develop a definition which is neither too narrow nor too broad. A narrow definition might fail to provide adequate protection because too much information might be excluded from its ambit. A very broad definition, on the other hand, might provide protection to an unreasonably wide range of information thereby resulting in unreasonable restrictions on access.[41] The chosen classification and definition will influence the choice of protection mechanism. Suitable regulatory mechanisms include primary legislation, subordinate legislation, and industry codes.

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39 Ibid 6-8 and Annexed Tables of Information.
40 Op cit note 38.
41 Laurie op cit note 1 at 106.

Everett observes that 'the distinction between genetic and non-genetic medical information is central to the legal changes arising from the genetic privacy movement.'[42] I draw on Everett's observation in this research. I adopt the approach that any legal response to the challenges posed by genetic information must begin with a classification of genetic information. For the purposes of this research, genetic information is seen as medical information which gives rise to new legal challenges. The main reason for the close scrutiny of genetic information is its link with computer technology, the increasing number of genetic databases worldwide, and the unique third-party interest in genetic information. A suitable response will entail either developing new legislation or amending existing legislation to meet the demands of genetic information. Once again the response will, to a large extent, be determined by the classification of genetic information.

1.3 THE CONCEPT OF GENETIC PRIVACY

Privacy is entrenched as a fundamental right in the Bill of Rights.[43] Section 14 of the Constitution provides that –

> 'Everyone has the right to privacy, which includes the right not to have –
> (a) their person or home searched;
> (b) their property searched;
> (c) their possessions seized; or
> (d) the privacy of their communications infringed.'

The wording of s 14 makes it clear that this list is not exhaustive. The Constitution provides broad protection for the right to privacy but the right is not unlimited. De Waal et al identify three concerns which the right to privacy seeks to protect:

(1) the right to be left alone;

(2) the right to development of the individual personality; and

(3) informational privacy.[44]

This research advances the idea that genetic privacy falls within the realm of informational privacy and should therefore be protected by the right to privacy.

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[42] Margaret Everett 'Can you keep a (genetic) secret? The genetic privacy movement' (2004) 13:4 *Journal of Genetic Counselling* 273 at 278.

[43] Constitution of the Republic of South Africa Act 108 of 1996, ch 2, s 14.

[44] Johan De Waal, Iain Currie & Gerhard Erasmus *The Bill of Rights Handbook* 3ed (2000) 270.

Privacy is an amorphous concept[45] which has long been the subject of legal and philosophical debate. The issue of privacy has been discussed, debated, and thoroughly analysed from many perspectives. Privacy is undoubtedly an amorphous concept surrounded by a plethora of academic literature and intellectually stimulating scholarly debate. After much discussion on the topic, this concept remains as elusive as ever. This is borne out by the observation of the Constitutional Court in *Bernstein v Bester* that the 'use of this term has not been unproblematic'.[46] In making this observation the court referred to the varying definitions that have been accorded to privacy both nationally and internationally.

The debate has intensified in the wake of new technologies which pose new challenges to the concept of privacy. Computer technology and genetic technology are prime examples of areas that demand fresh scrutiny of existing privacy regimes. A combination of both technologies poses a major challenge to privacy in the traditional sense. Laurie aptly points out that 'there was no such concept as genetic privacy before scientific advances provided us with the means to gather and manipulate genetic information.'[47] The concept of genetic privacy is even more complex and thought-provoking than the traditional concept of privacy. This may be attributed to the new dimension added by genetic information to the traditional concept of health or medical information. As observed by Lemmens and Austin, genetic information takes the traditional concept of health information to a new level for various reasons.[48] It will be argued here that this, in turn, takes the privacy issue to a new level.

Laurie correctly observes that 'the history of privacy has been beleaguered by obscanturism and imprecision'[49] but he argues that the amorphous nature of privacy does not mean that it cannot or should not be protected.[50] He takes the view that the law has an important role to play in the protection of privacy and that the issue of genetic privacy must be addressed regardless of the challenges that lie ahead. This research, to a large extent, takes up the challenge identified by Laurie.

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45 *Bernstein & others v Bester & others* 1996 (2) SA 751 (CC) at 787-8.
46 Ibid 791.
47 Op cit note 1at 25.
48 Op cit note 35.
49 Op cit note 1 at 26.
50 Ibid 51.

Gostin suggests that one way of attaining reasonable privacy protection is by developing 'rigorous legal safeguards.'[51] Writing in 1995, he found that existing legal 'safeguards were inadequate, fragmented, inconsistent, and contained many gaps in coverage.'[52] It has been suggested in the literature that de-identifying genetic data renders it anonymous thereby reducing the need for privacy protection. Gostin notes that advances in computer technology have made it possible to search multiple databases resulting in the ability to link genetic information to an individual. He concludes that non-linked genetic data is not a guarantee of anonymity and that all genetic information must be accorded due privacy protection. Gostin's concern lies with those privacy statutes which exempt anonymous genetic information from their ambit of application. He argues that privacy protections must be put in place to prevent so-called anonymous genetic data from being linked to individuals.[53]

Genetic privacy usually focuses on informational privacy. The protection of genetic information privacy is aimed at preventing the unauthorised disclosure of private information, thereby preventing consequential harm. Kim proposes a privacy paradigm as opposed to an anti-discrimination approach for the protection of genetic information.[54] This is simply because the flow of information is easier to monitor and enforce as opposed to the use of information once it is in the hands of an insurer or employer.

Access to genetic information is largely unchartered territory in South Africa at this stage. There is a patchwork of protections against unfair discrimination, medical testing in the employment sphere, and privacy in general, but in essence the matter is entirely new. The South African Law Reform Commission (SALRC) recently completed an investigation into data protection with a view to developing a data protection statute for South Africa.[55] A Bill[56] has been developed, which takes the form of a general data protection statute which still leaves the door open for sectoral laws and industry codes of practice. The draft Bill makes provision for the protection of health information privacy. It also considers the protection of information pertaining to 'inherited characteristics'.

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51 Lawrence O. Gostin 'Genetic privacy' (1995) 23 *Journal of Law, Medicine and Ethics* 320 at 324.
52 Ibid.
53 Ibid 322.
54 Pauline T. Kim 'Genetic discrimination, genetic privacy: Rethinking employee protections for a brave new workplace' (2002) 96 Northwestern University Law Review 1497 at 1551.
55 South African Law Reform Commission (Project 124) *Privacy and Data Protection.*
56 B9-2009.

Protecting genetic information privacy, like other forms of privacy, is a balancing act. It is necessary, when implementing regulatory mechanisms, to ensure that the rights of the individual do not unreasonably curtail research efforts which could benefit the public. It is clear from the literature review that the concept of genetic privacy is a challenging one that has attracted attention from many quarters. It has not been satisfactorily addressed to date and is by no means a problem that is easily solved. It is therefore important to learn from the experiences of other jurisdictions and to reach a point where differing approaches can be critically analysed for the benefit of South Africa. Hence, the cross-jurisdictional review.

A review of international regulatory responses to the protection of human genetic information reveals that most countries acknowledge a need to protect genetic information although the approaches vary in form and scope. I do not propose the wholesale adoption of any jurisdiction's approach on the protection of genetic information privacy. What I attempt to do, through this research, is to inform policymakers and legislators of the debates surrounding genetic information privacy and to propose an eclectic approach for South Africa. This entails proposing the development of genetic privacy legislation which will provide comprehensive privacy protection for genetic information. This approach should obviate the need for further legislation, thereby preventing the development of overlapping or conflicting statutes and regulations. It will also promote consistency in an area which is riddled with problems. Proposing the development of genetic privacy legislation while rejecting the core arguments supporting genetics exceptionalism might appear to be contradictory when viewed in the light of existing literature. The reviewed literature indicates a link between specific genetic privacy protection legislation and genetics exceptionalism. It will be argued here that it is not the nature of genetic information itself which justifies separate legislative treatment but the unique third-party interest shown in it, coupled with its potential for misuse and advances in bioinformatics. Essentially, this amounts to a rejection of genetics exceptionalism and the genetic inclusivist approach. It is an alternative approach which represents a compromise position for reasons which differ from those already advanced in the reviewed literature.

1.4 ISSUES ADDRESSED IN THE STUDY

There are many issues and concerns pertaining to access to and disclosure of genetic information. The deciphering of the human genome has ushered in a new era of genetics which poses its own challenges to traditional legal concepts and regulatory frameworks. Most countries recognise the need for genetic privacy protection. This research explores the different approaches adopted in selected jurisdictions as well as the underlying reasons for the variation in approaches.

Section 14 of the Constitution provides individuals with a right to privacy which includes the right not to be subject to searches of their person, home or property; seizure of their possessions; or violation of private communications. Even though the right to privacy enjoys constitutional protection, the challenges posed by a combination of genetic technology and information technology require legislative intervention. Neethling et al note that the creation of databanks 'pose an immense threat to the individual' due to the use of computer technology.[57] It is clear that data protection legislation is required in South Africa but this raises further issues pertaining to the exact scope of such legislation. The second issue relates to the nature of genetic information as encapsulated in the ongoing academic debate about genetics exceptionalism. The choice of regulatory intervention depends, to a large extent, on the definition of genetic information.

Many of the concerns around the use of genetic information may be attributable to genetics exceptionalism. Some of these concerns do have merit and therefore warrant attention. The first concern is the potential for violation of individual privacy rights due to an inadequate regulatory framework for the protection of genetic information. The second concern is the impact of inadequate privacy protection on international collaborative research prospects for South African researchers. Due to globalisation and the importance of medical research it is crucial that South Africa positions itself as an international role-player. This means acknowledging the importance of comparative law in the development of regulatory measures for South Africa. Cross-border flow of data may be necessary in international collaborative research. If South Africa fails to promulgate adequate data protection legislation, this flow of data may not be possible in certain cases, for example, in the case of data transfer between South Africa and member states of the European Union.

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[57] Op cit note 22.

What is further sought is the means of dealing with genetic data in an information privacy regime. General data protection legislation might not adequately address the challenges posed by genetic information. Even though general data protection legislation is being developed in South Africa, the issue of how it may improve genetic information protection must still be assessed in the light of regulatory developments in other countries. The Organisation for Economic Co-operation and Development (OECD) is considering extending membership to South Africa. That decision will be affected by South Africa's ability to adopt OECD practices, policies, and standards. It is therefore crucial for legislators to consider this aspect when developing legislation.

A significant aspect of this study is the identification of privacy concerns surrounding genetic information. There have been inquiries in other countries but there is no empirical evidence in this regard in South Africa due to the fact that the area of genetic privacy is still in its infancy here. In 2001 the Life Offices' Association (LOA) developed a Code of Genetic Testing as part of its Code of Conduct.[58] The introduction to the Code noted that various consumer groups had indicated concern about genetic testing and its impact on the availability of insurance. This concern extended to the potential misuse of genetic information by the insurance industry. In 2009 the Association for Savings and Investment SA (ASISA)[59] issued a similar Standard on Genetic Testing which replaced the LOA Code.[60] The introduction to the document states that changes to the policy may become necessary in time depending on changes in technology and consumer attitudes. It is apparent that the insurance industry is monitoring developments in the area of genetics and that their policies will be amended accordingly. The law should be equally proactive and should not be allowed to lag behind industry in this regard.

The following issues are accordingly addressed in this study:

(a) The challenges posed by genetic databases.

(b) Access to genetic information by insurers, employers, and researchers.

(c) The current state of privacy protection in South Africa. This includes the identification of inadequacies and gaps in the legal framework.

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[58] Life Offices' Association *Code of Conduc*t (2001) ch 20.

[59] The LOA was disbanded in 2008 and its functions were subsumed by the Association for Savings and Investment SA (ASISA), which is a representative body for many savings, investment, and insurance organisations, including the LOA.

[60] *Standard on Genetic Testing* (2009) available at http://www.asisa.org.za/index.php/members/codes.html, accessed on 17 April 2012.

(d) The introduction of a privilege for the protection of genetic information in order to protect genetic information from disclosure in court proceedings.

(e) The state of genetic information protection in selected countries.

(f) Scope for changes to the existing legal framework in order to achieve an adequate level of genetic privacy protection.

1.5 RESEARCH METHODS AND SCOPE

This is primarily a legal study which incorporates aspects of bioethics and philosophy. The areas of law that are covered are insurance, labour, evidence, and medical law. Two methods of analysis are used; namely, legal and ethical analysis. Legal issues are addressed by analysing national laws, international laws, international conventions, and treaties. Bioethical issues are addressed through the study of national and international ethical guidelines. Both areas of research are supported by secondary sources; namely, academic literature in books and journals, institutional research reports, and internet sources.

The research commences with a summary of the legal and ethical debates surrounding genetic information privacy. The purpose of such a discussion is to provide background information on the multifarious, controversial, and often polarised views on the protection of genetic information. Such sensitisation is necessary in order to foster an understanding of the legal and ethical challenges that are posed by genetic information. An overview of the most common concerns associated with genetic information is also provided with the aim of justifying the call for legislative protection of genetic privacy. Secondary sources of information are mainly used for this purpose.

A crucial aspect of this research is the cross-jurisdictional review of legal, ethical, and policy developments in Australia, Canada, the Netherlands, the United Kingdom and the United States of America. The positions in the constituent states, countries, territories, and provinces are not discussed in detail but where significant differences are observed, these are noted. National laws, international conventions, and treaties are analysed for this purpose. The findings of this review are recommended for lawmaking efforts in South Africa.

The discussion of the South African position is based on the analysis of the constitution, case law, common law, ethical guidelines, institutional codes of practice, professional rules, and

academic literature. The research concludes with recommendations for improvements to the South African information protection regime.

On a theoretical level this research favours neither the genetics exceptionalist approach nor the genetic inclusivist approach in their entirety. It adopts a middle ground, with the aim of finding a legally sound solution to the challenges posed by genetic information. It is based on the view that genetic information is distinctive enough to warrant renewed scrutiny of existing regulatory mechanisms in order to determine their adequacy for the protection of this type of information. The approach may be described as eclectic and pragmatic.

In South Africa privacy is protected by the common law and the constitution. I accept that informational privacy is the most suitable framework for dealing with genetic privacy. This research accordingly focuses on informational privacy. The right of informational privacy protects individual autonomy by preventing forced disclosure of information or unauthorised acquisition of information about an individual. I adopt the view that controlling the flow of genetic information is key to protecting genetic information.

The legal, ethical, and policy issues are analysed in relation to the academic literature on genetic privacy and international regulatory responses in the selected jurisdictions. The different regulatory responses are reviewed with a view to finding a compass which will point South African legislators in the right direction. The view is taken that there is no need to 'reinvent the wheel'. As Partlett points out, '[l]ike the advantage of the second in line to manufacture or market products, lawmakers garner valuable information in observing the trials, tribulations, and triumphs of another's law reform efforts.'[61] The approaches in the selected jurisdictions are therefore critically analysed for characteristics which could prove beneficial to South Africa. The aim is to find a pragmatic approach which fits the South African situation whilst avoiding the pitfalls of genetics exceptionalism and the genetic inclusivist approach.

The scope of this research is limited in three respects. First, Asian countries are not included in the cross-jurisdictional review due to the noticeable absence of genetic privacy protection in these jurisdictions. It was accordingly expected that this research would reap minimal benefit from a study of genetic privacy in Asian jurisdictions, hence the exclusion. The emphasis has been placed on those countries which have made noticeable progress in this area and which

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[61] David F Partlett 'Misuse of genetic information: The common law and professionals' liability' (2003) 42 *Washburn Law Journal* 500 at 509.

therefore have much to offer in terms of solutions and lessons based on experience. Secondly, since the aim of this research is to promote genetic privacy protection in South Africa, a comprehensive analysis of genetic discrimination is not undertaken. The brief discussions of genetic discrimination are merely a means to an end, which is that of justifying the need for genetic privacy protection. Thirdly, this research focuses on the protection of privacy in the context of information derived from genetic samples and not on actual genetic material or samples from which such information may be derived. The focus is accordingly on informational privacy. Privacy concerns relating to tissue banks and biorepositories are therefore not addressed.

1.6 OUTLINE OF CHAPTERS

Chapter one is an introduction to the research. It provides background information, objectives of the study, an exposition of the concept of genetic privacy as well as the surrounding debates, discussion of the issues and concerns relevant to the protection of genetic privacy, a theoretical framework which indicates what perspective is adopted in relation to the academic debates inherent in a newly emerging field, and a statement of the research methodology.

Chapter two provides an overview of forensic and research DNA databases because of their inextricable link with the concerns which gave impetus to this research. The concern over the creation of genetic databases and the potential for third party access to personal information have given rise to renewed calls for further protection of individual privacy. The threat of violation of privacy is heightened because of the link between genetic technology, information technology, and the creation of databases of genetic information. These aspects are addressed with a view to justifying the undertaking of this study.

Chapter three provides an overview of the interests of employers, insurers, and researchers in genetic information and the need for privacy protection as a mechanism to prevent genetic discrimination which could arise from the violation of privacy. Similar to the previous chapter, this chapter is intended to justify the need for an adequate genetic privacy regulatory framework in South Africa. Chapter four provides a legal exposition of the right to privacy in South Africa and culminates in a discussion of the right to genetic information privacy. Chapter five deals exclusively with evidentiary privilege insofar as it may be extended to genetic information.

Chapter six deals with legislative developments in selected jurisdictions; namely, Australia, Canada, the Netherlands, the United Kingdom and the United States of America. The Netherlands has characteristics which make it suitable for this purpose: first, it is a member State of the European Union; secondly, it is a signatory to the Convention on Human Rights and Biomedicine;[62] and thirdly, it has data protection legislation which is also intended for genetic privacy protection. The Convention on Human Rights and Biomedicine is important because it is a binding instrument in the area of genetic privacy protection. The Netherlands differs from the other jurisdictions under review to the extent that it has legislation aimed at protecting genetic privacy together with a moratorium on the use of genetic information by insurance companies.

The United Kingdom and Australia are considered for the insight that they can provide through the research they have already undertaken into genetic privacy and the reform recommendations they have proposed. The Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council undertook a joint inquiry into the protection of human genetic samples and information.[63] The project has been described as 'the most comprehensive consideration of the ethical, legal and social implications of the "New Genetics" ever undertaken.'[64] The Human Genetics Commission in the United Kingdom has conducted two relevant inquiries into genetic information.[65] The work of the commission is ongoing and provides valuable insight into public attitudes and concerns relating to genetic information. The recommendations made by the Commission are based on actual public concerns and not just on perceptions of policymakers and legislators.

Canadian developments are of interest and are based on the work of the Canadian Biotechnology Advisory Committee. An analysis of the Canadian position is intended to indicate how general privacy legislation may be used to protect genetic privacy. In the United States of America most of the relevant legislation has been developed within an anti-discrimination paradigm and most legislative measures exist at state level only. The individual States have

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62 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* (1997).

63 Supra note 7.

64 Ibid 33.

65 HGC Discussion Document op cit note 75; Human Genetics Commission *Inside Information: Balancing Interests in the Use of Personal Genetic Data* Summary Report (2002).

adopted divergent approaches to the protection of genetic information with emphasis being placed on prevention of improper use. The American position does help to demonstrate why a privacy approach has been favoured over an anti-discrimination approach in this research.

Chapter seven focuses on legal and industry developments in South Africa relating to the protection of genetic privacy. The following specific instruments are critically anlaysed: the Personal Data Protection Bill;[66] the Employment Equity Act 55 of 1988; and the Code of Conduct of ASISA.[67] Chapter eight concludes this research. It also contains recommendations for legislative intervention to adequately address the protection of genetic privacy in South Africa.

[66] Supra note 56.
[67] Supra note 60.

CHAPTER II

GENETIC DATABASES

2.1 INTRODUCTION

> 'Whether established for the purpose of finding genes, predicting, diagnosing, or treating genetic disease, or identifying criminal suspects, soldiers missing in action, or other missing persons, DNA banks and DNA data banks hold tremendous promise. But DNA banking and DNA data banking also raise novel legal, ethical, and public policy challenges.'[1]

The purpose of this chapter is to highlight and discuss the issues and concerns pertaining to genetic databases with the aim of supporting the argument that there is a need for genetic privacy legislation in South Africa. The right to privacy is considered in the context of genetic information contained in databases. The acquisition, use and retention of DNA samples and profiles affect the individual's right to privacy. Allen notes that genetic privacy denotes informational privacy since it requires the confidentiality of genetic information as well limits on third-party access to genetic information.[2]

Deoxyribonucleic acid (DNA) is an acid molecule found in the nucleus of cells. It carries genetic information in the cell. The structure of DNA was discovered in 1953 by Francis Crick and James Watson. It is accepted that no two individuals, except for identical twins, have the same DNA profile. This is why DNA is referred to as a 'distinctive biometric identifier'. This is the factor that makes DNA an invaluable tool in criminal investigation. Biological samples such as hair, blood, semen, saliva, and skin are taken from the subject for DNA analysis. Non-coding sections of DNA (sometimes referred to as 'junk DNA') are analysed to generate a DNA profile. The profile is expressed as a set of numbers and a sex chromosome.

A database is defined as 'a collection of data which is organized, prioritised and available for consultation, the content of which can evolve by the addition of updated

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1 Jean E. McEwen 'DNA Data Banks' in Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 232.

2 Anita L Allen 'Genetic Privacy: Concepts and Values' in Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 33.

information, and which, in this day and age, is always computerised, according to a variety of structures.'[3] A databank/biobank refers to a collection of biological samples such as saliva, hair, semen, and blood, from which DNA can be extracted. A genetic database usually refers to the former or to a combination of the two. The terms 'DNA database' and 'genetic database' are used interchangeably here because genetic information is derived from biological samples through DNA analysis.

Issues and concerns relating to forensic and research databases are discussed here. DNA databases are useful tools in clinical medicine, genetic research, and forensic science. They prove particularly useful in the investigation of crimes where the recidivism rates are high, for example, sexual offences. In addition to proving guilt, they are being used to exonerate the innocent.[4] They are also useful for pharmacogenomics research. This chapter culminates in conclusions which will be useful for the future regulation of genetic databases in South Africa.

2.2 FORENSIC DNA DATABASES

(a) The emergence and development of forensic DNA databases

Fingerprint analyis is the oldest biometric technique used for identification purposes. The first documented interest in fingerprints was a paper written in 1684 by Dr Nehemiah Grew. The first British court conviction using fingerprint evidence was obtained in 1902. Fingerprinting science was followed by blood-group antigen typing and then by DNA profiling. Sir Alec Jeffreys, a British geneticist, developed DNA profiling in 1984. He found that DNA contains certain distinctive markers which differ in individuals. He called these markers mini-satellites and the process became known as DNA fingerprinting.[5]

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[3] Anne Cambon-Thomsen, Clémentine Sallée, Emmanuelle Rial-Sebbag & Bartha Maria Knoppers 'Populational genetic databases: Is a specific ethical and legal framework necessary?' (2005) 3:1 *GenEdit* 1.

[4] The Innocence Project in the United States of America is an excellent example of this. See http://www.innocenceproject.org accessed on 10 December 2008.

[5] Melissa Lee Phillips 'Crime scene genetics: Transforming forensic science through molecular technologies' (2008) 58:6 *BioScience* 484 at 485.

Polymerase chain reaction (PCR), a molecular biological method for amplifying DNA,[6] was subsequently developed by Kary Mullis. In 1993 Mullis was awarded the Nobel Prize in Chemistry for his development of the PCR technique.[7] This technique makes it possible to artificially replicate an individual DNA segment of any genetic material several million times. In forensics, PCR has proved very useful as it makes it possible to analyse the DNA in very small biological samples such as a drop of blood. PCR forms the basis of all current forensic DNA analysis methods.

The PCR method facilitated the creation of DNA databases. It has been noted that prior to the discovery of PCR, the use of DNA fingerprinting was reactive.[8] A suspect had to be identified in order to obtain a DNA sample for comparison with a sample obtained from a crime scene. DNA databases have allowed police to be proactive in their investigation of cases. Now all that is required is a crime scene sample which can be compared against profiles contained in the database. The benefits of DNA databases have been found to include 'the potential to make speedy and robust suspected offender identifications through automated profile comparisons in centralised criminal justice databases; the ability to confidently eliminate innocent suspects from investigation; the increased likelihood of generating reliable and persuasive evidence for use in court; a reduction in the cost of many investigations; the likely deterrent effect of DNA databasing on potential criminal offenders; and a possible increase in public confidence in policing and in the wider judicial process.'[9]

The world's first forensic DNA database, the National DNA Database (NDNAD), was established in Britain in 1995. This is currently the world's largest forensic database per head of the population.[10] It contains samples and profiles from individuals who are suspected of, charged with, reported for or convicted of a recordable offence. It is seen

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6 See http://www.informationheadquarters.com/SARS/Polymerase_chain_reaction.shtml, accessed on 26 April 2012.

7 Ibid.

8 Robin Williams & Paul Johnson 'Inclusiveness, effectiveness and intrusiveness: Issues in the developing uses of DNA profiling in support of criminal investigations' (2005) 33:3 *Journal of Law, Medicine & Ethics* 545 at 546.

9 Ibid.

10 Privacy International 'United Kingdom Privacy Profile' (January 26, 2011) available at https://www.privacyinternational.org/article/united-kingdom-privacy-profile, accessed on 6 March 2012.

as a 'model example of the installation and use of forensic DNA databasing.'[11] A number of countries have since established national forensic databases which contain DNA profiles from suspects and convicted offenders as well as crime scene samples.

The benefits of DNA databases are substantial and undeniable. This technology makes it possible to solve criminal cases which previously would have remained unsolved. The use of DNA technology in the criminal justice system has been described as the most significant development in forensic science since fingerprinting.[12] [13] It has also been referred to as 'the gold standard for identification in contemporary society.'[14] As noted by leading commentators, 'although DNA banking and data banking take place in a variety of contexts, nowhere have these activities proliferated more rapidly than in the area of law enforcement.'[15] The combination of genetics and information technology has resulted in a powerful crime-fighting tool.

(b) Issues and concerns relating to forensic DNA databases

The creation of forensic DNA databases has been acknowledged as one of the areas of greatest controversy.[16] Notwithstanding the benefits of DNA databases, they do pose enormous challenges. Basic issues such as definitions of genomic terms have been fraught with difficulty. It has been noted that the 'potential uses and abuses of forensic databases are considerable.'[17] Legal parameters need to be set as in the case of the NDNAD in the United Kingdom.[18] However, the legislative framework must not have an inhibitory effect on crime detection and prosecution. It is imperative that a balance be struck between the individual's right to privacy and society's need for crime reduction.

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11 Paul Johnson & Robin Williams 'Internationalizing New Technologies of Crime Control: Forensic DNA Databasing and Datasharing in the European Union (2007) 17:2 *Policing & Society* 103 at 106.

12 Aaron P. Stevens 'Arresting crime: Expanding the scope of DNA databases in America' (2001) 79 *Texas Law Review* 921.

13 Op cit note 8.

14 Ibid.

15 McEwen op cit note 1at 232.

16 Nuffield Council on Bioethics 'The forensic use of bioinformation: ethical issues' (2007) available at http://www.nuffieldbioethics.org/bioinformation, accessed on 19 April 2012.

17 Ibid ch 7 at 91.

18 Discussed further at 157 below.

The legal challenges arise in the context of the secondary use of data without the consent of the individuals from whom such data originate; cross-border sharing of data; the inclusion of data from minors; the inclusion of data from arrestees; and the indefinite storage of data. All of these issues pose threats to individual privacy. Forensic DNA databases have been the subject of much controversy and have initiated debate on the need for legal regulation.

There is no uniformity in the approaches to databases. Numerous differences exist with regard to the categories of persons included in databases, retention periods, and criteria for destruction of samples. This lack of harmonisation poses its own challenges for the cross-border sharing of data and international policing efforts. There is no generally accepted minimum standard of protection applicable to information contained in forensic DNA databases. Data sharing is becoming increasingly important for law enforcement purposes. The challenge lies in developing legislation that will prescribe adequate protection for all DNA information leaving any jurisdiction as well as affording adequate protection to DNA information brought from outside the jurisdiction. Uniformity in the level of protection is pivotal to the success of cross-border law enforcement initiatives.

The issue of human rights is important when dealing with forensic DNA databases. A delicate balancing act is required in order to protect the privacy of the individual whilst respecting the interest of the State in addressing crime. It is possible to achieve this balance through legislation. Of major concern is the retention of DNA samples and profiles of persons who have not been convicted of offences. From a human rights perspective it is easier to justify retaining DNA information of persons who are convicted of crimes as opposed to retaining the information of those who are not convicted. If the constitutionality of the retention of DNA samples and profiles of an unconvicted person is challenged as an invasion of the right to privacy, it will be difficult to prove a justifiable limitation of the right. The weighing up of competing interests by the European Court of Human Rights (ECtHR) in M*arper v The United Kingdom*[19] is proof of this. Legislation which seeks only to further the interests of the State in detecting and

[19] *S and Marper v The United Kingdom* 30562/04 [2008] ECHR 1581 (4 December 2008).

preventing crime is, however, not advisable as it serves only to erode public confidence in the use of invaluable technology.

The decision of the ECtHR in *Marper*[20] is of great value to this research as it objectively analyses the impact of the United Kingdom's NDNAD on the right to privacy. It is also a judgment dealing with the world's first and largest DNA database which has had great influence in the rest of the world. It must be given serious consideration even by countries outside the European Union because it has the potential to influence national judiciaries when considering international law for the purpose of delivering judgment. The United Kingdom has played a pioneering role in this field but this judgment proves that the rules regulating the NDNAD are not necessarily the most progressive in terms of respect for human rights.

(i) Secondary use of data

> 'While issues such as who should be included in a database, how long profiles should be retained, and what searches can be conducted, are often clearly established in specific legislative language, the uses to which samples can be put subsequent to a usable database profile being developed is rarely so specifically regulated. Except for the small minority of countries that require the relatively expeditious destruction of samples once profiling has been performed and checked, countries generally fail to identify what uses may or may not be made of biological material. Given the potential uses, both appropriate or not, legal and illegal, it is surprising how little attention has been paid, globally, to the issue of the non-forensic uses of forensic samples.'[21]

One of the challenges posed in the case of genetic databases arises from the unauthorised use of samples or the secondary use of samples. This entails the use of data for purposes other than those for which they were originally collected. For example, DNA obtained from an accused during criminal investigations should not be used for research and vice versa. Also, where a donor consents to the use of a sample for research in one specific instance, that sample should not be used for any other research because the donor has not consented thereto. In relation to forensic databases the main concerns are the use of database information to study the genetics of criminal behaviour and to infer ethnicity.

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[20] Ibid.

[21] Christopher H. Asplen, *The Non-Forensic Use of Biological samples Taken for Forensic Purposes: An International Perspective* (Report prepared for the American Society of Law, Medicine and Ethics) 1.

There is a need for legislative safeguards to prevent the inappropriate use of information contained in forensic databases. It has consistently been argued that the loci used for forensic purposes contain non-coding sequences and can therefore not be used for other purposes such as determining genetic predisposition to illness. This argument is correct only insofar as it relates to DNA profiles. It cannot succeed where DNA samples are in issue. DNA samples can always be reanalyzed and put to inappropriate uses in the future.

Sample destruction is the only way of preventing further use of samples. In Europe the EU Directive 95/46/EC deals with the protection of individuals insofar as the processing of personal data and the free movement of such data are concerned. Article 3 of the Directive provides that it 'does not apply to the processing of personal data when such processing operations involve the activities of a State in criminal law.' This results in the exclusion of forensic information from the ambit of the Directive. The Directive will, however, become applicable as soon as forensic information is used for purposes outside the scope of criminal law. This must be borne in mind by agencies seeking to access forensic information for non-forensic purposes. The Directive therefore does provide a certain level of protection in the event of the secondary use of genetic information.

(ii) Cross-border transfer of data

The concern lies in the sharing of data between countries that do not necessarily offer similar levels of legal protection. This jeopardises the right to privacy. The Prüm Treaty[22] (also referred to as Schengen III)[23] is a multilateral agreement between Germany, Austria, Spain, France, Belgium, Luxemborg and the Netherlands aimed at preventing cross-border crime and promoting cross-border policing. Finland, Italy, Portugal, Slovenia, Greece, Sweden, Bulgaria, Romania, Slovakia, and Hungary have also signed the treaty.
It provides for the creation of a network of national databases to promote the exchange of information between law enforcement authorities in the contracting States. Provision is

[22] Signed on 27 May 2005 by the Netherlands, Austria, Germany, Belgium, Luxemborg, Spain and France. Thereafter Finland, Italy, Portugal, Slovenia, Greece, Sweden, Bulgaria, Romania, Slovakia, and Hungary also signed the treaty.

[23] Even though it is not a part of the Schengen Treaty, it is referred to as Schengen III because it was initiated by the same group of countries that signed the Schengen agreement.

made for reciprocal access to databases containing DNA profiles. The provisions of the multilateral agreement have been integrated into the legislative framework of the European Union under the Third Pillar. The treaty has been incorporated into a Council Decision which is binding on all member States. 'While the treaty represents progress in the field of cooperation against crime, the implications of this treaty are far reaching. It raises privacy and data protection issues which will affect all EU citizens, primarily due to the absence of common legally binding data protection standards.'[24]

The possibility of linkages of databases across borders exacerbates concerns relating to privacy. Concerns are at their peak in the United Kingdom due to the British government's assent to the Prüm Treaty. The concern is that the samples and profiles of innocent individuals as contained in the NDNAD will now be accessible to other countries. It has been argued that accession to the Prüm Treaty without informed debate sets a dangerous precedent for the European Union and that 'privacy has become subservient to security.'[25] In 2001 member states of the European Union agreed on the use of a common set of DNA markers so as to facilitate the cross-border exchange of DNA profiles.[26] Of crucial importance here is the European Union Data Protection Directive[27] which permits transfer of data to countries outside the European Union only if such countries provide an adequate level of protection for such data.

(iii) Retention of samples and profiles of persons not convicted of crimes

This issue requires serious consideration. Of even greater concern is the trend towards obtaining samples from persons who are merely arrested and not subsequently charged or convicted. The *Marper* judgment[28] is invaluable in this respect as it discusses the impact of such actions on the individual's right to privacy. In *Marper* the applicants argued that the retention of DNA samples and profiles of unconvicted persons is not proportionate to the aim of detecting and preventing crime. The court observed that the protection

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[24] Sylvia Kierkegaard 'The Prüm decision – An unconditional fishing expedition in 'Big Brother' Europe' (2008) 24:3 *Computer Law & Security Report* 243.

[25] Ibid 251.

[26] EU-Council Resolution 201/C187/01.

[27] 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, Article 25.

[28] Supra note 19.

afforded by the Convention for the Protection of Human Rights and Fundamental Freedoms 'would be unacceptably weakened if the use of modern scientific techniques in the criminal-justice system were allowed at any cost and without carefully balancing the potential benefits of the extensive use of such techniques against important private-life interests.'[29] The court engaged in a balancing exercise to determine whether the retention of the applicants' DNA was justifiable or not. It acknowledged the importance of DNA information in fighting crime. Notwithstanding this it clearly stated that the question is not whether the retention of DNA information may in general be regarded as justified but whether the retention of DNA information of persons suspected, but not convicted, is justified.[30] It held that the retention of profiles of unconvicted persons violates their right to privacy.

(iv) Retention of samples and profiles of children

The United Nations Guidelines for the Prevention of Juvenile Delinquency (Riyadh Guidelines) provides that: '...youthful behaviour or conduct that does not conform to overall social norms and values is often part of the maturation and growth process and tends to disappear spontaneously in most individuals with the transition to adulthood; in the predominant opinion of experts, labelling a young person as "deviant," "delinquent" or "pre-delinquent" often contributes to the development of a consistent pattern of undesirable behaviour by young persons.'[31] The inclusion of children's samples and profiles in a forensic database will serve only to stigmatise them. It is in total conflict with the Riyadh Guidelines.

(v) Profile and sample retention periods

It is often argued that in order for forensic databases to operate effectively, police must be given the power to retain DNA profiles obtained from samples. A few controversial issues arise here:

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29 Supra note 19 para 112.

30 Supra note 19 para 106.

31 Articles 5(e) and (f) of the UN Guidelines for the Prevention of Juvenile Delinquency (*The Riyadh Guidelines*) (1990) Adopted and proclaimed by General Assembly resolution 45/112 of 14 December 1990 available at http://www.unhchr.ch/html/menu3/b/h_comp47.htm, accessed on 20 December 2008.

(1) Is it necessary to retain profiles and the samples that were used to generate such profiles? Forensic DNA databases are created for the sole purpose of utilising stored DNA information as a tool in solving crimes. Proceeding on this basis, only the retention of DNA profiles can be justified. The sample is only a means to an end, which is the creation of a DNA profile to be used for comparison against other profiles contained in a database. It is submitted that once the sample has served its purpose there can be no legitimate justification for retaining it.

(2) What purpose is sought to be achieved by the retention of samples? The argument frequently made in favour of retaining samples is that DNA will be available for future analysis using new and superior technologies. The mere retention of samples poses an enormous threat to individual privacy since the sample can always be used for further analysis unrelated to forensic purposes long after the individual is acquitted or released from prison. This is hard to justify in a democratic society based on constitutional values and principles.

(3) If retention is necessary, what time limits, if any, should apply?

In the United Kingdom bodily samples and DNA profiles may be retained indefinitely. This approach is hard to justify especially when coupled with the fact that some of these profiles and samples are obtained from people who are arrested but not subsequently charged or convicted. There are a number of decided cases which successfully challenged the legality of identification using DNA profiles which should have been removed from the database. *R v B*[32] was a case involving the rape of a 66-year old woman. A DNA profile was obtained from the semen and was entered in the National DNA database. A year later the defendant was arrested and charged in connection with an unrelated offence of burglary. A saliva sample was taken from him. The defendant was subsequently acquitted of the charge of burglary and the sample should have been destroyed as soon as practicable after the acquittal but it was not. A match was subsequently made between the DNA profile obtained from the semen and the DNA profile obtained from saliva taken from the defendant. On the basis of the match between the two DNA profiles, the police arrested the defendant in connection with the rape of the 66-year old woman. The police then obtained a DNA profile from a sample of hair

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[32] *Attorney General's Reference* (No. 3 of 1999) [2000] 2 Cr. App. R.416.

plucked from the defendant's head and compared this to the DNA profile obtained from the semen. On the basis of a match they charged the defendant with burglary, assault and rape relating to the woman.

The trial judge held that the DNA evidence was inadmissible as the saliva sample which had been used in generating the initial match should have been destroyed after the defendant's acquittal on the burglary charge. The court was basically saying that had it not been for the unlawful retention of the saliva sample, the whole series of events resulting in the defendant being charged with rape would not have materialised. No initial match between the DNA profile obtained from the semen and the DNA profile obtained from the saliva would have been possible; the defendant would not have been arrested in connection with the rape, the sample of plucked hair would not have been obtained after the defendant's arrest in connection with the rape; a second DNA match between the DNA profile obtained from the semen and the DNA profile obtained from the plucked hair would not have been possible, and the defendant would not have been subsequently prosecuted, had it not been for the illegal retention of the saliva sample. The defendant was accordingly found not guilty.

In *R v Weir*[33] the defendant had been charged with drug related offences. A saliva sample had been taken from him and sent for DNA profiling. The case against the defendant was discontinued but the DNA sample was not destroyed. During investigation of a subsequent burglary the police found a match between the defendant's profile and a crime scene profile. The defendant was arrested and two blood samples were taken which confirmed the match. He was convicted and sentenced to life imprisonment. He appealed against his conviction on the grounds that the saliva sample should have been destroyed. The Court of Appeal overturned the conviction indicating that the Police and Criminal Evidence Act of 1984[34] prohibited the use of the saliva sample in the investigation relating to the burglary.

The defendants in the cases discussed above had been found guilty of crimes on the basis of DNA profile matches in cases where such profiles should have been removed

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33 [2001] 2 Cr. App. R.9.
34 1984 c. 60.

from the database. The Criminal Justice and Police Act[35] was subsequently promulgated to alleviate the problems being encountered with the retention of profiles. This Act permits the indefinite retention of samples and profiles of unconvicted persons. In this regard the NDNAD is different from similar databases in other countries, including those in the rest of Europe.

The judgment of the ECtHR in *Marper*[36] is also important in this regard. The facts of the case are briefly as follows: both applicants were citizens of the United Kingdom. They had been arrested and charged in respect of different offences in 2001. At the time of the arrest S had been just eleven years old. Their fingerprints and DNA samples were taken upon arrest in accordance with the provisions of the Police and Criminal Evidence Act 1984. S was subsequently acquitted and the case against Marper was discontinued. Both applicants had then requested that their fingerprints and DNA samples be destroyed but both requests were refused. The applicants applied for judicial review of the decision by the police not to destroy their fingerprints and samples. The Administrative Court rejected their application.[37] This decision was upheld by the Court of Appeal.[38] The applicants thereafter appealed to the House of Lords but their appeals were dismissed.

The applicants then approached the ECtHR on the grounds that the retention of their fingerprints, biological samples, and DNA profiles by the police constituted an infringement of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms. Article 8 of the Convention provides as follows:

> '1. Everyone has the right to respect for his private…life…
> 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…for the prevention of disorder or crime…'

The applicants argued that the retention of their DNA samples and profiles was not necessary. They went on to submit that the power accorded to the police by the Criminal Justice and Police Act 2001 to retain samples and profiles of unconvicted persons was not proportionate to the aim of detecting and preventing crime. In determining the matter the court observed the following general principles:

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35 2001 c. 16.
36 Supra note 19.
37 *R (S and Marper) v Chief Constable of South Yorkshire* [2002] EWHC 478 (Admin).
38 *R (S and Marper) v Chief Constable of South Yorkshire* [2003] EWCA Civ. 1275.

(1) The concept of privacy covers both the physical and psychological integrity of the person.

(2) The mere storage of data relating to the private life of an individual amounts to a violation of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms.

In reaching the decision that the retention of biological samples and DNA profiles constituted an interference with the applicants' right to respect for their private lives as encapsulated in Article 8 of the Convention, the court noted the following:

(1) The United Kingdom is the only member state of the Council of Europe to expressly permit the indefinite retention of DNA profiles and samples of persons who have not been convicted of an offence. Other States have set limits on the retention and use of data in an attempt to achieve a balance between competing interests.

(2) In view of the potential future uses of DNA samples, the systematic retention thereof was sufficiently intrusive to amount to interference with the right to respect for private life as encapsulated in Article 8 of the Convention.

(3) DNA samples contain highly personal, sensitive information about the individual. This includes health-related information as well as information pertaining to relatives.

(4) Due to the nature and amount of personal information contained in samples, their retention per se amounts to a violation of the right to privacy. The fact that only the non-coding sections of DNA are currently used by law enforcement agencies, does not detract from the fact that retention is a violation of the right to privacy.

(5) The use of DNA profiles to identify genetic relationships causes its retention to be a violation of Article 8 of the Convention.

(6) The use of DNA profiles for inferring ethnicity makes their retention sensitive and capable of violating the right to private life.

The court observed that '[t]he protection afforded by Article 8 of the Convention would be unacceptably weakened if the use of modern scientific techniques in the criminal-justice system were allowed at any cost and without carefully balancing the potential benefits of the extensive use of such techniques against important private-life interests.'[39] The court also considered that 'any State claiming a pioneer role in the

[39] Supra note 19 para 112.

development of new technologies bears special responsibility for striking the right balance in this regard.'[40]

A comparison of the *Marper* decisions by courts of the United Kingdom[41] and that of the ECtHR[42] reveals a marked difference in approaches to privacy interests. The courts in the United Kingdom weighed the risks to the applicants against the benefits to the State in retaining DNA samples and profiles. They found that the risks to the applicants were not great and were outweighed by the benefits of prosecuting and preventing crime.[43] In arriving at this conclusion the courts emphasized the value of retained samples and profiles whilst underestimating the applicants' right to privacy. The ECtHR, on the other hand, found that the provision for retention failed to strike a balance between the interests of the applicants and that of the State. The court acknowledged the need for the use of modern technology in the fight against crime but still held that the retention of samples and profiles of persons who have not been convicted of offences amounts to a disproportionate interference with the right to respect for private life.

The ECtHR observed that 'the protection afforded by Article 8 of the Convention would be unacceptably weakened if the use of modern scientific techniques in the criminal-justice system were allowed at any cost and without carefully balancing the potential benefits of the extensive use of such techniques against important private-life interests.'[44] The court also considered that 'any State claiming a pioneer role in the development of new technologies bears special responsibility for striking the right balance in this regard.'[45]

This judgment is clearly progressive and centred on respect for human rights. A laudable aspect of the judgment is the refusal of the court to compromise human rights in the name of scientific progress. Those responsible for scientific advances are 'forced' to take responsibility for their pioneering actions. This court is not alone in its approach. It has been noted that 'scientists...have an ongoing responsibility to reflect on the human-rights issues raised by the technologies they develop, and to lobby for appropriate

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40 Ibid.
41 Supra notes 37 and 38.
42 Supra note 19.
43 Supra notes 37 and 38.
44 Supra note 19 para 112.
45 Ibid.

oversight and controls.'[46] It has been noted that the United Kingdom (excluding Scotland) has the 'most inclusive and far-reaching legislative framework authorising the collection, storage and use of forensic DNA samples in the world.'[47] It is evident that approaches aimed at specific periods of retention based on the nature of the offence are more likely to pass constitutional muster.

(vi) Speculative Searches

Speculative searching refers to the process where the DNA profile of an arrested person is compared to stored crime scene profiles obtained in respect of unsolved crimes. In the United Kingdom, s 23 of Home Office Circular 16/1995 clearly provided that the National DNA Database was intended as an intelligence database only and the results of any speculative search would not be used for prosecution purposes. Home Office Circular 58/2004 changed this position by amending s 23 to provide that an arrestee may be prosecuted on the basis of a match resulting from a speculative search, provided there was other supporting evidence.[48]

(c) South African concerns

The Criminal Law (Forensic Procedures) Amendment Bill[49] was drafted as part of the Department of Justice and Constitutional Development's review of the criminal justice system. The aim was to address certain shortcomings in the criminal justice system, including the absence of legislation to provide for the establishment and administration of a DNA database and the lack of legislative provision for the collection of DNA

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46 Editorial 'Watching Big Brother' (11 December 2008) 456:7223 *Nature* 675 at 676.

47 Williams & Johnson op cit note 8 at 547.

48 Section 23 of Home Office Circular 16/1995 provided that: '[t]he DNA database is an intelligence database only. It is not intended that the results of any analysis carried out solely for the database or that the fact that a match was found during a speculative search will be used for prosecuting purposes.' HOC 58/2004 provides that: '[s]peculative searches may be carried out of the National DNA Database and a suspect may now be charged on the basis of a match between a profile from DNA from the scene of the crime and a profile on the National DNA Database from an individual, so long as there is further supporting evidence.'

49 B2-2009.

evidence.[50] The Bill therefore provided inter alia for the creation of a DNA database to assist in addressing the high crime rate in South Africa. Phase one of the Bill was signed into law on 1 October 2010. The resultant Act[51] does not include provisions relating to the envisaged DNA database. It is expected that this aspect will be addressed by means of another Bill which will be referred to as the DNA Bill.

The proposed DNA database, called the National DNA Database of South Africa (NDDSA), is expected to contain biological samples as well as DNA profiles derived from such samples. It is also expected to contain five indexes; namely, crime scene index, reference index, convicted offenders index, volunteer index, and Personnel, contract and supplier elimination index. The provisions relating to DNA databases raises the following concerns:

(1) The Bill is applicable to adults and children. A child is defined as a person under the age of 18 years.[52] This is cause for concern as acknowledged by the European Court of Human Rights in the *Marper* decision.[53] The court emphasised the special position of minors in the criminal justice sphere and the need for protection of their privacy at criminal trials. In doing so, the court drew on the provisions of Article 40 of the United Nations Convention on the Rights of the Child, 1989.

(2) Clause 3 of the Bill seeks to insert s 36B into chapter 3 of the Criminal Procedure Act 55 of 1977. Section 36B(b) obliges a police official to take a non-intimate sample from arrested and convicted persons. A non-intimate sample is defined as 'a sample of hair other than pubic hair, a sample taken from a nail or from under a nail, a swab taken from the mouth (buccal swab); a blood finger prick; or a combination of these.'[54] DNA analysis is conducted on the sample and the results are included in the NDDSA. Non-intimate samples may also be taken without warrant from persons suspected of having committed an offence. This is for investigation purposes.

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50 See http://www.justice.gov.za/legislation/invitations/2008_CrimLaw_ForensicProceduresAmendmentBill.pdf accessed on 26 April 2012.

51 Criminal Law (Forensic Procedures) Amendment Act 6 of 2010.

52 Ibid.

53 Supra note 19.

54 Clause 2 (s 36A (1) *(i)* (i)-(v)). On the contrary, an intimate sample is defined in s 36A(1)*(g)* (i) – (iv) as 'a sample of blood other than a blood finger prick, semen or any other tissue fluid, urine or pubic hair; a dental impression; a swab taken from a person's body orifice other than the mouth; or a combination of these.'

(3) The Bill permits speculative searching of databases.[55] Speculative searching allows for comparison of DNA samples or profiles obtained in connection with a crime with those contained in the NDDSA. (Fingerprints will be cross-checked against those stored in the e-NATIS and HANIS systems.)

(4) Permanent retention of samples and profiles as envisaged by the Bill is problematic.[56] The wording of the Bill is similar to the relevant legislation in the United Kingdom. Provision is made for DNA samples to be retained after fulfilling the purpose for which they were taken or analysed. The Bill has identical provisions in respect of persons accused,[57] convicted,[58] and suspected[59] of committing crimes. The proposed section 15P(2)*(a)* provides that no DNA profile loaded onto the NDDSA may be destroyed.

(5) The abovementioned situation is exacerbated in the case of the retention of profiles of persons who have merely been arrested but have not been convicted of any offence. The rationale for the retention is unclear save to say that it helps to increase the size of the database. The inherent danger in this approach is that the database may be used for familial searching. An analysis of the *Marper* case[60] is useful in this respect. The applicants complained to the European Court of Human Rights about the retention of their fingerprints, biological samples and DNA profiles pursuant to s 64 (1A) of the Police and Criminal Evidence Act 1984. Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms provides for the right to respect for a person's private life. The applicants argued that the retention of their fingerprints, cellular samples and DNA profiles interfered with this right. They adopted the stance that such interference was more severe in the case of children due to the social stigma and psychological implications of such retention. The government of the United Kingdom submitted that the applicants' concerns were not substantial enough to amount to an interference under the Convention. Their argument was based on technical facts; namely,

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55 Clause 3 (Proposed s 36B(5) of the Criminal Procedure Act 51 of 1977); clause 9 (Proposed ch 5B, s 15M of the South African Police Service Act 68 of 1995).

56 Clause 3 (Proposed s 36B(6)*(a)* of the Criminal Procedure Act 51 of 1977); clause 9 (Proposed ch 5B, s 15P(1)*(a)*.

57 Clause 3 (Proposed s 36B(6)*(a)* of the Criminal Procedure Act 51 of 1977).

58 Ibid.

59 Clause 4 (Proposed s 36C(3)*(a)* of the Criminal Procedure Act 51 of 1977).

60 Supra note 19.

that the profiles stored in the database were merely sequences of numbers and the information in the database was of such a nature that it posed no threat to the reputation of the applicants. The court held that due to the '…nature and amount of personal information contained in cellular samples, their retention *per se* must be regarded as interfering with the right to respect for the private lives of the individuals concerned.'[61]

(6) The provision relating to sharing of NDDSA information with foreign law enforcement agencies poses a great threat to privacy of individuals. Volunteers whose information is contained in the volunteers index on the NDDSA are particularly vulnerable. There is no provision in clause 9 of the Bill requiring that a volunteer must be informed that his/her information may be shared with foreign law enforcement agencies. The concern with cross-border sharing of data is that the safeguards which exist in South Africa may not necessarily exist in the recipient country. There would no longer be any control over the handling, storage and use of the data once it leaves South Africa. This has the potential to compromise the right to privacy. Even within Europe, concerns have been raised about sharing or exchanging information amongst States.

(7) Clause 9 of the Bill provides for s 15K to be included in the South African Police Service Act stating that consent given by a volunteer cannot be withdrawn. The rationale behind such a legislative provision is unknown. Even minors who become volunteers by virtue of a parent's or guardian's consent, cannot have their profiles removed from the database. This is the only plausible conclusion based on the fact that the relevant section applies to children but provides no exceptions to accommodate them. Problems are likely to arise when a minor, whose information has been included on the volunteer's index by virtue of parental consent, subsequently and upon the attainment of majority status, decides to have his/her information removed from the database. The Bill is rigid in its approach with no provision being made for exceptional or extraordinary cases.

The position that is envisaged in the Bill is untenable. Many of the provisions violate the right to privacy and will not pass constitutional muster. The *Marper* case is a good example of how competing rights should be balanced. It is hoped that the provisions in the Bill will be tempered as the Bill proceeds through the legislative process. If not, it risks being successfully challenged in court.

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[61] Supra note 19 para 73.

2.3 GENETIC RESEARCH DATABASES

(a) The emergence of genetic research databases

In addition to forensic DNA databases there are other DNA databases which raise privacy concerns. Other genetic databases are created mainly for the purpose of research. They usually contain data which is obtained through DNA analysis as well as the biological material from which DNA samples are derived. Population genetic databases are used largely for medical and pharmacogenomics research. Sutrop observes that '…all population- based genetic database projects have the same goal – they intend to identify susceptibility genes for common diseases and attempt to improve the medical care and health of the populations involved.'[62]

Iceland may be regarded as the pioneer in the creation of population genetic databases. In 1998 a private biotechnology company, deCODE Genetics, was licensed by the Icelandic government to compile an electronic database correlating the genetic, genealogical, and medical information of the entire population of Iceland. This was authorised through the promulgation of the Health Sector Database Act.[63] Three separate but interlinked databases were envisaged. Presumed consent was considered sufficient for the medical and genealogical records databases and citizens had the choice to opt out of the medical records database. Genetic samples from the entire Icelandic population were required for the development of the genebank and these samples could only be obtained if citizens gave informed consent. In May 2000, the Icelandic Biobanks Act[64] was passed, which allowed deCODE Genetics to indirectly access samples held by other institutions. This process would be to the detriment of citizens as it would result in the informed consent requirement being bypassed by decode Genetics. It was also in clear contravention of the universally accepted ethical requirement of informed consent for research involving human participants.

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62 Margit Sutrop 'Human genetic databases: ethical, legal and social issues' (2004) 8 *TRAMES* 5 at 6.
63 Act No. 139/1998.
64 Act No. 110/2000.

In addition to being the first population genetic database, the Icelandic Health Sector Database attracted the most criticism for the reasons briefly mentioned above.[65] In 2003 the enabling statute, the Health Sector Database Act,[66] was declared unconstitutional by the Icelandic Supreme Court.[67] The court found that the Health Sector Database Act did not adequately protect the right to privacy since individuals could still be identified through the data contained in the database. The main reason for the court's decision was that the Act violated the provisions on privacy contained in the Icelandic Constitution.[68] This case study is useful for any jurisdiction contemplating the creation of genetic databases.

After the initiation of the Icelandic Health Sector Database, databases were created in Estonia (Estonian Genome Project); Latvia (Unified Genome Database of Latvian Population); Canada (CARTaGENE); Singapore (Genome Institute of Singapore); Sweden (UmanGenomics); and the United Kingdom (UK BioBank).

(b) Concerns

There are numerous concerns relating to the protection of privacy in the context of genetic research databases. Godard et al agree that DNA banking practices pose a threat to privacy.[69]

(i) Protection of privacy

Insofar as population genetic databases are concerned, there is a need to reassure members of the public that their personal information will be adequately protected. History and experience have diminished the trust between government and citizens. As

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65 See Hilary Rose *The Commodification of Bioinformation: The Icelandic Health Sector Database* (2001) 21 (Project funded by the Wellcome Trust) available at http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/WTD003281.pdf accessed on 20 April 2012.

66 Supra note 63.

67 *Ragnhildur Gudmundsdóttir v.The State of Iceland* No. 151/2003 (27 November 2003), available at http://epic.org/privacy/genetic/iceland_decision.pdf accessed on 20 April 2012.

68 Paragraph 1 of Article 71 of the Icelandic Constitution provides that 'Everyone shall enjoy freedom from interference with privacy, home and family life.'

69 Béatrice Godard, Jörg Schmidtke, Jean-Jacques Cassiman & Ségolène Aymé 'Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective' (2003) 11:2 *European Journal of Human Genetics* S88 at S102.

aptly pointed out by Sankar, '[f]ew lessons from history and little in current politics reassure us that DNA held by the government is safe from being used for purposes that its citizens – if granted a choice- would prefer to avoid. DNA collections that now seem little more than a clever hedge against the randomness of violent crime and wartime death, could become, without proper controls, a source for wide-ranging medical and social discrimination.'[70]

Sankar's argument is not without merit as it is based on actual events which took place in the United States of America in the 1930's and 1940's. She recalls the manner in which fingerprints taken by the armed forces fell into the hands of the Federal Bureau of Investigation due to a changing political climate and became part of their records. She notes that resistance by the armed forces based on protection of their members from stigmatisation eventually gave way to national security concerns. The point she makes is that there can never be any complete guarantee that DNA collected for one purpose will not be used by other government agencies for other purposes. Her suggestion therefore is that it is better not to collect DNA unless it is clearly necessary to do so. This, it is submitted, is a fair argument based on unfortunate historical events. The question which arises is how to protect the privacy of individuals in cases where their genetic information has been collected for a necessary purpose.

(ii) Access to genetic data for forensic purposes

Concern arises from the inevitable interest of law enforcement agencies in the data contained in population genetic databases. Even though law enforcement agencies have developed their own DNA databases, they are aware of the limitations of such databases; namely, that these are restricted to persons who have had some contact with the law. Potential access to research databases by law enforcement authorities threatens the privacy of database donors. There has already been a decided case in the United Kingdom where information was seized from records of a clinical trial at a prison to prove that the accused had been aware of his positive HIV status during the period in

[70] Pamela Sankar 'Topics for our times: The proliferation and risks of government DNA Databases' (1997) 87:3 *American Journal of Public Health* 336 at 337.

which he had engaged in unprotected sexual intercourse with his girlfriend.[71] As a result of the accused's conduct and his failure to disclose his HIV status to his girlfriend, she had become infected with the virus. The prosecution had sought a court order for access to records of a health testing programme which the accused had participated in during a previous period of incarceration. The court adopted the stance that the right of society to the proper investigation of crime outweighed any confidentiality interest. The court accordingly granted an order for de-encryption of the data and disclosure thereof. Based on this evidence, the accused received a five-year jail sentence for reckless and culpable conduct. This case proves that information contained in non-forensic databases is not fully protected from disclosure for forensic purposes.

(iii) Adverse impact on genetic research

Lack of regulation of research databases may deter individuals from participating in genetic research. Even though consent is usually obtained for use of personal information in research, no consent is obtained for forensic use of personal information. It is to be expected that individuals would be reluctant to volunteer as research participants if they suspect that they their participation could cause them harm.[72] [73]

(iv) Cross-border sharing of genetic data

It has been noted that '[w]hile biobanks are increasingly recognised as a crucial infrastructure for research, at the same time the widely varied practices in biobanking…may also pose a barrier to cross-border research and collaboration by limiting access to samples and data.'[74] It is important to ensure that genetic data receives a similar level of protection in all jurisdictions which it may be transferred to. For this reason there have been calls for harmonisation of biobanking practices.[75]

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71 *Her Majesty's Advocate v Stephan Robert Kelly* [2001] Scot HC 7 (20 February 2001).

72 C. Slack, G. Lindegger, E. Vardas, L. Richter, A. Strode & D. Wassenaar 'Ethical issues in HIV vaccine trials in South Africa' (2000) 96 *South African Journal of Science* 290 at 291.

73 David Green & Frederick R. Rickles 'Enhancing participation in clinical research: Keys to obtaining informed consent' (January 2007) 5:1 *The Journal of Supportive Oncology* 48.

74 Eleni Zika, Daniele Paci, Tobias Schulte in den Bäumen, Anette Braun, Sylvie RijKers-Defrasne, Mylène Deschênes, Isabel Fortier, Jens Laage-Hellman, Christian A. Scerri, Dolores Ibarreta, Document prepared for the European Commission *Biobanks in Europe: Prospects for Harmonisation and Networking* (2010) *v.*

75 Ibid.

Godard et al accordingly conclude that since DNA banking raises legal issues it may be necessary to 'control the flow of banked DNA and DNA data; develop policies to regulate DNA banking more closely, and [e]nsure that DNA banking can perform its function without impinging on the rights and interests of individuals who have their DNA sample or DNA data in a bank.'[76] It is argued in this study that these objectives are best addressed through law.

2.4 CONCLUSIONS

There is a need for the legal regulation of DNA databases to prevent misuse of genetic information. Our constantly increasing knowledge of human genetics is facilitating our use of genetic information in previously unimaginable areas. DNA technology has increased in prominence over the last two decades. The proliferation of DNA databases is proof of this. Legislative intervention is necessary to address the identified challenges so as to ultimately protect the individual's right to privacy. The justification for legislative intervention has been discussed in chapter one.

The greatest challenge posed by the advent of forensic DNA databases is finding a way to balance the competing interests of the State in solving or detecting crime and the interests of the individual in preventing violations of his/her right to privacy. Legislation needs to carefully balance the rights of the State and the individual since both parties have interests worthy of legal protection. The decision of the ECtHR in *Marper*[77] supports this conclusion.

There is clearly a need for legislation to regulate forensic DNA databases in order to protect genetic privacy. Samples cannot be covered by a data protection statute because they do not qualify as information for the purposes of data protection but this can be remedied by the introduction of a genetic privacy Act. An effective and constitutionally sound genetic privacy statute must make provision for the following:

(1) An oversight body to monitor databases and to decide on requests for access to data.

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[76] Op cit note 69.
[77] Supra note 19.

(2) Profile entry criteria and sampling (whose data should be included in the database and which categories of persons should have their DNA samples taken).

(3) Profile removal/ sample destruction criteria.

(4) Different periods of retention for data based on the nature of the crime. A schedule of crimes should be appended to the legislation. Only crimes against the person and all sexual offences warrant permanent retention of data on the database

(5) Express prohibition against the use of data contained in forensic DNA databases for research and vice versa

(6) A minimum age for inclusion in a forensic DNA database. This should be linked to the age of criminal responsibility

(7) An option for revocation of consent by volunteers. The irrevocability of consent of volunteers is neither reasonable nor justifiable. Provision should be made for volunteers to revoke consent at any time. This need is even more pressing in the case of minors.

(8) Rules for the cross-border sharing of genetic data contained in forensic and non-forensic DNA databases.

The detection of crime and the conduct of prosecutions are priorities of governments across the world. It is a particularly serious issue in South Africa because of the high crime rate, especially violent crimes against the person. Forensic science has an important role to play in the criminal justice arena but it has to be used in a manner that does not amount to an unjustifiable limitation of the constitutionally entrenched right to privacy.

Information contained in all genetic databases must be protected from unauthorised disclosure as well as indiscriminate use. The flow of genetic information to third parties such as insurance companies, employers, and researchers must be regulated so as not to violate the human rights of individuals whose data is stored in these databases. This issue is discussed in the next chapter.

CHAPTER III

GENETIC DISCRIMINATION

3.1 INTRODUCTION

Concerns relating to genetic discrimination raise new legal issues as the use of genetic technologies becomes more widespread. The fear of genetic discrimination could result in clinical genetic testing not being utilised sufficiently or at all by the public. This would defeat the aim of the Human Genome Project. The sequencing of the human genome, as accomplished by the Human Genome Project, holds great promise for health care in terms of genetic testing, pharmacogenomics, and gene therapy. It is therefore necessary for policymakers and legislators to identify and remove obstacles to the realisation of the potential of the sequencing of the human genome. One of the ways to achieve this is by protecting genetic privacy. This research proceeds from the premise that the potential for genetic discrimination can be minimised by regulating access to genetic information. Any legal response should therefore focus on controlling access to genetic information rather than attempting to control the use of genetic information once it is in the possession of a third party.

There are many areas of potential genetic discrimination such as housing, welfare benefits, education, insurance, and employment. This list is not exhaustive. Insurance and employment are, however, the two areas that are most often considered in discussions on genetic discrimination. Partlett suggests that 'insurance and employment are the two prime areas where genetic information may be misused.'[1] This is borne out by one definition that genetic discrimination refers to 'differential treatment due to genetic status of an individual or family member with respect to employment and/or insurance benefits'.[2] A discussion of genetic discrimination in the insurance and employment spheres is therefore necessary for the purposes of this research. The first

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1 David F Partlett 'Misuse of genetic information: The common law and professionals' liability' (2003) 42 *Washburn Law Journal* 489 at 500.

2 Nicole L. Pfeffer, Patricia McCarthy Veach, & Bonnie S. LeRoy 'An investigation of genetic counselors' discussions of genetic discrimination with cancer risk patients' (2003) 12:5 *Journal of Genetic Counselling* 419 at 420.

part of this chapter provides an overview of the interests of employers and insurers in genetic information, the reasons for such interests, and the nature of the threat posed by those interests.

The second aspect that is discussed in this chapter pertains to genetic research involving human participants. The reason for this discussion is that genetic information which is discovered in the course of research renders participants vulnerable to genetic discrimination in the event of such information being disclosed to employers or insurers. The effect on family and ethnic group members is also mentioned briefly in an attempt to determine the adequacy of the conventional consent-based approach to vulnerability in research. The concept of vulnerability and its possible extension to genetic research participants as a group is therefore canvassed in this chapter.

The potential for genetic discrimination and the role of privacy protection as a tool for the prevention of genetic discrimination are discussed here. This chapter, like the previous one, is intended to justify the need for genetic privacy protection legislation in South Africa due to the potential for genetic discrimination in the absence of such protection and the inadequacy of the current ethical framework. It is not the aim of this chapter to comprehensively discuss genetic discrimination in any sector. A comprehensive discourse on genetic discrimination is an academic exercise in its own right and cannot be done justice to within the parameters of this research. Although a detailed discussion of genetic discrimination is beyond the scope of this research, a brief discussion is warranted insofar as genetic discrimination provides motivation for the introduction of genetic privacy protection. The actual incidence or mere fear of genetic discrimination is considered a catalyst for the introduction of genetic privacy protection. For these reasons, it receives attention here.

3.2 INSURANCE

Life insurance is intended to provide financial security to individuals and families in the event of death. It therefore serves an important societal purpose even though it is a private contract between two parties. Information relating to inter alia an individual's age, sex, health status, lifestyle, and family medical history are indicative of the nature of

the risk being insured against and are therefore used for underwriting purposes. Genetic information, which can be used to determine the risk profile of an applicant, would therefore by be regarded by the insurance industry as important for the purpose of insurance underwriting.

Insofar as insurance is concerned, this discussion will focus on life insurance due to the fact that an individual's risk status is considered in the calculation of life insurance premiums. The position in respect of health care is totally different. The national health system comprises a private health system and a public health system. The Medical Schemes Act[3] defines the national health system as 'the system within the Republic, whether within the public or private sector, in which the individual components are concerned with the financing, provision or delivery of health services.'[4] The two systems operate concurrently. With private health care as provided for by medical aid schemes, contributions are determined on the basis of income and/or the number of dependants.[5] The Medical Schemes Act clearly states that the terms and conditions applicable to the admission of a person as a member of a medical aid scheme shall not provide for any other grounds, including age, sex, past or present state of health.[6] State-funded healthcare does not exclude cover for any illness or disease. It follows that the results of genetic tests cannot be used in the determination of contributions in the private health sector and no disease will be excluded from cover by the public health system on the grounds of it having a genetic component. The issue of differential treatment based on genetic factors will therefore not arise in the context of health care. However, the potential for unfair differential treatment does exist in the case of life insurance and for this reason the discussion in this chapter will be confined to genetic discrimination in life insurance as justification for the introduction of genetic privacy legislation in South Africa.

Insurers have an interest in genetic information for underwriting purposes. This is acknowledged by the South African Medical Research Council (MRC) in its ethical

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3 Act 131 of 1998.
4 Ibid s 1.
5 Supra note 3, s 29(1)(*n*).
6 Ibid.

guidelines.[7] Access to all relevant information is in keeping with the principle of uberrimae fides (utmost good faith), which is the cornerstone of insurance. Insurers could possibly obtain genetic information in one of two ways: they may require applicants for insurance to undergo genetic testing or they may request applicants to disclose results of previous genetic tests. This clearly poses a problem for individuals seeking insurance. Three approaches to the problem can be identified: legislative prohibition, moratoria and the status quo.[8]

The legislative approach addresses the problem by using legislation to protect genetic privacy as is done in the Netherlands[9] or to prevent genetic discrimination as is the case in the United States of America. In Canada general privacy legislation[10] may be used to protect genetic privacy. This approach has been criticised by Joly et al for promoting genetic reductionism and genetic determinism.[11] Moratoria on the use of genetic information by insurance companies are in place in the Netherlands[12] and in the United Kingdom. This approach provides an interim solution which is flexible and may be changed quite easily as the science of human genetics develops. Although the use of moratoria seems less rigid, concerns have been raised about enforcement.[13] The third approach of maintaining the status quo entails making no changes to the existing position. It is seen as slightly less attractive because it ignores the gravity of public concern about genetic discrimination.[14]

At this stage the actuarial relevance of genetic information has not yet been determined. This may explain why there is not yet active lobbying by the insurance industry either for access to the results of genetic tests or for applicants to undergo compulsory genetic testing as part of the application process. It is anticipated that once genetic tests becomes more readily available to the public and the use of such tests

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7 South African Medical Research Council *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* (2002) Guideline 3.3.4.1.1, available at http://www.mrc.ac.za/ethics/ethicsbook2.pdf, accessed on 4 August 2011.

8 Yann Joly, Bartha M Knoppers & Béatrice Godard 'Genetic information and life insurance: a 'real' risk' (2003) 11:8 *European Journal of Human Genetics* 561 at 562.

9 The position in the Netherlands is unique to the extent that it has legislation aimed at protecting genetic privacy together with a moratorium on the use of genetic information by insurance companies.

10 Personal Information Protection and Electronic Documents Act (PIPEDA) S.C 2000, C.5.

11 Joly et al op cit note 8.

12 Supra note 9.

13 Joly et al op cit note 8.

14 Ibid.

becomes more widespread, insurance companies will be better positioned to start conducting actuarial studies in order to determine the actuarial relevance of genetic information. Once that happens, genetic information will become very significant for the insurance industry and serious attempts will be made to gain access to genetic information. It is for this very reason that genetic information must be protected from unauthorised disclosure.

(a) Concerns

(i) Unfair Discrimination

Knowledge of a person's genetic status may lead to unfair discrimination. Genetic discrimination is defined as 'the differential treatment of individuals or their relatives due to actual or presumed genetic differences as opposed to discrimination based on phenotype'.[15] Differential treatment based on the results of genetic testing becomes especially problematic when discrimination arises from the results of predictive genetic testing as opposed to diagnostic testing.

At this stage the mere access to genetic information by insurers and employers is cause for concern. It has been observed that 'this has created a climate of fear in a field that should rather be teeming with hope and promise' and that 'some people are now reluctant to be tested for fear that the information will be used against them'.[16] In 1997 United States Jewish leaders requested officials of the National Human Genome Research Institute (NHGRI) to develop guidelines for genetic research on Ashkenazi Jews.[17] They then met with members of the National Institutes of Health in April 1998, to discuss the meaning of genetic research for Jews; concern about the lack of legal protection against genetic discrimination; and fears of stigmatisation and denial of jobs

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15 Billings PR, Kohn MA, de Cuevas M, Beckwith J, Alper JS, Natowicz MR. 'Discrimination as a consequence of genetic testing.' (1992) 50 *American Journal of Human Genetics* 476.

16 Royal Society of South Africa, Minutes of meeting held on 21 September 2005, summary adapted from Jacquie Greenberg 'Genetic testing and related ethical issues' (2005) 23:1 *Continuing Medical Education* 18, available at http://www.rssa.uct.ac.za/meetings/min05sep.htm, accessed on13 June 2006.

17 Sally Lehrmann 'Jewish leaders seek genetic guidelines' (1997) 389 *Nature News* 322.

and health insurance.[18] This is due to the fact that genetic research appears to have targeted Ashkenazi Jews since they are at increased risk for certain genetic disorders. Common genetic disorders in the Ashkenazi Jewish population include Tay-Sachs disease, Gaucher disease (type 1), Bloom Syndrome, Canavan disease, torsion dystonia, familial dysautonomia, fanconi anaemia (type C), mucolipidosis IV, Niemann-Pick disease (type A), congenital deafness, and non-classical adrenal hyperplasia.[19] Recent research has found that Ashkenazi Jewish women are at higher risk of developing breast[20] and ovarian[21] cancers. The diseases most often referred to in literature on the topic are Tay-Sachs disease and Gaucher disease due to the high disease incidence and carrier frequency rates amongst Askenazi Jews. Gaucher disease is the most common genetic disorder amongst Ashkenazi Jews with one in ten members of the population being a carrier of the Gaucher gene.[22] Tay-Sachs disease is an incurable neurodegenerative disorder. According to Charrow, one in every 26 – 30 members of the Ashkenazi Jewish population is a carrier of the Tay-sachs gene.[23] The concern is that employers and insurers may discriminate against members of this group simply on the basis of their ethnicity without regard to the fact that not everyone is affected or that some members are merely disease mutation carriers.

(ii) Adverse selection

Adverse selection has been defined as 'the process by which prospective policyholders may gain financial advantage through insurance purchase decisions based on risk characteristics known to them but unknown and not revealed to the insurer'.[24] This is possible where a prospective insured has undergone genetic testing and, with full knowledge of the gravity of the test results, applies for insurance without disclosing such

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[18] Meredith Wadman 'Jewish leaders meet NIH chiefs on genetic stigmatization fears' (1998) 392:6679 *Nature* 851.

[19] Joel Charrow 'Ashkenazi Jewish genetic disorders' (2004) 3:3-4 *Familial Cancer* 201 at 202.

[20] Rubinstein WS 'Hereditary breast cancer in Jews' (2004) 3:3-4 *Familial Cancer* 249.

[21] Robles-Díaz L, Goldfrank DJ, Kauff ND, Robson M, Offit K 'Hereditary ovarian cancer in Ashkenazi Jews' (2004) 3:3-4 *Familial Cancer* 259.

[22] Op cit note 19 at 203.

[23] Ibid 202.

[24] Krupa Subramanian, Jean Lemaire, John C. Hershey, Mark V. Pauly, Katrina Armstrong & David A. Asch 'Estimating adverse selection costs from genetic testing for breast and ovarian cancer: The case of life insurance (1999) 66:4 *The Journal of Risk and Insurance* 531.

test results to the insurer. The insurer is then not able to properly assess the risk. It creates concern because it threatens the viability of the insurance industry which in itself is based on uncertainty as to the materialisation of risks insured against. The problem becomes more serious when exorbitant amounts of cover are applied for. Polborn et al observe that governmental prohibition of the use of genetic information in the underwriting process will lead to 'regulatory adverse selection'.[25] This statement is correct but the predicted harshness of such a situation may be tempered by the restriction of the prohibition to applications for insurance cover under a specified amount. Insurers should be allowed to request the disclosure of genetic test results once the stipulated amount is exceeded. This would prevent 'regulatory adverse selection' as described by Polborn et al.[26]

(iii) Adverse impact on future research prospects

Genetic research requires the participation of human participants. It is to be expected that individuals would be reluctant to volunteer as research participants if they suspect that they could suffer harm as a result of their participation.[27] Harm may not necessarily be restricted to physical harm. Monnye argues that 'South Africa's unwillingness to recognise social and economic risks which will lead to protective measures being put in place will discourage future enrolments of prospective participants in research.'[28] In the case of genetic research this would mean that failure to acknowledge the potential for stigmatisation and genetic discrimination could lead to difficulty in recruiting research participants. Green and Rickles observe that 'it has become increasingly difficult to recruit individuals to participate in clinical research' and they suggest various possible reasons for such difficulty.[29] The reasons suggested by Green and Rickles do not include

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[25] Mattias K. Polborn, Michael Hoy & Asha Sadanand 'Advantageous effects of regulatory adverse selection in the life insurance market' (2006) 116:508 *Economic Journal* 327.

[26] Ibid.

[27] C. Slack, G. Lindegger, E. Vardas, L. Richter, A. Strode & D. Wassenaar 'Ethical issues in HIV vaccine trials in South Africa' (2000) 96 *South African Journal of Science* 290 at 291.

[28] Monnye SL 'Protection of human participants from risks in biomedical research: An analysis of the law of South Africa and international ethical guidelines' (2003) 22 *Medicine and Law* 73 at 80.

[29] David Green & Frederick R. Rickles 'Enhancing participation in clinical research: Keys to obtaining informed consent' (January 2007) 5:1 *The Journal of Supportive Oncology* 48.

stigmatisation and discrimination but that may simply be attributed to the fact that their discussion is not focused on genetic research.

Stigmatisation and discrimination are risks that must be addressed in genetic research since these acts could lead to social and economic harm. In view of concerns relating to potential genetic discrimination and stigmatisation, genetic research participants must be assured that their genetic information will not be disclosed to third parties, especially insurance companies and employers. Failure to do so could result in unethical research practices and that in turn could result in the very difficulty described by Green and Rickles.[30] The question which arises is whether ethical guidelines can adequately protect the privacy of genetic research participants. This question is answered by analysing relevant international and national ethical guidelines, cases of unethical research involving human participants, and relevant literature.

In addition to the Nuremberg Code,[31] the Declaration of Helsinki,[32] and the WHO/CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects,[33] all of which govern human research generally, there are two international instruments which deal specifically with human genetic data and research. The Universal Declaration on the Human Genome and Human Rights was adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) in 1997.[34] Article 7 of this Declaration provides that 'genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.' The principles enunciated in the Declaration are standard-setting and non-binding in nature. Article 7 therefore clearly relies on law as a tool for the promotion and enforcement of the principle of confidentiality. Article 22 provides that 'States should make every effort to promote the

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30 Ibid 48-49.

31 Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 Vol. 2 at 181-182.

32 World Medical Association *Declaration of Helsinki: Ethical principles for medical research involving human subjects* Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and last amended by the 59th WMA General Assembly, Seoul, Korea, October 2008, available at http://www.wma.net/en/30publications/10policies/b3/index.html, accessed on 27 May 2011.

33 *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) available at http://www.cioms.ch/publications/layout_guide2002.pdf, accessed on 29 May 2011.

34 Available at http://portal.unesco.org/en/ev.phpRL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html, accessed on 27 July 2011.

principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.' As will be demonstrated below,[35] ethical principles on their own have proven to be ineffective in curbing unethical research practices. This may be due to the fact that ethical guidelines lack enforceability. Legislation, on the other hand, can provide methods of enforcement and penalties for non-compliance. Based on the examples provided below[36] it is argued here that legislation is the 'appropriate measure' for enforcement of ethical principles.

The second instrument, the International Declaration on Human Genetic Data, was adopted by UNESCO in 2003.[37] The aims of this Declaration are mainly to 'ensure the protection of human rights in the collection, processing, use and storage of human genetic data whilst giving due consideration to freedom of research; to set out guiding principles for the formulation of legislation and policies on the collection, processing, use and storage of human genetic data; and to form the basis for guidelines of good practices in these areas.'[38] Like the Universal Declaration on the Human Genome and Human Rights,[39] this Declaration is also a standard-setting document which is not binding on UNESCO's member States. Article 4(a) accords special status to human genetic data. Based on this special status, article 4(b) provides that '[d]ue 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.' Do ethical guidelines provide an 'appropriate level' of protection for the privacy of human genetic research participants? Once again, in light of the cases of unethical research practices discussed below,[40] it is fair to conclude that ethical guidelines do not provide an appropriate level of protection. It follows from this conclusion that other steps need to be taken in order to provide an appropriate level of protection which should include enforcement mechanisms as well as penalties for non-compliance. These are issues that do not feature in the two

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35 At 60 – 61 below.
36 Ibid.
37 Available at http://portal.unesco.org/en/ev.phpURL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html, accessed on 27 July 2011.
38 Ibid Article 1(a).
39 Supra note 34.
40 At 60-61 below.

UNESCO Declarations discussed above.[41] Due to the nature of the Declarations, no enforcement mechanisms or penalties for non-compliance can be built into them.

Article 14 of the International Declaration on Human Genetic Data[42] deals with privacy and confidentiality and provides as follows:

> '(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. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.
> (c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.
> (d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.
> (e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.'

The above article refers to domestic law as a protection mechanism in respect of genetic data. This implies that domestic law should clarify how genetic privacy will be protected. This includes the protection of genetic data stored in genetic databases.[43] The question which arises is whether existing South African law is adequate for this purpose. As explained below,[44] HIV vaccine research and genetic research share many common ethical concerns. The issues raised and conclusions reached by Strode et al in relation to HIV vaccine research can therefore be extended to genetic research. Strode et al consider

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41 Supra notes 34 and 37.
42 Supra note 37.
43 As discussed in ch 2.
44 At 59-60 below.

the current legal framework to be 'inconsistent, ambiguous, and incomplete.'[45] Despite the existence of the National Health Act[46] and ethical guidelines dealing specifically with HIV vaccine research in South Africa, Strode et al call for 'specific legislation' to protect trial participants in HIV vaccine research.[47] Their review of the existing ethical-legal framework leads them to conclude inter alia that research ethics committees should be compelled by law to apply national ethical standards and that law is needed to deal with issues such as protection of vulnerable research participants, informed consent, privacy and confidentiality in research, and protection from stigma.[48] The question as to whether South African law is adequate for the protection of genetic privacy must be answered in the negative. The adequacy of South African law on privacy is explored further in chapter four.

At the domestic level, the Department of Health has issued guidelines which provide a basis for the scientific and ethical integrity of research involving human participants.[49] This includes protecting the rights and safety of research participants although no reference to genetic research appears anywhere in the document. It provides that 'participants' right to privacy must be protected at all costs'[50] but refers only to the technological aspects of privacy protection. The guidelines also provide that 'Access to source data[51] must take place within the requirements of the privacy legislation.'[52] No mention is made of the specific legislation that is being referred to.

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45 Ann Strode, Catherine Slack & Muriel Mushariwa 'HIV vaccine research – South Africa's ethical-legal framework and its ability to promote the welfare of trial participants' (2005) 95:8 *South African Medical Journal* 598 at 601.

46 Act 61 of 2003.

47 Op cit note 45 at 600.

48 Ibid.

49 *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* (2006) 2 ed, available at http://www.doh.gov.za/docs/factsheets/guidelines/clinical/2006/index.html, accessed on 29 July 2011.

50 Ibid guideline 1.2.6.

51 Ibid Appendix F defines source data as: 'All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).'

52 Ibid guideline 5.1.5.

The guidelines also specify the types of research that need additional attention. These are:

(1) Research involving collectivities;

(2) research involving indigenous medical systems;

(3) emergency care research;

(4) research involving innovative therapy or interventions;

(5) research involving vulnerable communities; and

(6) HIV and AIDS clinical and epidemiological research.[53]

It is interesting to note the special provision in respect of HIV and AIDS as well as the glaring absence of any reference to genetic research. Unfortunately the drafters of the guidelines, who deemed it necessary to make special provision for HIV and epidemiological research, failed to acknowledge that similar considerations apply to genetic research. Special provision for individuals with genetic disorders could prove useful in attracting research participants as well as protecting them from harm in research. These guidelines, by their very nature, are vague. Much is left to the interpretation of the reader. This is far from ideal in an area as new and as complex as genetics.

The Department of Health has also issued guidelines on ethics in health research.[54] Guideline 9 deals specifically with human genetic research[55] and the privacy issues that are pertinent to genetic research.[56] It acknowledges that in addition to the usual ethical issues inherent in human research, there are additional ethical issues which are unique to genetic research. The approach to genetic research as reflected in these guidelines is most encouraging for those seeking greater protection for human genetic research participants. Unfortunately, though, these guidelines are not legally binding. Research Ethics Committees are 'encouraged to adopt these principles to guide their efforts in assessing all health research projects.'[57] This is followed by a note that 'Compliance with these standards and with other national and international scripts reassures the public

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53 Ibid guideline 2.3.

54 *Ethics in Health Research: Principles, Structures and Processes* (2004) available at http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html, accessed on 29 July 2011.

55 Ibid 42.

56 Ibid guideline 9.2.

57 Ibid clause 1.6.

that the rights, safety and well being of study participants are protected.'[58] The lack of enforcement mechanisms generally is a problem that is discussed by Strode et al in their analysis of the ethical-legal framework in respect of HIV vaccine research.[59] Strode et al also suggest that research ethics committees be compelled by law to adopt national research ethics standards.[60] Until that happens, there can be no guarantee of the application of these useful guidelines.

The MRC has published guidelines entitled 'Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research.'[61] Guideline 3 deals specifically with genetic research and practice. This document merely contains recommendations as to how various ethical issues should be approached and often calls on the Department of Health to issue guidance on different matters such as maintaining confidentiality of genetic registers. Unfortunately the guidelines are vague and not very helpful to those seeking definite answers to ethical questions posed by human genetic research. The guidelines merely reiterate much of the relevant existing legal and ethical principles without taking matters any further.

As part of its guidelines for good practice in the health care professions, the Health Professions Council of South Africa (HPCSA) has published guidelines entitled 'General Ethical Guidelines for Health Researchers.'[62] These are based inter alia on the South African Constitution; the Department of Health's guidelines on Ethics in Health Research: Principles, Structures and Processes; the Medical Research Council's Guidelines for Ethics in Medical Research; and the Declaration of Helsinki.[63] Guideline 6.4 provides that health researchers should always 'Recognise the right of research participants to expect that health researchers will not pass on any personal and confidential information that the latter learn in the course of their professional duties, unless the research participants agree; not breach confidentiality without sound reason and without the knowledge and consent of the research participants; and protect the

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58 Ibid.
59 Strode et al op cit note 45.
60 Ibid 600.
61 Supra note 7.
62 (May 2008) available at http://www.hpcsa.co.za/conduct_generic_ethical_rules.php accessed on 29 July 2011.
63 Ibid clause 2.3

confidentiality of research data or other disclosures made by research participants.'[64] These guidelines also categorise the inappropriate disclosure of research participant data as an act of scientific misconduct.[65] These 'ethical guidelines embody the ideals to which members of professions should aspire and subscribe.'[66] The document states that 'a failure to do so may result in disciplinary action by the HPCSA and legal consequences.'[67] Of all the guidelines discussed thus far, this is the only one that mentions consequences for any breach thereof. It is unfortunate though that these guidelines can only be enforced against health researchers who are registered with the HPCSA. The gap pertaining to lack of enforcement mechanisms still applies to all other health researchers.

It is acknowledged that international and national ethical guidelines do provide for the protection of confidentiality in research but history indicates that ethics alone cannot be relied upon to protect research participants. Despite the existence of various ethical guidelines, many cases of unethical research have come to light over the years.[68] South Africa, like other developing countries with a high burden of disease and high levels of poverty, is undoubtedly an attractive research site for researchers from developed countries.[69] This is prevalent in the Human Immunodeficiency Virus (HIV) vaccine research which has been the focus of much attention by international researchers and the cause of much of the controversy regarding unethical research in South Africa. Even though this is not yet the case with genetic research, it is foreseeable that genetic research will follow a similar path as more indigenous populations are targeted for genetic research purposes. The ethical issues in HIV vaccine research are almost identical to those that plague the area of genetic research. Strode et al identify the ethical issues in HIV vaccine research as those pertaining to international collaborations, vulnerable research participants, high levels of discrimination and stigma surrounding HIV, human rights issues, and potential conflict between public needs and participants' rights and

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64 Ibid guideline 6.4.
65 Ibid guideline 9.2.6.
66 Ibid clause 2.2.
67 Ibid.
68 Tuskegee and Willowbrook studies discussed at 74 below.
69 Amanda Silverio 'HIV research in Africa: A series of paradoxes' (2002) 3:2 *Stanford Journal of International Relations* available at http://www.stanford.edu/group/sjir/3.2.05_silverio.html accessed on 22 July 2011.

interests.[70] Due to these ethical issues, they call for 'substantive and procedural ethical-legal safeguards…for research participants, while such critical research is facilitated.'[71] These are the very same ethical issues which must be addressed in human genetic research. For the purpose of proving the inadequacy of ethical guidelines in protecting human participants in research, literature on the efficacy of ethical principles relating to HIV vaccine research will be briefly examined and the conclusions will be extended to genetic research due to the common ethical issues shared by the two areas of research. This justifies the discussion and the conclusions reached below.

Many commentators have observed that the ACTG 106 clinical trial[72] involving the study of interventions for the prevention of mother-to-child transmission of HIV, failed to comply with ethical guidelines relating to the standard of care in developing countries.[73,74,75] Lurie and Wolfe are highly critical of the 'double standards' that sometimes come into play when designing research to be conducted in developing countries.[76] They refuse to accept that research which is considered unethical in developed countries can be considered ethical in developing countries. Angell observes that '[t]here appears to be a general retreat from the clear principles enunciated in the Nuremberg Code and the Declaration of Helsinki as applied to research in the Third World.'[77] Both authors call for a greater commitment to ethical standards. In the absence of such commitment there can be no guarantee of protection for research participants. Annas observes that 'On the international level we have already seen that the Nuremberg Code, the Helsinki Declaration, and WHO/CIOMS guidelines are almost universally seen as advisory and ethical only. They have no legal status in most individual countries, and they provide no mechanism for accountability or sanction of

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70 Strode et al op cit note 45.
71 Ibid.
72 AIDS Clinical Trials Group Study 106.
73 Lurie, Peter & Wolfe, Sidney M 'Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries' (1997) 337:12 *The New England Journal of Medicine* 853.
74 Angell, Marcia 'The ethics of clinical research in the third world' (1997) 337:12 *The New England Journal of Medicine* 847.
75 Silverio op cit note 69.
76 Lurie & Wolfe op cit note 73.
77 Angell op cit note 74 at 849.

researchers who disregard their precepts.'[78] It is clear from these comments and observations that ethical standards need enforcement and that mechanisms for such enforcement need to be created. It is unlikely that these ethical instruments will be completely effective in curbing unethical research practices in a field as complex, diverse, and challenging as human genetics.

Research Ethics Committees have a crucial role to play in ensuring that research is conducted in an ethical manner.[79] The Starting Antiretroviral Therapy at Three Points in Tuberculosis Therapy (SAPIT) clinical trial is a good example of failure to protect research participants from research-related harm. The SAPIT trial was conducted in South Africa from June 2005 to July 2008 with the aim of determining the optimal time for the initiation of antiretroviral therapy (ART) in patients who were co-infected with HIV and tuberculosis (TB).[80] As part of the study design one randomly assigned group of participants (sequential group) was to receive ART only after completion of TB treatment and not at any point during TB treatment. More deaths occurred in this group than in the other two groups which received ART at different points during TB treatment (integrated groups). The study has been criticised mainly on two grounds. The first criticism is that ethical guidelines on the standard of care were not adhered to insofar as the sequential group was concerned. Boulle et al find that by delaying ART until the completion of TB treatment, the SAPIT study failed to comply with the Declaration of Helsinki's recommendation[81] or the South African Antiretroviral Treatment Guidelines[82] relating to the standard of care.[83] They also find that participants were denied beneficial treatment which they would ordinarily have received had they not been assigned to the

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78 Annas, George J. 'The changing landscape of human experimentation: Nuremberg, Helsinki, and beyond.' (1992) 2:2 *Health Matrix: Journal of Law-Medicine* 119 at 126.

79 Udo Schüklenk 'Oversight, oversight, oversight' Editorial (2011) 25:3 *Bioethics* ii.

80 Abdool Karim, Salim S; Naidoo, Kogieleum; Grobler, Anneke; Padayatchi, Nesri; Baxter, Cheryl; Gray, Andrew; Gengiah, Tanuja; Nair, Gonasagrie; Bamber, Sheila; Singh, Aarthi; Khan, Munira; Pienaar, Jacqueline; El-Sadr, Wafaa; Friedland, Gerald & Karim, Quarraisha Abdool 'Timing of initiation of antiretroviral drugs during tuberculosis therapy' (2010) 362:8 *The New England Journal of Medicine* 697.

81 Supra note 32.

82 Department of Health *National Antiretroviral Treatment Guidelines* (2004) 1ed South Africa at 18, available at http://www.hst.org.za/uploads/files/sa_ART_Guidelines1.pdf accessed on 22 September 2011.

83 Andrew Boulle, Polly Clayden, Karen Cohen, Ted Cohen Fransesca, Krista Dong, Nathan Geffen, Ashraf Grimwood, Rocio Hurtado, Christopher Kenyon, Stephen Lawn, Gary Maartens, Graeme Meintjies, Marc Mendelson, Megan Murray, Molebong Rangaka, Ian Sanne, David Spencer, Jantjie Taljaard, Ebrahim Variava, W D Francois Venter & Douglas Wilson 'Prolonged deferral of antiretroviral therapy in the SAPIT trial: Did we need a clinical trial to tell us that this would increase mortality?' (2010) 100:9 *South African Medical Journal* 566 at 570.

sequential group in the SAPIT trial.[84] The second criticism relates to the quality of ethical review. Boulle et al conclude that 'the ethical training of investigators and capacity of ethics committees in South Africa should be improved.'[85]

Cleaton-Jones and Wassenaar respond to the abovementioned criticisms by comparing the relevant South African ethical requirements with federal regulations in the United States and by concluding that the former are 'more stringent.'[86] They argue that the South African ethical framework is in no way inferior to the position in the United States of America. They do acknowledge, however, that 'the structural, legal and ethics requirements for ethics review of research in South Africa do not necessarily prevent poor-quality review from occurring.'[87] They also agree with Boulle et al[88] that there is room for improvement as regards the training of research ethics committees but hasten to point out that the issue of training is not peculiar to South Africa.[89]

Based on the historical trail of unethical research as well as the more recent cases of unethical research that have been conducted in developing countries, it must be argued that Schüklenk is correct in his observation that 'it seems that we have good reasons to be worried about the implementation of research ethics standards.'[90] Schüklenk's observation is not made with specific reference to South Africa but with regard to research ethics committees in general. It is evident that the system of ethical review by research ethics committees is not working exactly as intended, thereby jeopardising future research. Strode et al observe a fragmented approach to human research ethics in South Africa[91] and point to the legally non-binding nature[92] of ethical guidelines. Their review of the existing ethical-legal framework in South Africa leads them to conclude

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84 Ibid 571.
85 Ibid.
86 P Cleaton-Jones & D Wassenaar 'Protection of human participants in health research – a comparison of some US federal regulations and South African research ethics guidelines' (2010) 100:11 *South African Medical Journal* 710 at 715.
87 Ibid 715-716.
88 Boulle et al op cit note 83.
89 Cleaton-Jones & Wassenaar op cit note 86.
90 Udo Schüklenk 'Protecting the vulnerable: testing times for clinical research ethics' (2000) 51 *Social Science & Medicine* 969 at 976.
91 Strode et al op cit note 45 at 600.
92 Ibid 599.

inter alia that research ethics committees should be compelled by law to apply national ethical standards.[93]

There is clearly a need for adequate genetic privacy safeguards so as to promote genetic research and to fully realise the potential of the strides made by the Human Genome Project. Such safeguards can only be created via legislation dealing specifically with the complex legal and ethical issues pertaining to genetic research. This conclusion is supported by the observation of Strode et al that 'The ethical-legal framework has, for the most part, the necessary institutions and some of the guidelines, but does not have many of the laws needed to protect and promote the rights of persons participating in research…'[94] It also appears to be widely accepted that research ethics committees are not functioning optimally. Based on this it is fair to argue that the protection which is anticipated through the control and oversight to be exercised by research ethics committees may not necessarily materialise in all cases. This is particularly true in respect of genetic research which is complex and relatively new. Research ethics committees may not be adequately equipped to deal with the ethical challenges posed by genetic research. This automatically creates a gap in protection for genetic research participants.

Non-binding ethical guidelines, non-specific legal protection, and the questionable capacity of research ethics committees do not augur well for the future of genetic research in South Africa. It leaves research participants open to exploitation by researchers who are more likely to target research sites that are less regulated. It also creates the difficulty described by Green and Rickles,[95] which is that of reduced willingness to participate in research. The gap in research protection must be closed and that can only be achieved through legislation dealing with the complex legal and ethical issues that prevail in genetic research. This is the only way to secure participation in research and to protect research participants from research-related harm.

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93 Ibid 600.
94 Ibid.
95 Green & Rickles op cit note 29.

(iv) Adverse impact on clinical medicine

Knowledge of an individual's genetic susceptibility to a particular disease makes it possible to design a treatment programme to prevent or delay onset of the disease. This is especially the case with complex diseases such as diabetes, asthma, cancer, and heart disease, to name a few. Complex diseases are sometimes referred to as multifactorial diseases since they can be traced to a combination of multiple genes and environmental factors. Due to the influence of environmental factors, their time of onset and severity are more difficult to predict than is the case with single-gene disorders. In order to obtain preventative health care, an affected individual must first undergo genetic testing. Genetic testing is defined as 'an analysis performed on human DNA, RNA, genes, and/or chromosomes to detect heritable or acquired genotypes, mutations, phenotypes, or karyotypes that cause or are likely to cause a specific disease or condition.'[96] Without genetic testing it becomes difficult to detect susceptibility and devise appropriate preventive strategies for affected individuals.

It is anticipated that genetic testing will, in due course, form a major component of clinical medicine insofar as it has the potential to assist in clinical decision-making. This is mainly due to the fact that almost all diseases have a genetic component.[97] In the absence of adequate privacy protection mechanisms, however, individuals are likely to fear genetic discrimination based on the results of genetic testing and are therefore less likely to undergo such testing. Privacy protection paves the way for the integration of genetic testing into the health care system.

3.3 EMPLOYMENT

An understanding of the objections to employers' access to genetic information necessitates reference to the historical applications of genetic screening initiatives in the workplace. There are published cases of genetic screening initiatives in the United States

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[96] Report of the Secretary's Advisory Committee on Genetic Testing *Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT* (July 2000) at 1, available at http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf accessed on 7 February 2009.

[97] Collins FS & McCusick VA 'Implications of the Human Genome Project for medical science' (2001) 285 *Journal of the American Medical Association* 540.

of America which have given rise to concerns about possible genetic discrimination.[98] There was also a case in Germany where a teacher was refused permanent employment because she had a family history of Huntington's disease.[99] The following statement by Miller, a commissioner at the Equal Employment Opportunity Commission in the United States of America, is noteworthy:

> 'We constantly are learning of the discovery of new genes. As the science of genetics explodes and the technology becomes more accessible, the issue of how society protects its workers against the misuse of genetic information become more important and legal and policy development in the area, more compelling. My concern, and a concern shared by many, is that if employers are permitted to consider genetic information in making personnel decisions, people may be unfairly barred or removed from employment for reasons that are wholly unrelated to their ability to perform their jobs.'[100]

Kim argues that societal interests require that employers not be given access to the genetic information of employees.[101] Employees naturally fear loss of employment or reduced employment prospects. This would be a major concern in countries which have high unemployment rates, high levels of poverty, and inadequate health care systems. The issue of consent to testing is important in the employment sphere. The question is whether it is correct to speak of voluntary informed consent in such an unbalanced relationship. Due to the power imbalance between employer and employee, it can never be assumed that an employee's consent to genetic testing is voluntary.

Miller states that '[l]egal protections are essential so that scientific breakthroughs are realised, privacy is preserved, and the workplace remains free from discrimination. Moreover, law can provide a uniform standard of conduct regarding the use of genetic information in the workplace.'[102] In the employment context genetic discrimination may arise from an employer's access to genetic information which discloses a susceptibility to

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98 In *Norman-Bloodsaw v Lawrence Berkeley Laboratoy* 135 F.3d 1260 (9th Cir. 1998), blood tests for sickle cell trait amongst black employees were found to give rise to a Title VII claim.
Echazabal v Chevron USA 213 F.3d 1098 (9th Cir.2000).
Bentivegna v United States Dept of Labour 694 F.2d 619 (9th Cir. 1982).

99 Jane Burgermeister 'Teacher was refused job because relatives have Huntington's Disease' (2003) 327 *British Medical Journal* 827.

100 Paul Miller is a commissioner at the Equal Employment Opportunity Commission, the federal agency charged with enforcing workplace antidiscrimination laws in the United States of America.

101 Pauline T. Kim 'Genetic discrimination, genetic privacy: Rethinking employee protections for a brave new workplace' (2002) 96:4 *Northwestern University Law Review* 1497 at 1543.

102 Paul Miller, Human Genome Program, U.S. Department of Energy 'Analyzing Genetic Discrimination in the Workplace' (February 2002) 12: 1-2 *Human Genome News* available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/09workplace.shtml, accessed on 2 February 2009.

workplace hazards. This is a challenging situation which requires a careful balancing of the employer's duty to prevent occupational injuries and diseases with the employee's right not to be unfairly discriminated against. Law can be used to prevent workplace discrimination. This can be achieved by statutory protection of genetic privacy coupled with appropriate sanctions for contraventions of the statute.

(a) Reasons for employers' interest in genetic information

Why would employers want to access employees' genetic information? One of the reasons advanced by employers has been the protection of employees from workplace hazards. In the early American case of *Bentivegna v United States Department of Labor*[103] the court rejected this paternalistic approach of the employer in excluding a building repairer with diabetes from the workplace. Thereafter in the case of *International Union v Johnson Controls Inc*[104] the United States Supreme Court also rejected the paternalism of the employer and held that, regardless of the supposed good intentions of the employer, their policy was still discriminatory. In this case the employer's 'fetal protection' policy prohibited fertile women from being employed in positions where they would be exposed to lead. The employer submitted that its policy was intended to prevent the women from harmful exposure to lead. The Supreme Court held that the employer's fetal-protection policy was sex discrimination forbidden under Title VII of the Civil Rights Act of 1964 for the following reasons:

(1) the policy was facially discriminatory by requiring only female employees to prove that they were not capable of reproducing. Exposure to unacceptable levels of lead had been shown to also affect sperm count and the policy should therefore have been made equally applicable to male employees;

(2) the employer's choice to treat all female employees as potentially pregnant showed sex discrimination; and

(3) the beneficence of the employer's purpose did not undermine the conclusion that the employer's policy was sex discrimination.

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[103] Supra note 98.

[104] 499 US 187 (1991).

In the American case of *Echazabal v Chevron USA*[105] the court found that the employer had acted in contravention of federal disability discrimination law by refusing to rehire an employee who had a liver condition. The court reached this decision even though the employer's reason for not wanting to re-employ the individual was that his existing liver condition might be aggravated by exposure to hazardous chemicals. A second possible justification for employers' interest in genetic information is the protection of co-workers from risks associated with a genetic disorder of a colleague. A good example would be that of an employee who operates a forklift at a construction site and who has a disease which causes him to have seizures. In this case it may be argued that the employer has a duty to provide a safe working environment for all workers and therefore has a right to know about risks posed by one worker to the safety of other workers.

A contrary argument would be that even an employee who does not have a genetic predisposition to such a disease can have a sudden physiological reaction to an unknown factor, which may endanger the lives of co-workers. For example, exposure to heat, hunger, dehydration, and other 'non-genetic' factors, could also cause a person to lose unconsciousness. These are eventualities which no employer can always guard against. In order to balance the scales, however, it is submitted that where such an incident does occur, the employer must investigate the cause thereof. Even so, the employer should not be entitled to see the results of any genetic test. Based on the results of any tests that are done, the examining physician should determine whether the employee is fit to continue working in that particular position and should advise the employer accordingly. At no stage should the employee's medical diagnosis be disclosed to the employer.

A third reason that could be advanced by employers is the protection of the public. Commercial airline pilots are often used as an example to support this argument. In this case it may be necessary to draw a distinction between the results of diagnostic and predictive tests. Diagnostic genetic testing reveals whether a person has a particular disease at the time of testing. Predictive genetic testing can be divided into two categories, namely predictive presymptomatic and predictive predispositional. Predictive presymptomatic tests reveal with certainty whether or not a person will develop a

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[105] Supra note 98.

particular disease sometime in the future whilst predictive predispositional tests simply indicate whether a person has a risk of developing a particular disease. The issue here is whether or not employees who exhibit no clinical signs of disease should be subjected to genetic testing by the employer or have results of previous genetic tests disclosed to the employer. It is submitted that due to the inherent requirements of a particular job or based on clinical signs, the employer may require the employee to undergo genetic testing. However, the attending physician should be prohibited from disclosing the results of any testing to the employer, save to inform the employer that the employee is not fit for that particular position. This needs to have the force of law and genetic privacy legislation is clearly the answer.

Employers may possibly also be motivated by economic considerations to conduct genetic testing on employees. They could be interested in reducing compensation claims, excluding people who would need a lot of time off work due to illness thereby hampering productivity, and generally keeping costs down. Whether or not this is acceptable depends to a large extent on the nature of the employer's business. Based on inherent requirements of a job, an employer may resort to genetic testing. Examples would be jobs where there is exposure to hazardous chemicals (unsuitable for individuals with asthma); repetitive movements (unsuitable for those who have carpal tunnel syndrome); strenuous activity (not suited to those who have or who are carriers of sickle cell anaemia). This list is not exhaustive. The circumstances of each case will have to be investigated and a decision will have to be made on the merits.

Legislation should be developed which prohibits the disclosure of genetic information to employers but which also provides that employers may request genetic testing in clearly prescribed circumstances if they can justify it based on strict criteria specified by the legislation. The approach of the legislature and the courts to the issue of HIV testing in the workplace may prove instructive in this regard. South Africa's Employment Equity Act[106] has a provision relating to HIV testing, which prohibits the testing of an employee for the purpose of determining HIV status, unless such testing is found to be

[106] Act 55 of 1998.

justifiable by the Labour Court.[107] In the case of *Joy Mining Machinery v NUMSA*[108] the court listed the following relevant factors:

(1) the prohibition of unfair discrimination;

(2) the need for HIV testing;

(3) the purpose of the test;

(4) the medical facts of the case;

(5) employment conditions;

(6) social policy;

(7) the fair distribution of employee benefits;

(8) the inherent requirements of the job; and

(9) the category of the employees concerned.[109]

The Court indicated that it also required information on:

(1) the attitude of the employees;

(2) whether the test was voluntary;

(3) the financing of the tests;

(4) pre-test preparation and counselling; and

(5) the nature of the test and post-test counselling.[110]

The court noted, however, that these additional factors do not go to justifiability but are merely for the purpose of assisting the court in its deliberations. Even though this case deals with HIV testing, it does provide some indication of the approach of the courts in dealing with sensitive issues in the workplace.

(b) Form and extent of protection

Kim suggests that preventing harm in these contexts is most suitably addressed by the implementation of genetic information privacy protection as opposed to the creation of anti-discriminatory measures. This is simply because the flow of information is easier to

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[107] Ibid s 7(2).

[108] *Joy Mining Machinery (A division of Harnischfeger (SA) (Pty) Ltd) v NUMSA & others* [2002] 4 BLLR 372 (LC).

[109] Ibid 378.

[110] Ibid 379.

monitor and enforce as opposed to the use of information once it is in the hands of an insurer or employer.[111] Kim argues as follows:

> 'The issue of genetic privacy, then, is prior to that of discrimination. If employers have access to workers' genetic information, divining when they have used that information improperly will be extremely difficult. If, however, that information is unavailable, discrimination on the basis of genetic traits becomes impossible. Those concerned about preventing genetic discrimination, then, ought to be concerned first and foremost with protecting the privacy of workers' genetic information.'[112]

Kim favours an objective form of legal protection as opposed to a subjective test. Insofar as the choice of a particular law is concerned, Kim accordingly argues that 'the problem of genetic discrimination in the workplace is better understood using the model of privacy rights rather than the traditional antidiscrimination paradigm. Recasting the problem in this way…shifts the focus of any legal response away from divining an employer's "true" motivation, and toward defining and controlling the flow of protected information'.[113] This view has merit. Proving an employer's true intention would be difficult and may only result in the dilution of any protection sought to be afforded by anti-discrimination legislation.

It has been observed that restrictions on the collection of genetic information are often limited to future genetic testing and do not protect existing genetic information. Article 12 of the Convention on Human Rights and Biomedicine, which states that genetic tests may be done only for health purposes or for scientific research linked to health purposes, and not for selective purposes in the domains of work or insurance, is cited as an example.[114] Legislation, regulations, rules, and industry codes must also protect existing genetic information. This may not be entirely possible with regard to insurance due to fears of adverse selection but there is no reason why it cannot be done in the employment sphere. It is, after all, unlikely that an individual who has had a genetic test which reveals a predisposition to a certain disease will consciously seek employment in an environment which will bring about the onset of the disease. For example, a reasonable person who has a genetic predisposition to asthma will not seek employment

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111 Kim op cit note 101.
112 Ibid 1537.
113 Ibid 1501.
114 Peter S Harper, Sjef Gevers, Guido de Wert, Susan Creighton, Yvonne Bombard & Michael R Hayden 'Genetic testing and Huntington's disease: Issues of employment' (April 2004) 3 *The Lancet Neurology* 249 at 250.

in a chemical plant where he or she will be exposed to harmful chemical fumes on a daily basis. I submit that the number of prospective employees who might ignore the results of predictive genetic tests is too small to have any significant adverse impact on the employer's business so as to warrant the disclosure of the employee's genetic information.

3.4 GENETIC RESEARCH AND THE CONCEPT OF VULNERABILITY

The Bill of Rights contained in the Constitution of South Africa provides that '[e]veryone has the right to bodily and psychological integrity, which includes the right…not to be subjected to medical or scientific experiments without their informed consent.'[115] In accordance with this constitutional right, the National Health Act[116] seeks to protect research participants against unethical research practices. Section 71 provides as follows:

'(1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-
(a) in the prescribed manner; and
(b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.'

Except for the National Health Act,[117] no other legislation seeks to enforce the constitutional rights of research participants.

The foundational principles of ethical research in South Africa are respect for the dignity of persons, beneficence and non-maleficence, and justice.[118] In practice this requires inter alia risk-benefit assessments, precautionary measures to protect the privacy of participants, and informed consent. There are various domestic[119] and international[120] ethical guidelines which do provide some form of protection to research participants in

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115 Act 108 of 1996, s 12(2)(c).
116 Supra note 46.
117 Ibid.
118 Supra note 49.
119 Department of Health *Human Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth Defects and Disabilities* Pretoria, South Africa (2001).
Department of Health *National Guidelines for the Care and Prevention of the Most Common Genetic Disorders, Birth Defects and Disabilities* Pretoria, South Africa (2005).
Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* Pretoria, South Africa (2006).

South Africa but these cannot be legally enforced. The domestic ethical guidelines are discussed in detail in chapter seven. It is important for the purpose of this discussion to note the following observations regarding human genetic research as contained in the Research Ethics Guidelines issued by the Department of Health in 2004:

> 'Participants may be at risk of harm arising from the use of genetic information, including stigmatisation or unfair discrimination, and adoption of exclusionary policies. Researchers should recognise that special care must be taken to protect the privacy and confidentiality of genetic information. Research ethics committees should require researchers to consider whether a proposed genetic study might lead to a potential harm to participants, and what steps can be implemented to obviate such harm. The results of genetic tests, especially those that provide information about future health, could be used, potentially, by third parties such as insurance companies and employers to assist with decisions concerning research participants and their families. By participating in genetic research, people should not be put at risk of being deprived of benefits available to other members of the community.'[121]

These observations clearly reflect an acknowledgement that external harm may befall genetic research participants and the guidelines aim to address the threat via ethical principles of research. Whether this amounts to adequate protection in the context of genetic research is a question which will be addressed further in this chapter.

The issue of vulnerability is important in medical research involving human participants. The importance of this issue is heightened in the context of genetic research which often targets ethnic groups and families. Such groups and families become vulnerable to external harm in the form of genetic discrimination. The discovery of the prevalence of certain genetic disorders in certain ethnic groups has created concern amongst members of such groups. Examples would be the prevalence of Tay-Sachs disease and breast cancer amongst individuals of Ashkenazi Jewish descent as well as sickle-cell disease amongst African Americans. The possible implications of such discoveries for employment and insurance prospects amongst such groups must be addressed. Unfortunately there does not appear to be consensus on the definition of

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Department of Health *Ethics in Health Research: Principles, Structures and Processes* Pretoria, South Africa (2004).
South African Medical Research Council *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* (2002).
A Dhai, N Msomi & DJ McQuoid-Mason *Code of Ethical Practice for Medical Biotechnology Research in South Africa* (2005).
Health Professions Council of South Africa *Guidelines for Good Practice in the Health Care Professions – Confidentiality: Protecting and Providing Information*. Pretoria, South Africa (2008).

[120] Supra notes 31, 32, 33, 34 and 37.

[121] Supra note 54.

vulnerability in bioethics discourse. What is clear, though, is that the concept remains a useful one even though it evades precise definition.

Genetic research holds great promise for medical science and must therefore be encouraged. In order for such research to continue and for its potential to be fully realised, it is necessary to alleviate the fear of genetic discrimination. Whether this can be achieved by the requirement of informed consent and the conventional concept of vulnerability is debatable. The aim of this discussion is to identify the deficiencies in the current framework.

(a) Historical Background

The atrocities committed by German Nazi scientists and physicians during World War II were exposed during the Nuremberg medical trials[122] (often referred to as the Doctors' Trials) held in 1946. During the trials it emerged that prisoners in concentration camps had been used as research subjects in inhumane and degrading experiments without their consent. These experiments caused enormous pain, suffering, permanent disability, and often death. The gravity of the revelations made during the trial led to the development of the Nuremberg Code[123] in August 1947. This Code sets out the following ten basic ethical principles of clinical research:

(a) Voluntary consent of subjects is essential.

(b) The research must be necessary and for the good of society.

(c) The research must be justifiable on the basis of anticipated results.

(d) Unnecessary physical and mental suffering and injury should be avoided.

(e) Research should not be undertaken where there is reason to believe that death or disabling injury may result.

(f) The degree of risk to be taken should not be greater than that determined by the humanitarian importance of the objective of the research.

(g) Steps must be taken to protect subjects against even remote possibilities of injury, disability, or death.

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[122] *U.S.A v Karl Brandt et al* (held under the provisions of Control Council Law No.10 from 21 November 1946 – 20 August 1947) available at http://nuremberg.harvard.law.edu accessed on 14 April 2011.

[123] Supra note 31.

(h) Research should be undertaken only by persons qualified to do so.

(i) A subject should have the right to withdraw from an experiment at any stage.

(j) A researcher must be prepared to terminate an experiment at any stage if he has cause to believe that continuation is likely to result in injury, disability or death of the subject.[124]

The Nuremberg Code is a concise statement of ethical principles. In 1964 the World Medical Association developed the Declaration of Helsinki[125] which is a statement of guiding ethical principles for those who undertake research involving human participants. This document is more comprehensive and far-reaching than the Nuremberg Code. It recognises that some research participants are vulnerable and need special protection. It also emphasizes respect for the privacy of research participants.

Unfortunately the Nuremberg Code and the Declaration of Helsinki were not entirely successful in curbing unethical research practices. Beecher, a Harvard researcher, exposed more than twenty unethical studies in an article published in 1966.[126] A well-known example of unconscionable and unethical research is that of the Tuskegee Study of untreated syphilis which was conducted in the United States from 1930 to 1970. In that experiment a group of four hundred poor and uneducated African-American men with syphilis were left untreated for a period of forty years so that researchers could follow the natural course of the disease. At the time penicillin had been identified as treatment for syphilis but this information was withheld from the participants. Eventually congressional hearings were held and the study was terminated. Another well-known case is that of hepatitis research at the Willowbrook State School for mentally disabled children in New York. Between 1956 and 1972 children at this school were used as 'subjects' to study the course of infectious hepatitis and to test the effects of potential treatment.

The ensuing furore caused by the exposure of these unethical studies prompted the government of the United States of America to take action to regulate clinical research. The first step was the passing of the National Research Act of 1974, which created the

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[124] The Nuremberg Code uses the term 'human subjects'. This term is used in this thesis only where the instrument which is being discussed uses such term. In all other instances the term 'research participant' is used.

[125] Supra note 32.

[126] Beecher HK 'Ethics and clinical research' (1966) 274 *New England Journal of Medicine* 1354.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission compiled the Belmont Report[127] which discussed three ethical principles of research, namely, respect for persons, beneficence, and justice. The report specifically acknowledges vulnerable groups and bases their non-involvement in research on the principle of justice. In this regard it provides as follows:

> 'One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.'[128]

In 2002 the Council for International Organizations and Medical Sciences (CIOMS) and the World Health Organisation (WHO) developed International Ethical Guidelines for Biomedical Research Involving Human Subjects.[129] These guidelines provide that 'all research involving human subjects should be conducted in accordance with the basic ethical principles, namely respect for persons, beneficence and justice.'[130] They deal with the application of ethical guidelines in research involving human participants. According to the guidelines '[r]espect for persons incorporates at least two fundamental ethical considerations; namely:

> (a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
> (b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.'[131]

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[127] In 1973 the U.S. Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which issued the Belmont Report in 1979.

[128] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report - Ethical Principles and Guidelines for the protection of human subjects of research* (1979) at Part C item 3 available at http://ohsr.od.nih.gov/guidelines/belmont.html accessed on 3 August 2011.

[129] Supra note 33.

[130] Supra note 33 guideline 18.

[131] Supra note 33 at 17.

(b) Vulnerability in genetic research

All of the instruments discussed above take cognisance of the fact that certain individuals and groups need more protection than others in the research setting. Such groups are deemed 'vulnerable' and more stringent requirements accordingly apply for approval of their participation in research. Two major problems with the concept of vulnerability in research involving human participants can be identified: lack of consensus regarding the definition of vulnerability and failure of conventional definitions of vulnerability to adapt to 'new' areas of research. The unfortunate result of these problems is that some search participants who genuinely require additional protection cannot and do not receive it. This ultimately compromises important research. The problem is heightened in the area of genetic research which is sensitive but crucial for advances in medicine and health care.

The issue of vulnerability is undoubtedly very important in research involving human participants. The Universal Declaration on Bioethics and Human Rights[132] provides specifically for respect for human vulnerability. Article 8 provides that 'In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.' The International Bioethics Committee (IBC) of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) recently released a Report on the Principle of Respect for Human Vulnerability and Personal Integrity.[133] This report focuses on article 8 of the Universal Declaration on Bioethics and Human Rights[134] and points out that 'the specific task of this Article is to address special vulnerabilities that occur, whether as a consequence of personal disability, environmental burdens or social injustice, in the contexts of health care, research and the application of emerging technologies in the biomedical sciences.'[135]

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[132] Adopted by the United Nations Educational, Scientific and Cultural Organisation on 19 October 2005 available at http://portal.unesco.org/en/ev.phpURL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html accessed on 29 May 2011.

[133] IBC Report *Principle of Respect for Human Vulnerability and Personal Integrity* (22 June 2011) available at http://unesdoc.unesco.org/images/0018/001895/189591e.pdf accessed on 21 September 2011.

[134] Supra note 132.

[135] Supra note 133 item 5.

Unfortunately the concept of vulnerability in research involving human participants evades precise definition. Various definitions may be found in international and domestic ethical guidelines but none are completely adequate. The following examples are indicative of the vagueness surrounding this concept. The previous (2004) version of the Declaration of Helsinki[136] described vulnerability as follows:

> 'Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.'[137]

The current (2008) version of the Declaration of Helsinki[138] provides as follows:

> 'Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.'[139]

The CIOMS guidelines[140] define vulnerability as 'a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.'[141] The guidelines also provide that 'vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.[142] Groups that are deemed vulnerable are those who lack the capacity to consent; subordinate members of hierarchical groups such as medical and nursing students, subordinate hospital and laboratory personnel, employees of pharmaceutical companies, and members of the armed forces or police; elderly persons; residents of nursing homes; people receiving

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136 World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants* Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and last amended by the 55th WMA General Assembly, Tokyo, Japan, October 2004.
137 Ibid Article 8.
138 Supra note 32.
139 Ibid Article 9.
140 Supra note 33.
141 Ibid 18.
142 Ibid 64. Commentary on Guideline 13.

welfare benefits or social assistance and other poor people and the unemployed; patients in emergency rooms; some ethnic and racial minority groups; homeless persons; nomads; refugees or displaced persons; prisoners; patients with incurable disease; individuals who are politically powerless; and members of communities unfamiliar with modern medical concepts.[143] There are no specific guidelines dealing with genetic research.

The South African position is reflective of the international consent-based approach. Research ethics guidelines issued by the Department of Health (DOH) define vulnerable participants as follows:

> 'Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable participants include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.'[144]

The DOH guidelines for clinical trials[145] identify participants whose involvement need special attention. These include children and adolescents; women; people with mental disabilities or substance abuse related disorders; persons in dependent relationships or comparable situations; prisoners; and persons highly dependent on medical care.[146] In a similar vein the MRC regards pregnant women, children, adolescents, prisoners, people with mental disabilities, the elderly, students, and persons in dependent relationships as special groups who require special attention.[147] The emphasis in both sets of guidelines is on capacity to provide informed consent and voluntariness.

Unfortunately none of the abovementioned instruments regard genetic research participants as vulnerable even though they are exposed to an increased risk of stigmatisation (social harm) as well as potential discrimination by insurers and employers

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143 Ibid 64 -65.
144 Supra note 54 at 60.
145 Supra note 49.
146 Ibid 16.
147 South African Medical Research Council *Guidelines on Ethics in Medical Research: General Principles* (2002) guideline 7.1.3. available at http://www.mrc.ac.za/ethics/ethicsbook1.pdf accessed on 4 August 2011.

(economic harm). Due to the nature of genetic information, genetic research participants are more susceptible to social and economic harm than other human research participants are. The IBC report on vulnerability, recognises 'threats to privacy engendered by the possession of genetic information' which 'would include access to the genetic data of patients by researchers, insurance companies, employers and governments.'[148] The report notes further that 'Such disclosures would engender major vulnerabilities to restrictions of civil liberties.'[149] Even though this is the case, genetic research participants are not deemed vulnerable either by international or domestic ethical instruments. The aim here is to find the reasons for such non-inclusion and to suggest ways to remedy the situation so as to adequately protect human genetic research participants.

It is argued here that the problem of non-inclusion of genetic research participants as a vulnerable group lies with the foundation of the definition of vulnerability. The conventional view, as reflected in the international and domestic ethical guidelines discussed above,[150] is that vulnerable persons are those who lack the ability to provide informed consent and those who are susceptible to coercion. This includes mentally disabled persons, children, prisoners, pregnant women, foetuses, economically or educationally disadvantaged persons. The conventional grounds on which additional protection is required cannot accommodate genetic research participants as a vulnerable group. The determination of vulnerability is based on lack of capacity to consent and on susceptibility to coercion or exploitation, neither of which is automatically satisfied in the case of genetic research participants.

Levine et al are of the view that existing definitions are both 'too broad and too narrow.'[151] They argue that the concept has lost its force because too many groups are now considered vulnerable. This is why the existing definitions may be considered too broad. On the other hand, they argue that certain research participants who do require

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148 Supra note 133 item 37.
149 Ibid.
150 At 76 - 78 above.
151 Carol Levine; Ruth Faden; Christine Grady; Dale Hammerschmidt ; Lisa Eckenwiler & Jeremy Sugarman 'The limitations of 'vulnerability' as a protection for human research participants' (2004) 4:3 *The American Journal of Bioethics* 44.

additional protection are not receiving it because they are not deemed vulnerable.[152] This is where existing definitions prove to be too narrow. Levine et al are critical of the 'almost exclusive emphasis' on capacity to give consent, to the exclusion of other factors.[153] They argue that this results in the concept of vulnerability being too narrow. Hurst shares this view as she also argues that current definitions of vulnerability are either too broad or too narrow.[154] She refers to definitions which 'encompass humanity in its entirety' as overly broad.[155] Definitions which restrict vulnerability exclusively to those who lack the capacity to give informed consent or who are more susceptible to exploitation, are viewed by Hurst as being too narrow.[156] Such narrow definitions inevitably exclude certain participants who require greater protection. In the end such narrow definitions may defeat the very purpose of the concept of vulnerability in research, which is to protect participants from harm. These arguments indicate that the conventional definition of vulnerability should be revisited.

Research Ethics Committees evaluate special risks in respect of vulnerable groups. However, due to the generally accepted conventional definition of vulnerability, research participants cannot be regarded as vulnerable purely on the basis of their participation in genetic research. This is so even though there are special risks that must be considered in genetic research. There is thus clearly a deficiency in the current framework which must be addressed if critical genetic research, which is ultimately in the interest of humanity as a whole, is to be fostered. The following observation by Levine et al captures the cause of the problem relating to the concept of vulnerability:

> 'The concept of vulnerability, however, fails to address less settled situations arising from the context in which contemporary research is conducted. The research enterprise has changed dramatically since the 1970s when the current approach to understanding the ethical issues was largely formulated. Unlike the research that set the context for the existing ethical framework, research today has many complicating features, including increasing privatization and globalization of research; a growing number of complex, multisite trials and office-based trials, with treating physicians as researchers; rapid development in the pipelines for novel agents, many based on genomic and proteomic

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152 Ibid 47.
153 Ibid 46.
154 Samia A. Hurst 'Vulnerability in research and health care: Describing the elephant in the room?' (2008) 22:4 *Bioethics* 191 at 191-192.
155 Ibid.
156 Ibid.

> discoveries; and, most recently, an elevated concern with public health threats such as bioterrorism and new or resurgent infectious diseases.'[157]

It is apparent that the definition of vulnerability has not kept pace with the changing scope of research involving human participants. Genetic research brings to the fore two major issues for consideration. First, the increased potential for social and economic harm needs to be considered. The first step would be the due recognition of social and economic harm. These types of harm are not new to research ethics and are referred to in the Belmont Report.[158] Monnye argues, however, that social and economic risks have not received due recognition in South Africa.[159] His criticism is supported by reported cases demonstrating the consequences of non-recognition of social and economic risks in South Africa specifically.[160] Among these consequences are employment discrimination and physical harm inflicted by members of a community on one individual due to the disclosure of individuals' HIV status. These consequences are possible in the case of the disclosure of genetic conditions as well since individuals belonging to ethnic groups/communities with a known susceptibility to certain genetic conditions may be stigmatised or discriminated against. The example of the Ashkenazi Jewish population may be used here in support of this assertion. As discussed above,[161] in 1997 United States Jewish leaders met with members of the National Institute of Health to discuss the meaning of genetic research for Jews; concern about the lack of legal protection against genetic discrimination; and fears of stigmatisation and denial of jobs and health insurance.[162]

Based on Monnye's argument as well as the concerns of the Ashkenazi Jewish population, it can be argued that potential social and economic harm need to be dealt with in research in order to protect research participants and thereby foster research in critical areas such as genetics. The definition of vulnerability needs to evolve in order to address this issue. Such evolution requires the recognition of other harms in addition to the conventional physical harm associated with research. This recognition will facilitate the revision of the definition of vulnerability to include susceptibility to other types of harm.

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157 Levine et al op cit note 151.
158 Supra note 128 Part C item 2.
159 Op cit note 28 at 80.
160 Ibid.
161 At 50 above.
162 Wadman op cit note 18.

It is clearly not helpful to rely on outdated concepts which cannot satisfactorily address new challenges in research. The definition of vulnerability must be revisited if the concept is to retain its usefulness as a tool for the protection of human research participants.

Secondly, the potential for harm to family members and members of ethnic groups, who may not themselves be participants in research (non-participants), must be seriously considered in deciding whether or not to extend the definition of vulnerability to include genetic research participants. As mentioned above, the definitions of vulnerability, both internationally and domestically, are predominantly consent-based.[163] In terms of this approach individuals who lack capacity to consent or who are more likely to be coerced or exploited, are deemed vulnerable. If applied to genetic research, it means that 'non-vulnerable' participants will be informed of the risks and benefits applicable to the research and they will be requested to agree to participate with full knowledge of such risks and benefits. It is assumed that all risks, including potential risks to non-participants will be disclosed by researchers. The difficulty here lies in the fact that participation of one individual in research may have social and economic consequences for non-participants. The individual may be willing to bear the risk of social and economic harm in his/her personal capacity and this will be indicated by his/her furnishing of informed consent. There is, however, no guarantee or proof that non-participants would be willing to bear those same risks.

Can the consent which is furnished by a genetic research participant be deemed to apply in respect of affected non-participants? The answer has to be 'no' simply because a research participant does not have inherent legal authority to consent for or on behalf of non-participants. One then has to address this dilemma. I submit that the solution lies in classifying all genetic research participants as vulnerable, thereby creating an automatic responsibility for researchers to implement additional safeguards in genetic research as is the position with research involving other vulnerable groups. The current position is that genetic research will require additional safeguards only where it involves existing vulnerable groups. Such groups include those who lack the ability to provide informed consent and those who are susceptible to coercion. Genetic research participants cannot

[163] At 76 -79 above.

be accommodated within the existing consent-based definition of vulnerability. The suggested inclusion of genetic research participants as a vulnerable group would therefore require an extension of the definition of vulnerability as discussed further below.[164]

The suggested extension of the definition of vulnerability may be justified further on the basis of the importance of genetic research as acknowledged by UNESCO'S International Declaration on Human Genetic Data.[165] The Declaration recognises that 'human genetic data have a special status on account of their sensitive nature.'[166] It also acknowledges that 'the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine.'[167] Article 7 of the Declaration deals specifically with non-discrimination and non-stigmatisation. It provides as follows:

> '(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.
> (b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.'

The Declaration captures the benefits of and threats to genetic research. It is clear that genetic information is necessary for scientific progress and that certain types of genetic research can only be conducted amongst certain population groups. Adequate safeguards must be put in place to secure the participation of the required groups. The Declaration indicates what steps should be taken by States to protect the privacy of individuals. It is expected that the required level of protection will be achieved through domestic law. Genetic information requires additional protection because it can also reveal sensitive information about family members who may not themselves have been involved in the research. As mentioned above, there is thus the potential for harm to non-participants as well.[168] There are so many issues to consider in genetic research that evaluation of special risks should be compulsory for research ethics committees. This can only be

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164 At 84 below.
165 Supra note 37.
166 Ibid Article 4.
167 Ibid Preamble.
168 At 82 above.

guaranteed if genetic research participants are deemed to be a vulnerable group on the basis of their increased susceptibility to social and economic harm.

It is clear from the discussion above that the conventional consent-based approach to vulnerability is not adequate for genetic research. This is due mainly to the familial and hereditary characteristics of genetic information. I would therefore argue that the solution lies in extending the definition of vulnerability to include increased susceptibility to additional harm due to or resulting from participation in research. It will then become possible to classify human genetic research participants as vulnerable purely on the basis of increased susceptibility to social and economic harm in the form of stigmatisation and discrimination by insurers and employers. The classification of genetic research participants as vulnerable will compel research ethics committees to insist upon more stringent privacy protection mechanisms for genetic research, thereby protecting participants and affected non-participants from research-related harms. This vulnerability should be recognised by law and research ethics committees should be legally compelled to ensure compliance with the requirements for additional protection.

The suggested extension of vulnerable groups to include genetic research participants is likely to receive criticism on two grounds. The first criticism is likely to be that too many groups are already deemed vulnerable and the addition of a further group serves only to further stretch the limited resources of research ethics committees whilst making the concept of vulnerability 'too nebulous to be meaningful.'[169] Levine et al are critical of the ongoing extension of the category of vulnerable groups.[170] They analyse the definitions of vulnerability in the Declaration of Helsinki[171] and in the CIOMS guidelines[172] and conclude that nowadays almost everyone is considered vulnerable in the context of research. For this reason they consider vulnerability to be too broad to make a significant impact on the protection of research participants.

The second criticism is likely to relate to the categorisation of all genetic research participants as vulnerable. Levine et al argue that 'the strategy of relying on categorical

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169 Levine et al op cit note 151 at 46.
170 Ibid.
171 Supra note 32.
172 Supra note 33.

vulnerability…is flawed.'[173] An obvious flaw which they discuss is the stereotyping of 'whole categories of individuals' without any thought being given to the special circumstances of the individuals who fall within a particular category.[174] Categorical vulnerability focuses on the whole rather than the constituent parts of a vulnerable group. The criticisms leveled by Levine et al are clearly not without merit. They do, however, attempt to temper their criticisms by stating as follows: 'public policy is a blunt instrument and sometimes it is necessary to set cut-offs or designate whole groups for special treatment because individualised decision making is not feasible.'[175]

Levine et al are not alone in their views regarding the flaws in the concept of categorical vulnerability. Schroeder and Arnason have since taken the argument a step further by raising the issue of false categorisations.[176] In order to illustrate their point they use an example of an unemployed person in Sweden versus an unemployed person in Zimbabwe.[177] Both of these individuals share the unfortunate plight of being unemployed but the Swedish person is undoubtedly better off because of the extent of the support that he/she receives from the State. The situation of an unemployed Zimbabwean is more desperate and he/she is therefore more susceptible to exploitation for research purposes. This example shows that even though certain individuals may share a common characteristic, their susceptibility to harm may not be the same due to other factors. It clearly demonstrates the dangers of categorizing entire groups as vulnerable without considering relative risks. Schroeder and Arnason make a valid point which must be addressed if the concept of vulnerability is to continue being used for the protection of human research participants.

In response to the criticisms by Levine et al and Schroeder and Arnason against the categorisation approach, it must be pointed out that genetic research lends itself to the conventional categorisation approach and there is no possibility of a false categorisation. This is so because all genetic research participants, irrespective of personal attributes or circumstances, are susceptible to stigmatisation and genetic discrimination. The IBC

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173 Levine et al op cit note 151 at 47.
174 Ibid 46.
175 Ibid 47.
176 Doris Schroeder & Gardar Arnason 'Vulnerability: Too vague and too broad?' (2009) 18 *Cambridge Quarterly of Healthcare Ethics* 113.
177 Ibid 118.

report notes that 'while some groups of people can always be considered vulnerable because of their status (e.g. children), others may be vulnerable in one situation but not in another.'[178] Genetic research participants fall into the former group because their vulnerability is not determined by circumstances but by their status. After considering the opposing views on the issue of vulnerability in research, I must conclude that group categorisation is not satisfactory for medical research but is ideal for genetic research involving human participants.

3.5 CONCLUSIONS

Genetic discrimination in employment and insurance have not yet become major problems anywhere in the world but the fact that many governments are proactively taking steps to prevent genetic discrimination indicates an acceptance of the fact that there is no turning back from the genomic era. The rapidly advancing science of human genomics means that it is only a matter of time before the threat becomes reality. Failure of law and ethics to keep pace with the science of genomics means leaving people exposed to breaches of privacy, genetic discrimination, and exploitation in research. The fear of genetic discrimination has consequences for genetic research by deterring participation in such important and much-needed research. This should serve as sufficient motivation for the introduction of genetic privacy protection mechanisms. Preventing harm in the contexts of employment and insurance is most suitably addressed by the implementation of genetic information privacy protection as opposed to the creation of anti-discriminatory measures. This is simply because the flow of information is easier to monitor and enforce as opposed to the use of information once it is in the hands of an insurer or employer.[179]

In the insurance context there is clearly a need for the introduction of privacy protection mechanisms due to the importance of genetic information for underwriting purposes. The insurance industry is not yet actively lobbying for access to genetic information but that is only because the actuarial relevance of genetic information has not

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[178] Supra note 133 para 7.
[179] Kim op cit note 101.

yet been determined. Insurers are likely to seek access to genetic to genetic information in order to avoid adverse selection. Moratoria on the use of genetic information by insurance companies is one approach to protecting genetic privacy but concerns have been raised about enforcement.[180] Maintaining the status quo is another approach but it cannot be encouraged because it ignores the gravity of public concern about genetic discrimination.[181] In an area as sensitive and as far-reaching as human genetics, it is safer to rely on legislation as a protective mechanism due to its status and enforceability.

Employers could possibly seek to justify gaining access to genetic information of employees on the basis of protection of employees from workplace hazards, protection of co-workers, or protection of the public. They should, however, not have an automatic right of access to genetic information of employees.[182] Legislation, regulations, rules, and industry codes must protect existing genetic information. Genetic testing at the request of employers may be reasonable and necessary if it is based on the inherent requirements of a job but there is no need for the disclosure of actual test results to the employer. Based on the results of any genetic testing that is done, the examining physician should simply determine whether the employee is fit to continue working in that particular position and should advise the employer accordingly. Legislation should be developed which prohibits the disclosure of genetic information to employers but which also provides that employers may request genetic testing in clearly prescribed circumstances if they can justify it based on strict criteria specified by legislation.

Human participation in genetic research is necessary. In order to encourage such participation it is necessary to reassure prospective participants that their genetic information will be protected from unauthorised disclosure which could lead to stigmatisation and discrimination. Ethical guidelines do provide for the protection of human research participants but these lack enforcement mechanisms and Research Ethics Committees are not functioning optimally. Despite the existence of these mechanisms there are still many cases of unethical research practices in South Africa and the rest of the world. These mechanisms can therefore not be relied upon to enforce the protection of genetic research participants. Potential stigmatisation and genetic discrimination

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180 Joly et al op cit note 8.
181 Ibid.
182 Kim op cit note 101 at 1543.

arising from genetic research involving human participants warrants the introduction of genetic privacy legislation. Statutory genetic privacy protection will provide genetic research participants with the required assurances thereby encouraging participation in and fostering genetic research.

Genetic research participants are vulnerable to social and economic harm and they accordingly require additional protection in research. A unique aspect of genetic research is that the vulnerability of participants to social and economic harm, extends to non-participants as well due to the familial nature of genetic information. The conventional consent-based definition of vulnerability does not address the unique familial aspect of vulnerability in genetic research. If the concept is to retain any significance in genetic research, it must be extended to include considerations of susceptibility to additional harm in the form of social and economic harm. Based on the inherent susceptibility of genetic research participants to social and economic harm, they should automatically be deemed vulnerable. A classification of genetic research participants as vulnerable will compel researchers to consider additional protection for participants which will then also automatically address concerns regarding harm to non-participants.

Concerns relating to potential genetic discrimination and the need to promote genetic research require protection of genetic privacy. This protection can only be achieved through legislation. The adequacy of the South African privacy legislation in this respect is accordingly discussed in the next chapter.

CHAPTER IV

PRIVACY: THE SOUTH AFRICAN PERSPECTIVE

4.1 INTRODUCTION

The concept of privacy is a dynamic one which is constantly being reshaped in accordance with the changing needs of society. Privacy, as a right of personality, is constantly under threat due to modernisation, globalisation, innovation, and the introduction of new technologies. Since it is so affected by change, it cannot be a rigid concept. It has to promote legal certainty whilst simultaneously being flexible enough to accommodate societal demands and maintain efficacy, failing which it will only offer limited protection.

To this day privacy remains an elusive concept which evades precise legal definition. By its very nature it is a concept which is difficult to define. The discussion which follows on the various definitions proposed over the years by legal commentators, together with criticisms of such definitions, proves this point.

The right to privacy is protected by the common law and the Constitution.[1] Genetic information privacy is not yet the subject of debate in South Africa but it demands attention based on the reasons discussed in chapter one.[2] Even though the right to privacy enjoys constitutional protection, the challenges posed by a combination of genetic technology and information technology require legislative intervention. Urgent calls for legislative intervention in situations involving the collection of personal data have been spurred by the threat that this poses to the privacy of individuals.[3] Neethling et al observe that the creation of databanks 'pose an immense threat to the individual' due to the use of computer technology.[4] They also note that 'South African commentators are unanimous that the creation of such measures through legislation is a matter of great

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1 Constitution of the Republic of South Africa Act 108 of 1996.
2 Chapter 1 at 3.
3 J Neethling, J M Potgieter & P J Visser *Neethling's Law of Personality* 2 ed (2005) 267-271.
4 Ibid 267.

urgency.'[5] As far as genetic information is concerned, the threat arises in the context of the creation of DNA databases. There is no legislation in South Africa aimed at the regulation of human genetic databases. Insofar as the regulation of forensic DNA databases is concerned, the individual's right to privacy has to be balanced against the interest of the state in solving crime.

Data protection measures are clearly very limited in South Africa. The South African Law Reform Commission recently completed its investigation into personal data protection and also developed a draft data protection Bill for South Africa.[6] This draft Bill is a general data protection statute which stipulates general rules for data protection and is expected to be supplemented by sectoral laws and industry codes of practice.

This chapter commences with a historical perspective of the right to privacy. It traces the protection of personality rights from Roman and Roman-Dutch law to the current constitutional protection of the right to privacy in South Africa. The works of prominent Roman and Roman-Dutch jurists are considered together with contemporary legal literature and judicial decisions. This is followed by a discussion of the definition of privacy with brief examples of the various definitions that have been suggested. The aim of such an exercise is to highlight the inherent definitional difficulties posed by the concept and the resultant difficulty in devising adequate protection. The objective of this chapter is to illustrate how the law of privacy in South Africa has developed from Roman times to the current day and to determine whether current legal protection mechanisms can adequately protect genetic privacy.

4.2 HISTORICAL BACKGROUND

(a) Roman Law

The origins of the modern right to privacy can be traced to the protection of personality in Roman law. Originally the protection of personality in Roman law, through the Twelve

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5 Ibid 271.

6 South African Law Reform Commission Report (Project 124) *Report on Privacy and Data Protection* (2009).

Tables, was aimed at protecting bodily integrity.[7] Buckland observes that this was the first express legislation in the Roman state dealing with private law and that they consisted of ancient Latin custom together with some influence of Greek law.[8] As far as protection of personality was concerned, provision was made for the imposition of fixed pecuniary penalties in cases of physical harm to the person. 'Injuria'[9] referred to minor forms of physical injury.[10] McQuoid-Mason observes that Table VIII.1 penalised the making of defamatory statements, which conduct clearly did not constitute an affront to a person's bodily integrity, but did constitute an affront to the reputation and dignity of the person.[11] His argument is based on translations of Table VIII.1 as provided by Ortolan, Goodwin and De Villiers.[12] He accordingly argues that the Twelve Tables protected more than just bodily integrity as an aspect of personality.

McQuoid-Mason goes on to argue that the word 'injuriarum' as it appeared in Table VIII.4 included affronts to a person's honour.[13] His line of reasoning is that if Table VIII.1[14] dealt with infringements of reputation and dignity, and Tables VIII.2[15] and VIII.3[16] dealt with bodily injury, it follows that Table VIII.4 which is a general clause should apply to both. Table VIII.4 provides: 'si injuriarum faxit alteri, XXV poena sunto' which was translated as: 'for any injury whatsoever committed upon another the penalty shall be 25 asses.' Once again, McQuoid-Mason's arguments indicate that infringements of personality going beyond the physical realm, were recognised and penalised through the Twelve Tables. De Villiers, however, argues that at that stage the word 'injuria' had not yet acquired the meaning of an offence against the person, reputation or dignity.[17] He does concede, though, that an injuria may have involved

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7 Melius De Villiers *The Roman and Roman-Dutch Law of Injuries* (1899) 3; J A C Thomas *Textbook of Roman Law* (1976) 369; R G McKerron *The Law of Delict* 7ed (1971) 9; Neethling et al op cit note 3 at 40.

8 W W Buckland *A Text-Book of Roman Law From Augustus to Justinian* 3ed Revised by Peter Stein (1963) 1. Buckland states that the XII Tables were enacted about 450 B.C. by the Comitia Centuriata.

9 The words 'injuria' and 'iniuria' are used interchangeably, depending on the choice of the commentator being quoted or referred to.

10 Table VIII.4

11 David Jan McQuoid-Mason *The Law of Privacy in South Africa* (1978) 17.

12 Ibid.

13 Ibid 15-17.

14 Si qui occentassit, carmenve condisset, quod infamiam faxit, flagitiumve alteri, fusti feritor.

15 Si membrum rupsit, ni cum eo paxit, talio esto.

16 Si os fraxit, libero CCC, servo CL, poenae sunto.

17 De Villiers op cit note 7 at 2.

'some degree of ignominy'.[18] This also shows that ancient Romans were aware of affronts to dignity and saw the need to penalise such behavior, albeit in a subtle way.

The Twelve Tables were replaced by praetorian edicts out of necessity during the middle of the sixth century A.U.C.[19] The stagnant pecuniary penalties in terms of the Twelve Tables had become ineffective and the Romans were becoming more aware of personality infringements. The praetorian edicts introduced two significant changes to deal with these issues. First, they eliminated fixed pecuniary penalties by providing for the determination of the amount by judicial officers based on the seriousness of the injury. Secondly, they extended the actio injuriarum to non-physical interests.[20] McQuoid-Mason observes that certain non-physical interests protected by the edict, namely, convicium (public ridicule) and ademptata pudicitia (affronts to chastity) bear some resemblance to modern notions of privacy.[21] The praetors' edicts later became the actio injuriarum aestimatori, an action which has survived to this day.

The introduction of the Lex Cornelia de Iniuriis around the year 672 A.U.C.extended protection beyond the physical person to the non-physical realm, albeit by subjecting certain conduct to criminal sanctions. Provision was made for the offences of striking or beating another person. A distinction was drawn between the two acts. Beating was seen as an act causing physical pain whilst striking did not necessarily cause such pain. Striking was an offence regardless of the fact that it may not have caused physical pain. Of greater significance was the provision of an offence for forcibly entering the home of another.[22] McQuoid-Mason notes that 'this is often regarded as the best example of the recognition of a right to privacy by the Romans.'[23] Neethling observes that this amounts to recognition of privacy as a personality interest for the first time in Roman law.[24]

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18 Ibid fn14.
19 Ibid 4.
20 H F Jolowicz *Historical Introduction to the Study of Roman Law* 2 ed (1972) 287; Neethling et al op cit note 3 at 40.
21 McQuoid-Mason op cit note 11 at 19.
22 *Lex Cornelia de Iniuriis* D 47.10.5.1
23 McQuoid-Mason op cit note 11 at 21.
24 J Neethling 'Personality Infringement' in W A Joubert (founding ed) *The Law of South Africa* vol 20(1) First Reissue (1999) para 300.

Classical law considered the praetorian edicts together with the Lex Cornelia in extending the actio injuriarum to include any affront to another's personality rights, thereby creating a general delict in respect of infringements of personality rights.[25] The classical law recognised iniuriae relating to corpus, fama and dignitas. The former two were more easily defined whilst dignitas eluded definition. Neethling et al[26] and McQuoid-Mason[27] comment on the vagueness of this concept. In summarizing the legal position in classical law, Neethling et al state that the actio iniuriarum became available in all cases of infringements of corpus, fama, or dignitas and that dignitas was a wide concept encompassing those personality interests which had not been separately identified in Roman law.[28] Privacy was clearly included in the concept of dignitas.[29] The law recognised two forms of invasion of privacy, namely, forcible entry into another's home[30] and the premature disclosure of the contents of another's will.[31] McQuoid-Mason suggests, however, that in addition to these, several other forms of injuriae, similar to the modern concept of invasion of privacy in the United States, were recognised. These are intrusions, publication of private facts, and putting a person in a false light.[32] It is evident that privacy was becoming an important personality interest in the classical period. The three elements of the actio injuriarum were intention to injure (animus injuriandi), impairment of personality (corpus, fama or dignitas), and wrongfulness (boni mores).

The reign of Justinian is marked by the development of the Corpus Juris Civiliis. McQuoid-Mason correctly concludes that many of the examples of injuriae found in the Digest of Justinian would, in modern times, be recognised as invasions of privacy.[33]

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25 Neethling et al op cit note 3 at 42, 45; McQuoid-Mason op cit note 11 at 22.
26 Neethling et al op cit note 3 at 42.
27 McQuoid-Mason op cit note 11 at 22.
28 Neethling et al op cit note 3 at 45.
29 Ibid.
30 *Lex Cornelia* D 47.10.5pr.
31 Ibid D 9.2.41pr.
32 McQuoid-Mason op cit note 11 at 23.
33 Ibid 26.

(b) Roman-Dutch Law

The position in Roman-Dutch law reflected that of the classical Roman law. Voet's definition of injuria is based on the definition posed by the Roman jurist Ulpian.[34] This definition which provides that an injuria is 'a wrongful act committed in contempt of a free person by which his person, dignity, or reputation is intentionally impaired' has been accepted by South African courts.[35]

The Roman-Dutch law adopted the actio injuriarum from Roman law. The elements of the actio injuriarum, namely, intention, wrongfulness, and impairment of a personality right, remained the same as in Roman law. Wrongfulness was determined according to the prevailing boni mores of society. The concept of dignitas remained wide enough to encompass those personality rights which were not separately catered for, including privacy.

4.3 THE DEVELOPMENT OF THE LAW OF PRIVACY IN SOUTH AFRICA

(a) The definition of privacy

Various definitions of privacy have been proposed by lawyers and academic commentators over the years thereby stimulating legal and jurisprudential debate, provoking criticism, and encouraging constructive analysis, but with no generally accepted definition emerging. O'Regan J once remarked that this concept has troubled lawyers since at least the end of the nineteenth century.[36] Davis and Steenkamp, on a similar note, remark that 'the ambit and scope of privacy has been a vexed question for more than a century.'[37] Ackermann J described privacy as an amorphous and elusive concept which has been the subject of much scholarly debate.[38] Devenish describes

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34 D 47.10.1

35 *R v Umfaan* 1908 TS 62 at 66.

36 *NM & others v Smith & others (Freedom of Expression Institute as Amicus Curiae)* 2007 (5) SA 250 (CC) at 281A.

37 D M Davis & A Steenkamp 'Privacy' in M H Cheadle et al (eds) *South African Constitutional Law – The Bill of Rights* 2 ed (2005) 9-1.

38 *Bernstein & others v Bester & others* 1996 (2) SA 751 (CC) at 787-8.

privacy as 'a perplexingly paradoxical right'.[39] Neethling et al define privacy as 'an individual condition of life characterised by seclusion from the public and publicity' encompassing 'all those personal facts which the person concerned has himself determined to be excluded from the knowledge of outsiders and in respect of which he has the will that they be kept private'.[40] Neethling points out that it is the individual himself or herself who determines which of his or her private facts to disclose and in so doing determines the scope of his or her interest in privacy.[41] This definition, although accepted by the courts,[42] has not escaped criticism. Burchell comments that such a definition 'not only opens the floodgates of litigation to the hypersensitive but also creates an internal inconsistency in the law that some aspects of personality…are tested both subjectively and objectively while privacy would be tested subjectively only'.[43] This criticism lacks merit as it ignores the boni mores criterion which serves to limit claims of privacy to those which are reasonable. Neethling sets out the position quite succinctly as follows: 'privacy will be protected where a person has a subjective expectation of privacy…which society considers to be objectively reasonable…'[44]

McQuoid-Mason, in proposing a definition of invasion of privacy, refers to an individual's 'right to seclusion in his private life'.[45] A common thread which emerges from the suggested definitions of privacy is a right to seclusion in a person's private life. Neethling cautions against equating seclusion exclusively with spatial seclusion since this may create the incorrect impression that privacy entails only physical or spatial seclusion.[46]

The concept of 'the right to be left alone' surfaces frequently in discussions pertaining to the definition of the right to privacy. In *NM v Smith*[47] the Constitutional

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39 G E Devenish 'Constitutional Law' in W A Joubert (founding ed) *The Law of South Africa* vol 5(3) 2 ed para 69.

40 Neethling et al op cit note 3 at 32.

41 J Neethling 'The right to privacy, HIV/AIDS and media defendants' (2008) 125 *SALJ* 36 at 40.

42 *Bernstein* supra note 38 at 789; *National Media Ltd v Jooste* 1996 (3) SA 262 (A) at 271; *Universiteit van Pretoria v Tommie Meyer Films (Edms) Bpk* 1977 (4) SA 376 (T) at 384.

43 Jonathan Burchell 'The legal protection of privacy in South Africa: A transplantable hybrid' (March 2009) 13.1 *Electronic Journal of Comparative Law* at 19 available at http://www.ejcl.org/131/abs131-2.html accessed on 21 April 2012.

44 Neethling op cit note 41 at 41.

45 McQuoid-Mason op cit note 11 at 100.

46 Neethling et al op cit note 3 at 30.

47 Supra note 36.

Court, per Madala J, observed that the right to privacy is akin to the right to be left alone. This view has drawn criticism from Neethling who states that it is inadvisable to equate the right to privacy with a right to be left alone because the latter is too wide to be of practical benefit in these circumstances.[48] Neethling suggests that 'the right to be left alone, as a concept of the right to privacy, should therefore rather be left alone.'[49] Neethling's criticism is not without merit. The concept of a right to be left alone is too wide to be of assistance in curbing the definitional debate around the concept of privacy. Madala J also stated that 'privacy encompasses the right of a person to live his or her life as he or she pleases'.[50] Neethling once again rejects this view as he rightly feels that such a definition covers freedom of activity and not the right to privacy.[51]

The courts have also ventured definitions of privacy over the years. The Constitutional Court in the *Bernstein* case stated as follows:

> 'A very high level of protection is given to the individual's intimate personal sphere of life and the maintenance of its basic preconditions and there is a final untouchable sphere of human freedom that is beyond interference from any public authority. So much so that, in regard to this most intimate core of privacy, no justifiable limitation thereof can take place. But this most intimate core is narrowly construed. This inviolable core is left behind once an individual enters into relationships with persons outside this closest intimate sphere; the individual's activities then acquire a social dimension and the right of privacy in this context becomes subject to limitation.'[52]

This view was reiterated by the Constitutional Court in *NM v Smith*.[53] Neethling criticises this definition for being too narrow as it excludes those aspects of a person's life which may not necessarily form part of their inner sanctum but which he or she prefers to keep private.[54]

(b) Development of the Common Law

The South African law of delict is based on the principles of Roman and Roman-Dutch law. As discussed above, the actio injuriarum, a common law delictual action which is

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48 Neethling op cit note 41 at 38.
49 Ibid.
50 Supra note 36 at 261.
51 Neethling op cit note 41 at 39.
52 Supra note 38 at 794.
53 Supra note 36.
54 J Neethling 'The concept of privacy in South African law' 2005 (122) S*ALJ* 18 at 20.

used to protect privacy, originates from Roman and Roman-Dutch law. The inception of such principles into South African law was not, however, completely unhindered. Certain early court decisions sought to restrict the concept of dignitas to dignity and honour and to require insult (contumelia) as an element of this iniuria.[55] The Appellate Division rejected this approach in *Foulds v Smith*.[56] Van Den Heever J.A. observed that too much emphasis was being placed on the element of contumelia in the actio iniuriarum.[57] The courts thereafter, in the case which has been described as the 'locus classicus for the recognition of the right to privacy in South African law'[58] reiterated the point that insult was not an element of the iniuria relating to privacy.[59] Neethling supports the decision in *O'Keeffe v Argus Printing*[60] as being in conformity with the common law and recognizing privacy as an independent right of personality.[61] He submits that the independence of the right of privacy is confirmed by its recognition and protection as a fundamental right in the Bill of Rights.[62] His conclusion is that privacy is 'an independent right of personality which has been delimited as such within the concept of dignitas.'[63]

It is generally accepted that the infringement of privacy under the common law can take two forms only, namely, unauthorised intrusions and unauthorised disclosure of private information. The wrongfulness element of the actio injuriarum clearly adds a dimension of flexibility and contemporaneity to the action. Consideration of the prevailing boni mores of society prevents stagnation of the action but allows the action to remain relevant in any given time period. It also accommodates changing societal attitudes flowing from technological change and scientific advancement. It is evident that the actio injuriarum has survived to this day because of its ability, through the

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55 *Walker v Van Wezel* 1940 WLD 66 at 70; *R v Umfaan* 1908 TS 62 at 68; *Kidson v SA Associated Newspapers Ltd* 1957 (3) SA 461 (W) at 467; *Mhlongo v Bailey* 1958 (1) SA 370 (W) at 372; *R v Holliday* 1927 CPD 395 at 400-1.

56 1950 (1) SA 1 (A).

57 Ibid 11.

58 J Neethling, J M Potgieter & T J Scott *Case Book on the Law of Delict* (1991) 677; Neethling et al op cit note 3 at 217.

59 1954 (3) SA 244 (C).

60 Ibid.

61 Neethling op cit note 24 para 334.

62 Ibid.

63 Ibid.

wrongfulness element, to adapt to the changing needs of society. It is this facet of the action which is likely to pave the way for the protection of genetic privacy.

The advent of a democratic constitutional dispensation has neither eradicated nor diminished the importance of the common law in South Africa. The common law remains an important pillar of the legal system. Section 39(3) of the Constitution makes it clear that the common law retains its significance and applicability, insofar as it is consistent with the Bill of Rights. This is reaffirmed by section 8(3)(a) which obliges courts to apply and, where necessary, to develop the common law when giving effect to fundamental rights enshrined in the Bill of Rights. The section provides as follows:

> 'When applying a provision of the Bill of Rights to a natural or juristic person in terms of subsection (2), a court –
> (a) in order to give effect to a right in the Bill, must apply, or if necessary develop, the common law to the extent that legislation does not give effect to that right; and
> (b) may develop rules of the common law to limit the right, provided that the limitation is in accordance with section 36(1).'

It is clear that it is intended for the common law and the constitution to work in harmony so as to retain age-old legal principles which can only be enhanced by constitutional values, thereby achieving a legal order which is built on a strong foundation and is able to withstand legal scrutiny. This was the view of the Constitutional Court even when the interim Constitution[64] was in operation. In *Du Plessis v De Klerk*,[65] which dealt with the interim constitution,[66] Mahomed J remarked that:

> 'the common law is not to be trapped within the limitations of its past. It need not be interpreted in conditions of social and constitutional ossification. It needs to be revisited and revitalized with the spirit of the constitutional values defined in…chapter 3 of the constitution and with full regard to the purport and objects of that chapter.'[67]

He proceeds as follows:

> 'The interpretation which I have come to favour has the advantage of giving to the different Divisions of the Supreme Court, including its Appellate Division, a very clear and creative role in the active evolution of our constitutional jurisprudence by examining, and in suitable circumstances expanding, the traditional frontiers of the common law by infusing it with the spirit of chapter 3 of the Constitution and its purport and objects.'[68]

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64 Constitution of the Republic of South Africa Act 200 of 1993.
65 *Du Plessis & others v De Klerk & another* 1996 (3) SA 850 (CC).
66 Supra note 64.
67 Supra note 65 at 897E-F.
68 Ibid 897G-I.

Section 173 of the final Constitution empowers superior courts to develop the common law, taking into account the interests of justice. In developing the common law, the courts are obliged, in terms of section 39(2) of the Constitution, to promote the spirit, purport and objects of the Bill of Rights. Fulfilling this constitutional mandate is, however, not as simple as it appears on paper. In this regard Harms J duly observes as follows:

> 'Some believe that the common law is perfect and unaffected by the Bill of Rights. Others consider the Bill of Rights to have granted the judiciary a hunting licence on the common law, making the positive law a matter of judicial discretion and allowing the courts to infringe upon the domain of the legislature and to ignore precedents. The common law consists of a myriad rules developed over many centuries involving great minds. It represents a fine web, the disturbance of which at one point may have severe unexpected consequences elsewhere….The constitution…does not provide a trench from which the common law may be attacked…Sections 39(2) and 173 of the Constitution do not place a machete in the hands of the judge to decapitate or to castrate, but it provides modeling clay out of which art must be created capable of withstanding the heat of the oven'.[69]

The importance of common law is acknowledged in this excerpt and attention is drawn to the fact that in tampering with the common law, courts must consider the resultant ripple effects of such a course of action. There will invariably be situations where a given set of facts will trigger a reconsideration of relevant common law principles in the light of constitutional values. This does not mean that every situation requires such an approach. It is submitted that the Constitution acts as a catalyst for law reform. However, the undertaking of such reform by the courts poses its own challenges.

The Constitutional Court has cautioned against the blurring of roles of the legislature and the judiciary, pointing out that the doctrine of separation of powers must always be borne in mind in law reform. To this end, the Constitutional Court in *Masiya v Director of Public Prosecutions*,[70] per Nkabinde J, stated as follows:

> 'The development of the common law on the other hand is a power that has always vested in our Courts. It is exercised in an incremental fashion as the facts of each case require. This incremental manner has not changed but the Constitution in s 39(2) provides a paramount substantive consideration relevant to determining whether the common law requires development in any particular case. This does not detract from the constitutional

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[69] L T C Harms 'Development of the common law in view of sections 39(2) and 173 of the Constitution' 2004 (7) No.2 *Potchefstroom Electronic Law Journal* available at http://www.puk.ac.za/opencrms/export/PUK/html/fakulteite/regte/per/issuepages/2004Volume7no2/2004xx2x_harms_sum.pdf accessed on 8 February 2010.

[70] *Masiya v Director of Public Prosecutions, Pretoria & another* (*Centre for Applied Legal Studies & another, Amici Curiae)* 2007 (5) SA 30 (CC).

> recognition, as indicated above, that it is the Legislature that has the major responsibility for law reform. Courts must be astute to avoid the appropriation of the Legislature's role in law reform when developing the common law. The greater power given to the Courts to test legislation against the Constitution should not encourage them to adopt a method of common-law development which is closer to codification than incremental, fact-driven development.'[71]

Nkabinde J offered the view of Kentridge AJ in the *Du Plessis* case[72] as support for her approach to the separation of powers. In that case Kentridge AJ had quoted the following excerpt from the Canadian case of *R v Salituro*[73] in support of his own view:

> 'Judges can and should adapt the common law to reflect the changing social, moral and economic fabric of the country. Judges should not be quick to perpetuate rules whose social foundation has long since disappeared. Nonetheless there are significant constraints on the power of the judiciary to change the law…In a constitutional democracy such as ours it is the Legislature and not the courts which has the major responsibility for law reform…The judiciary should confine itself to those incremental changes which are necessary to keep the common law in step with the dynamic and evolving fabric of our society.'[74]

Carmichele v Minister of Safety and Security[75] is another example of a case where the Constitutional Court cautioned that the Legislature remains the major engine for law reform. This case dealt with the development of the common law delictual duty to act. Ackerman and Goldstone JJ quoted with approval the dictum in the Canadian judgment of *R v Salituro.*[76] They discussed the obligation imposed on courts by section 39(2) of the Constitution to develop the common law. They stressed the point that the obligation is not discretionary but that 'in exercising their powers to develop the common law, judges should be mindful of the fact that the major engine for law reform should be the Legislature and not the Judiciary.'[77]

The doctrine of separation of powers plays an important role where lawmaking is concerned. It should not, however, prove detrimental to the development of the common law, where such development is necessary so as to align the common law with constitutional values. The ultimate aim of the drafters of the Constitution is for constitutional values to permeate the common law. This can only be achieved if the

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71 Ibid 47B-E.
72 Supra note 65 at 886C-E.
73 (1992) 8 CRR (2d) 173; ([1991] 3 SCR 654).
74 Supra note 65 at 886C-E.
75 *Carmichele v Minister of Safety and Security & another* 2001 (4) SA 938 (CC).
76 Supra note 73.
77 Supra note 75 at 954D-E; 955F-H.

common law is developed with regard to the spirit, objects and purport of the Constitution.

Dersso draws attention to the two different sets of circumstances in which courts may be called upon to develop the common law.[78] The first situation arises where the common law has to be developed in order to align it with the Bill of Rights. Development in this situation is mandatory. The second situation arises where the common law has to be developed according to the changing social, moral and economic conditions in society. This would require incremental development which occurs on a case by case basis. Dersso correctly observes that the majority in the *Masiya case* failed to make this distinction.[79] He sums up the position regarding the separation of powers as follows:

> '…where the development of the common law is required in order to give full effect to the Bill of Rights, the separation of powers doctrine should not unduly hinder the courts. But such development can be legitimate and coheres with the doctrine of separation of powers only if it is limited to giving full effect to the Bill of Rights of the Constitution. Thus, where the development of the common law goes beyond what is required to give full effect to the Bill of Rights, it may unreasonably usurp the constitutionally mandated powers of the legislature and thus may amount to a breach of the doctrine of separation of powers. Outside of this, however, the development of the common law by courts to give effect to the Bill of Rights does not constitute a breach of the doctrine of separation of powers as it does not preclude the legislature from enacting laws in accordance with its legislative objectives.'[80]

It is submitted that in the *Masiya case* the Constitutional Court placed undue emphasis on separation of powers in an attempt to justify the decision not to develop the common law fully. Dersso's criticism of the reasoning of the majority is justifiable and meritorious. The majority judgment has been aptly criticised as a failure of the Constitutional Court to fulfil its constitutional mandate.

The approach of South African courts to the development of the common law is neither unanimous nor satisfactory. The controversial decision of the Constitutional Court in the *Masiya* case[81] bears testimony to this. The majority reiterated the stance adopted in a previous case before them that it is the legislature and not the judiciary which has the

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78 Solomon A Dersso 'The role of courts in the development of the common law under s 39(2): *Masiya v Director of Public Prosecutions Pretoria (The State) and Another*' CCT Case 54/06 (10 May 2007) 2007 (23: 2) *SAJHR* 373 at 383-4.

79 Ibid 384.

80 Ibid.

81 Supra note 70.

major responsibility for law reform.[82] It appears that the majority felt they would be usurping the role of the legislature if they were to extend the definition beyond the ambit of the facts presented to them. This judgment placed great emphasis on the doctrine of separation of powers, much to the detriment of necessary law reform.

The *Masiya* case, from its inception in the Regional Court, through to its conclusion in the Constitutional Court, illustrates the inconsistency in the approaches of our courts to the development of the common law. This judgment supports the statement above that the approach of our courts is neither consistent nor satisfactory. The approach of the majority reflects an element of rigidity which does not augur well for the development of the common law in accordance with constitutional values. It stifles rather than encourages development of the common law thus making it one that is likely to inhibit the progress of the law in step with societal, environmental and scientific change. Based on this rigid approach as well as the failure of the Constitutional Court to draw a distinction between situations where full development of the common law is mandatory and situations where incremental development is permitted, it appears likely that the issue of genetic privacy will be left in the hands of the Legislature unless facts peculiar to this issue are presented to the Constitutional Court. Even then one cannot be certain that this court will seize the opportunity presented to it. Partial development or incremental development of the common law by the judiciary will not suffice in this case.

The protection of genetic privacy cannot be left to the courts. Prior to the *Masiya* judgment,[83] the Constitutional Court displayed its reluctance to develop the common law in *NM v Smith*.[84] The applicants in this case were HIV positive women whose names had been published in a book by the respondents. The first respondent was a journalist who had authored the biography of the second respondent. The third respondent was the publisher of the book. The applicants contended that their rights to privacy, dignity and psychological integrity had been intentionally or negligently violated by the disclosure of their HIV status by the respondents. They based their claim for damages on the actio injuriarum. The applicants argued inter alia for the development of the actio injuriarum to provide a remedy in the case of negligent publication of confidential medical

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82 Ibid 46G-H.
83 Supra note 70.
84 Supra note 36.

information in line with the constitutional protection afforded to their rights of privacy, dignity and psychological integrity. They argued that those who negligently publish confidential medical information without consent should be held liable except where public interest demands otherwise.[85]

The majority held that the respondents knew or foresaw the possibility that the applicants had not consented to the disclosure of their identities in the book and that they knew that their conduct was wrongful. Based on this, the majority concluded that the respondents had the requisite animus injuriandi. As a result, they did not consider this an appropriate case for deviating from established principles of common law.[86] Madala J did, however, remark that the approach of the majority should not be interpreted to mean that the common law should or could never be developed as argued for by the applicants.[87] It is clear that the court was not dismissing the idea of developing the common law. The court simply did not consider such development to be required by the facts of the case.

Neethling correctly observes that in adopting such a stance 'the Constitutional Court missed a golden opportunity to develop the common law and introduce negligence liability for violation of the right to privacy, especially for media defendants.'[88] This was the first time that the issue of the development of the actio injuriarum relating to privacy had come before the courts.[89] The facts of this case provided the ideal opportunity for the court to consider extending the common law of privacy in line with the extended common law of defamation, especially since two of the respondents were considered to be media defendants.[90] The facts did not indicate conclusively that the respondents had acted intentionally. The judges held differing views as to whether intention had been established on the facts. It was therefore a case which was ripe for consideration of negligence as a fault criterion for invasions of privacy by media defendants but the court

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85 Ibid 266B.
86 Ibid 266D.
87 Ibid.
88 Neethling op cit note 41 at 43.
89 Supra note 36 at 296C-D.
90 Ibid 274H; 298A-C.

refused to do so. Neethling is therefore justified in stating that a golden opportunity has been missed.[91]

The next question which arises in the context of the development of the common law is whether the actio injuriarum adequately protects the right to privacy and if not, whether this sounds a call for the development of the common law relating to invasions of privacy. This question may be answered by reference to the development of the common law of defamation. Thomas observes that iniuria postulates intention since it has its basis in contumelia, and for that reason it cannot be extended to cover negligent acts.[92] Notwithstanding this basic principle, the common law of defamation has been extended by the introduction of a negligence criterion in respect of defamation by the media.

Views amongst members of the academic community are divided insofar as the introduction of a negligence criterion for invasion of privacy is concerned. Some argue that *National Media Ltd v Bogoshi*[93] introduced a negligence criterion for the media whilst others vehemently disagree with one commentator even suggesting that a limited negligence criterion has been introduced for defamation by the media. Neethling's view is that negligence has been accepted as a fault criterion for defamation by the mass media.[94] His view is that proof of the publication of defamatory statements by the media raises a presumption of negligence and the onus is then on the defendant to rebut the presumption. Midgley's view is that intention remains the sole fault criterion but the media may raise the defence of lack of knowledge of unlawfulness in cases where they were not negligent in publishing the offending material.[95] [96] He is of the opinion that the Supreme Court of Appeal did not intend to extend the fault criterion to include negligence. He supports his view with the statement that the court did not indicate that proof of publication would give rise to a presumption of fault either in the form of intention or negligence. He also points out that a presumption of negligence is different from a presumption of intention since the inquiry into negligence is objective rather than

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91 Neethling op cit note 41 at 43.
92 J A C Thomas *Textbook of Roman Law* (1976) 370.
93 *National Media Ltd & others v Bogoshi* 1998 (4) SA 1196 (A).
94 Neethling et al op cit note 3 at 167; Neethling op cit note 41 at 4.
95 J R Midgley 'Intention remains the fault criterion under the Actio Injuriarum' (2001) 118 *SALJ* 433.
96 J R Midgley 'Media liability for defamation' (1999) 116 *SALJ* 211 at 214-5.

subjective and for this reason public policy may not favour a presumption of negligence.[97]

Burchell accepts that the courts have recognised liability based on negligence in cases of defamation by the media. His view is that the *Bogoshi* judgment has introduced a defence of reasonable publication as well as a negligence criterion for defamation by the media.[98] He remarks that those commentators who dispute this do not attach sufficient weight to certain important aspects of the *Bogoshi* judgment. The first of these overlooked aspects, according to Burchell, is that the *Bogoshi* court did not need to overrule the decision in *Pakendorf v De Flamingh*[99] in order to introduce a new defence excluding unlawfulness since it is generally accepted that the list of defences excluding unlawfulness is not closed and the concept of strict liability did not exclude defences which negated unlawfulness. The second aspect identified by Burchell relates to the distinction between the unlawfulness inquiry and fault in regard to unlawfulness. His view is that since media defendants would be held liable unless they were not negligent in the circumstances of the case, the reference to 'ignorance or mistake at the level of lawfulness' did not refer to the unlawfulness inquiry but to the lack of knowledge of unlawfulness which had to be reasonable. He relies on the reasonableness element in support of his view that *Bogoshi* meant for the media to be held liable on the basis of negligence, which is an objective inquiry, as opposed to intention, which postulates a subjective inquiry.[100]

Scott rejects the idea of the *Bogoshi* judgment having introduced negligence as the new fault criterion. The only concession she makes is that *Bogoshi* may have introduced a limited negligence criterion by allowing a defendant to prove reasonable mistake only where such mistake negates the unlawfulness of conduct. Her view is that intention remains the fault criterion and a new defence of reasonable mistake has been introduced which may be pleaded only in respect of unlawfulness of conduct.[101] Fagan contends that

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97 Midgley op cit note 95 at 438.
98 Op cit note 43.
99 *Pakendorf en andere v De Flamingh* 1982 (3) SA 146 (A).
100 Supra note 93 at 1214A-F.
101 Helen Scott 'Liability for the mass publication of private information in South African law: *NM and others v Smith and others (Freedom of Expression Institute as Amicus Curiae)'* (May 2008) 12.1 *Electronic Journal of Comparative Law* available at http://www.ejcl.org/121/abs121-11.pdf accessed on 21 April 2012.

knowledge of unlawfulness is not an element of intention and for that reason the newly introduced defence of reasonable publication goes only to unlawfulness.[102]

This then begs the question whether there is room for negligent invasions of privacy in our law. The development of the common law of defamation might prove instructive in this regard as both are actionable under the actio injuriarum. The *Bogoshi* judgment [103] is a landmark ruling which changed the landscape of the common law of defamation in conformity with constitutional values. The appellants in this case were members of the media who were sued for damages arising from the publication of a series of allegedly defamatory articles. The lower court, in relying on the reasoning in *Pakendorf,*[104] found against them. On appeal the appellants contended that the *Pakendorf* case[105] had been wrongly decided. They argued that their defence that publication was lawful because it was reasonable and had been done without animus injuriandi was valid under the common law. They also argued in the alternative that strict liability of the press for defamation was unconstitutional since it infringed the right to freedom of speech and expression which was contrary to the spirit, purport and object of the constitution.

The Supreme Court of Appeal in *Bogoshi*[106] found that the common law had been incorrectly applied in *Pakendorf.*[107] The court found that the *Pakendorf*[108] court had not attempted to strike a balance between the right to reputation and freedom of expression. It appeared that freedom of expression had not been accorded the weight it deserves. The court, per Hefer JA, accordingly rejected the concept of strict liability, stating that this should have been done in *Pakendorf.* The judge made it clear that in arriving at this decision, the court was not engaging in the exercise of revising the common law of defamation so as to align it with constitutional values. The court was instead simply restating the common law principle which had been incorrectly stated in *Pakendorf.*[109] The court held that even though strict liability was found to be unacceptable, the media could not be allowed to escape liability on the basis of absence of animus injuriandi. In

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102 A Fagan'Rethinking wrongfulness in the law of delict' (2005) 122 *SALJ* 90 at 101-6.
103 Supra note 93.
104 Supra note 99.
105 Ibid.
106 Supra note 93.
107 Supra note 99.
108 Ibid.
109 Supra note 99.

adopting such an approach, the court had to find an alternative to strict liability. The court found a solution in the concept of negligence. This entailed holding media defendants liable unless they were not negligent in the circumstances. The court held that the onus is on the defendant to prove that he was not negligent and this could be achieved by proving that the publication was reasonable.[110]

The court in *Marais v Groenewald* [111] supported the *Bogoshi* decision[112] to develop the common law by introducing a negligence criterion in defamation actions under the actio injuriarum. Van Dijkhorst J based his support for the imposition of a negligence criterion on the approach adopted by Neethling.[113] He indicated that this reflected a balance between the right to a good name and the right to freedom of expression. He also remarked that the benefit of imposing liability based on negligence is that it prevents unjust situations where individuals who defame others are allowed to escape liability on the grounds that they lacked knowledge of the unlawfulness of their conduct even if such lack of knowledge was due to the defendant's own negligence. Since intention was the sole fault criterion for a defamation action under the actio injuriarum prior to the *Bogoshi* decision,[114] it followed that lack of knowledge of unlawfulness would be fatal to a plaintiff's claim.[115] Van Dijkhorst J went a step further than the *Bogoshi*[116] court by extending the negligence criterion to non-media defendants. He pointed out that the harm caused by a non-media defendant can be just as great as that caused by a media defendant and saw no reason to treat them differently.[117]

McQuoid-Mason poses the question whether the courts should recognise liability for negligent invasions of privacy.[118] In seeking an answer, he draws a parallel between actions for defamation and invasion of privacy. He notes that a plaintiff in a defamation action can succeed in a claim for patrimonial loss arising from the negligent making of a defamatory statement. He submits that the same ratio can be made applicable to

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110 Ibid 1214-5.
111 *Marais v Groenewald en 'n ander* 2001 (1) SA 634 (T) at 646-7.
112 Supra note 93.
113 Supra note 111 at 646D-E.
114 Supra note 93.
115 Supra note 111 at 646E-F.
116 Supra note 93.
117 Supra note 111 at 646E-H.
118 Op cit note 11 at 254.

invasions of privacy thereby allowing a plaintiff to claim for patrimonial loss resulting from the negligent invasion of his or her privacy. McQuoid-Mason's approach is only the starting point in the discussion as to whether there is room in our law for negligent invasions of privacy causing non-patrimonial loss. It is not a complete solution. He appears to be aware of the limitations of his approach when he states that the extension of the concept of patrimonial loss by the recognition of emotional shock as physical injury 'may have an important bearing on actions for negligent invasions of privacy.'[119] He proceeds to point out that a negligent invasion of privacy resulting in emotional shock may result in a claim for patrimonial loss.

What then is the legal position regarding negligent invasions of privacy resulting in non-patrimonial loss? This is clearly a lacuna in the law which must be addressed from a constitutional perspective. After all, the Constitution provides blanket protection of privacy without limits based on the type of fault. It is the common law that creates a distinction. The distinction is neither reasonable nor justifiable in a constitutional dispensation. It is clear that the current common law position treats personality infringements as less serious than physical harm by permitting claims for patrimonial loss arising out of intentional or negligent conduct under the actio legis aquiliae and the action for pain and suffering whilst claims for non-patrimonial loss due to impairment of personality are restricted to instances of intentional harm under the actio injuriarum. This position is untenable in a constitutional dispensation as it is contrary to constitutional values and it dilutes the importance of constitutionally entrenched personality rights such as the right to privacy.

In *NM v Smith,* Madala J, on behalf of the majority, noted that negligence does not suffice as a form of fault under the actio injuriarum.[120] O'Regan J, in a dissenting judgment, found that the respondents had not acted intentionally. This conclusion led her to inquire into whether negligence can suffice for breach of privacy. She concluded that members of the media should act with 'due care and respect for the right to privacy'[121] and they should be held liable for negligent invasions of privacy. Her conclusion was based on the development of the common law of defamation. She did not see a need to

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[119] Ibid 255.
[120] *S*upra note 36 at 266A.
[121] Ibid 297C-D.

differentiate between the fault criterion for defamation and that for invasions of privacy by the media.[122] She accordingly concluded that the media should be held liable for negligent invasions of privacy as is the case with defamation by the media.

Sachs J, in a separate judgment, adopted a similar approach to that of O'Regan J insofar as the development of the common law was concerned. He clearly stated that the relevant principles relating to defamation are 'eminently transportable to the law of privacy'.[123] This meant that he also agreed that the media should be held liable for negligent invasions of privacy. Langa CJ, in his separate judgment, also agreed with the approach of O'Regan J to the development of the common law. The Chief Justice recognised a need to hold the media to a higher standard than ordinary people. He did remark that he did not consider it appropriate to extend the negligence standard to ordinary people as that 'would be to extend the law too far into intensely personal space'.[124] This is regrettable as privacy is equally subject to invasion by ordinary people as by members of the media. The negative consequences of such a stance are discussed below.

The minority approach to the development of the common law as adopted by O'Regan J, Sachs J and Langa CJ reflects progressive thinking which is more likely to enable the Constitutional Court to fulfil its constitutional mandate than the approach adopted by the majority. Interestingly though, this otherwise laudable approach would have resulted in the second defendant being found not liable for invasion of privacy. This is because Langa CJ[125] and O'Regan J[126] held that the second respondent, who was the subject of the biography, was not a media defendant. As a result the negligence criterion would not have been applied to the second respondent. The inquiry would have ended once it was found that the second respondent had not acted with the requisite animus injuriandi. The first and third respondents, who were determined to be media defendants, would have been held liable on the basis of negligence.

This case reflects an unsatisfactory situation insofar as non-media defendants are concerned. It is clear that even though the second respondent was not a media defendant,

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122 Ibid 296F-H.
123 Ibid 302H.
124 Ibid 273G-H.
125 Ibid 275A.
126 Ibid 298A-C.

she was fully aware of the need for privacy in cases involving HIV-positive individuals. This is borne out by the following comment relating to the first and second respondents, by Sachs J:

> '…both have an honourable history of raising public awareness of the need to deal sympathetically and efficaciously with the pandemic. The fact that persons with their record are being called to account for failure to ensure that highly sensitive private medical facts about identified individuals were not inappropriately revealed, serves to underline the need to hold firmly to stringent standards of respect for privacy in this area. These are standards that the profession has set for itself, and that the law demands of all.'[127]

The facts of the case make it difficult to justify a finding that the second respondent was not liable. This case illustrates the need to extend the negligence criterion to non-media defendants. It proves, albeit on facts peculiar to this case, that a non-media defendant is not entirely different from a media defendant. I would argue that a non-media defendant is not so different from a media defendant as to justify the imposition of a negligence criterion in respect of one and not the other. In defamation cases a distinction between media and non-media defendants is drawn based on factors such as the greater potential of the media to cause harm by defamatory publication, resources available to the media to prevent harm, and the extent of the harm that can be caused by the media.[128] These factors are used to justify placing a heavier burden on the media. Non-media defendants can escape liability for defamation if they can rebut the presumption of animus injuriandi whilst media defendants have to prove that they did not act negligently.

The nature of the harm caused by invasions of privacy by media and non-media defendants is the same. The focus should accordingly be on the harm sought to be prevented as opposed to the extent of the harm that a particular entity is capable of causing. In the case of genetic privacy there is potential for unauthorised disclosure of or access to genetic information by employers, insurers, medical staff, and database controllers. All of these entities would be categorised as non-media defendants, which means that even if the common law is developed to impose liability for negligent invasions of privacy they cannot be held liable.

The situation can be rectified through further development of the common law. Such development will be mandatory if the courts consider the development necessary so as to

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[127] Ibid 304E-G.
[128] Ibid 296F-G; 297H-I.

align the common law with the Bill of Rights. Viewed through the lens of *NM v Smith*,[129] one cannot be certain that the courts will follow this route. On the other hand the courts may find that the desired changes to the common law are necessitated by changing social and moral conditions. If this latter view is taken, the courts will adopt an incremental approach to the development of the common law. This means that the possible extension of the common law to cover negligent invasions of privacy will be considered only if a case with the requisite facts presents itself.

This situation is far from satisfactory in the case of genetic privacy. Human genetics is a rapidly developing field. The law needs to keep pace with the science so as to provide adequate protection to individuals. Genetic information holds great potential for discrimination. Because of the serious consequences that may arise from a breach of genetic privacy, there is a need for proactive rather than reactive lawmaking. The common law must be developed when legislation does not regulate an issue. Based on the attitude and the uncertainty of our courts as to how to proceed in this arena, the necessary protection is more likely to be achieved through the Legislature and not through the judiciary. This would entail the promulgation of a genetic privacy statute which would inter alia prohibit all negligent invasions of genetic privacy.

(c) Constitutional developments

The South African Constitution[130] protects the right to privacy. Section 14 provides that:

> 'Everyone has the right to privacy, which includes the right not to have –
> (a) their person or home searched;
> (b) their property searched;
> (c) their possessions seized; or
> (d) the privacy of their communications infringed.'

The introductory line postulates a general right to privacy. It is thus obvious that the list which follows is not an exhaustive one. There is scope for the recognition of other aspects of the right to privacy. McQuoid-Mason identifies two groups of constitutional

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[129] Supra note 36.
[130] Supra note 1.

rights to privacy.[131] The first group entails protection against intrusions and interferences with private life. The second group protects privacy against disclosures of private facts.

The Bill of Rights has both vertical and horizontal application. It therefore regulates relationships between individuals and the State; as well as relationships between individuals. 'Individuals' includes juristic persons.[132] The vertical and horizontal application of the Bill of Rights prove significant in the context of genetic privacy which can be infringed by the State as well as by individuals, including juristic persons such as insurance companies and corporate employers. The right to privacy is not absolute. It may be limited in accordance with s 36 of the Constitution which provides for reasonable and justifiable limitations of rights. Section 7(2) of the Constitution places a duty on the State to respect, protect, promote and fulfil the rights in the Bill of Rights. This would include promulgating legislation for the protection of genetic privacy since the common law protection is inadequate.

How has the advent of the Constitution affected the right to privacy? This can be ascertained by a comparison of pre-constitutional and post-Constitutional Court cases which indicate the changing attitude of courts towards the protection of privacy. The development of the right to privacy can be traced through case law. A few specific approaches can be determined. The early decisions equated privacy with dignity. Contumelia, which was an essential element of infringements of dignitas, thus became an essential requirement for invasions of privacy. Thereafter the courts modified their approach to require an intention to insult. That constituted a clear improvement on the previous situation. The courts eventually progressed to viewing privacy as an independent right of personality within the concept of dignitas.

(i) Pre-constitution cases

Earlier cases of *R v Umfaan*,[133] *R v Holliday*,[134] and *R v R*[135] took the approach that infringements of dignitas required an element of degradation, insult or contumelia.

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131 McQuoid-Mason 'Privacy' in M Chaskalson et al (eds) *Constitutional Law of South Africa* 2 e d (2002) 38-22.
132 Supra note 130, s 8(2).
133 1908 TS 62.
134 1927 CPD 395.
135 1954 (2) SA 134 (N).

O'Keeffe v Argus Printing[136] has been referred to by Neethling as the locus classicus for the recognition of an independent right to privacy in South African law.[137] The plaintiff's claim under the action injuriarum arose out of the unauthorised publication of her photograph for advertising purposes. Watermeyer AJ interpreted the dignitas concept widely enough to include all rights relating to dignity, including the right to privacy. McKerron observes that this case went further than any previous case in recognizing the existence of a right to privacy in South African law.[138] In *S v A*,[139] Botha AJ accepted that the right to privacy is included in the concept of dignitas. He recognised the right to privacy as an independent personality right. This reasoning follows on from that in the *O'Keeffe* case.[140] *Universiteit van Pretoria v Tommie Meyer Films*[141] confirmed that the right to privacy is an independent right of personality within the concept of dignitas.[142]

(ii) Post-constitution cases

The judgment of *Bernstein v Bester*[143] has been referred to by Currie and de Waal as the Constitutional Court's 'richest and most comprehensive interpretation of the right'.[144] The applicants in this case challenged the constitutional validity of sections 417 and 418 of the Companies Act, 1973. They argued that these sections invade a witness's right to privacy by forcing the witness to disclose confidential documents. In addition they argued that the compulsory production of documents amounted to a seizure in terms of section 13 of the interim constitution.[145] The court conducted a thorough analysis of the right to privacy. This case describes the impact of the interaction between the individual and society on the right to privacy. The following note by the Constitutional Court is significant in this regard:

> 'The truism that no right is to be considered absolute implies that from the outset of interpretation each right is always already limited by every other right accruing to another citizen. In the context of privacy this would mean that it is only the inner sanctum of a

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136 *O'Keeffe v Argus Printing and Publishing Co Ltd & another* 1954 (3) SA 244 (C).
137 Neethling et al op cit note 3 at 217.
138 R G McKerron *The Law of Delict* 7 ed (1971) 54.
139 1971 (2) SA 293 (T) at 297.
140 Supra note 136.
141 *Universiteit van Pretoria v Tommie Meyer Films (Edms) Bpk* 1977 4 SA 376 (T).
142 Ibid 383-4.
143 Supra note 38.
144 Iain Currie & Johan de Waal *Bill of Rights Handbook* 5 ed (2005) 317.
145 Supra note 64.

> person, such as his/her family life, sexual preference and home environment, which is shielded from erosion by conflicting rights of the community. This implies that community rights and the rights of fellow members place a corresponding obligation on a citizen, thereby shaping the abstract notion of individualism towards identifying a concrete member of civil society. Privacy is acknowledged in the truly personal realm, but as a person moves into communal relations and activities such as business and social interaction, the scope of personal space shrinks accordingly.'[146]

The Constitutional Court's approach to privacy protection is set out in this case. The quotation indicates that the right to privacy is not absolute. It proceeds to explain how the right to privacy becomes attenuated. This is a useful approach in the context of limitation of the right to privacy. The court has continued to follow the *Bernstein* approach in subsequent cases as will become clear from the discussion of the cases below.

In *Mistry v Interim Medical and Dental Council of South Africa*[147] the applicant challenged the constitutionality of s 28(1) of the Medicines and Related Substances Control Act, 1965. The applicant argued that the powers given to inspectors to enter any premises where they reasonably suspect medicines to be and to inspect any document found there, violated the right to privacy under s 13 of the interim constitution.[148] Sachs J observed that a concept of a 'continuum of privacy rights' had been developed in the *Bernstein*[149] case.[150] He indicated that the continuum 'may be regarded as starting with a wholly inviolable inner self, moving to a relatively impervious sanctum of the home and personal life and ending in a public realm where privacy would only remotely be implicated.'[151] According to him, the determination as to whether a regulatory inspection amounts to a search or seizure in the context of the right to privacy, would have to be done on a case by case basis.[152] He considered the privacy continuum to be a useful tool in this inquiry. In respect of a search and seizure he noted that 'the more public the undertaking and the more regulated, the more attenuated would the right to privacy be and the less intense any possible invasion.'[153] The continuum concept serves as a useful tool in evaluating the extent of the invasiveness of a regulatory inspection.

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146 Supra note 38 at 788C-789A.
147 1998 (4) SA 1127 (CC).
148 Supra note 64.
149 Supra note 38.
150 Supra note 147 at 1144C-D.
151 Ibid 1144D.
152 Ibid 1144C.
153 Ibid 1144C-D.

The approach adopted by Sachs J in the *Mistry* case was followed in the Constitutional Court case of *Magajane v North West Gambling Board.*[154] This case dealt with the right to privacy in the context of regulatory inspections. The applicant challenged the constitutionality of sections 65(1)(*b)* and *(d)* of the North West Gambling Act, 2000. The applicant argued that these sections violated his right to privacy by authorizing inspections of unlicensed premises and seizures of property. The court relied heavily on its reasoning in *Mistry* in arriving at a decision. In so doing, Van Der Westhuizen J observed that 'this court undertook its most expansive consideration of the right to privacy in the context of regulatory inspections in *Mistry.*[155] Van Der Westhuizen J equated the 'continuum of privacy' with 'a series of concentric circles ranging from the core, most protected realms of privacy to the outer rings that would yield more readily to the rights of other citizens and the public interest.'[156] This concept can be traced back to the *Bernstein* case.[157]

In *NM v Smith*[158] the Constitutional Court reaffirmed its view of privacy as set out in the *Bernstein* case.[159] The court recognised the importance of privacy insofar as medical information is concerned.[160] The court regarded medical information as 'highly sensitive and personal information'.[161] The importance of privacy rights in the medical context and more specifically in HIV cases was reaffirmed by the court which noted that inadequate protection of privacy may have adverse consequences for the fight against the disease. Proper privacy protection, according to the court, would encourage HIV positive individuals to seek treatment and positively influence health policy.[162] The court rejected the respondents' assumption that private medical information remains private only while it is in the hands of physicians and medical staff. This, the court remarked, assumed that the individual automatically consented to disclosure of his or her medical information to persons outside the healthcare setting. Such an approach was fundamentally flawed as it

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154 *Magajane v Chairperson, North West Gambling Board* 2006 (5) SA 250 (CC).
155 Ibid 266G-H.
156 Ibid 266B; 268E.
157 Supra note 38.
158 Supra note 36.
159 Ibid 261G -262B.
160 Ibid 263A-J.
161 Ibid 263A.
162 Ibid 263B-E.

failed to consider the desire of the individual to keep his or her medical information confidential. This judgment has strengthened the right to privacy insofar as medical information is concerned.

It is clear from the discussion of the above cases why *Bernstein* has been referred to as the Constitutional Court's 'richest and most comprehensive interpretation of the right'[163] to privacy and why it continues to be followed by the court.

4.4 LEGISLATION AND LAW REFORM

The South African Law Reform Commission recently completed its investigation into privacy and data protection. The terms of reference for this investigation were as follows:

(1) To investigate all aspects regarding the protection of the right to privacy of a person in relation to the processing (collection, storage, use and communication) of his, her or its personal information by the State or another person.

(2) To recommend any legislative or other steps which should be taken in this regard.[164]

The report correctly notes that the right to privacy is not specifically protected by any particular piece of legislation.[165] There are certain statutes which do have clauses pertaining to protection of privacy but these statutes are not dedicated solely to privacy or information protection.[166] The Commission has recommended a draft Protection of Personal Information Bill[167] which is intended to remedy this problem insofar as the processing of personal information is concerned. It accordingly deals only with information privacy and protects only recorded information. The purpose of the bill is to give effect to the constitutional right to privacy by safeguarding a person's personal information when processed by responsible parties, subject to justifiable limitations that

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163 Op cit note 144 .
164 Supra note 6 at 13.
165 Ibid 21-22.
166 Ibid. The South African Reserve Bank Act 90 of 1989 and Local Government: Municipal Structures Act 117 of 1998 are cited as examples of such legislation.
167 Tabled in Parliament as B9/2009.

are aimed at balancing the right to privacy against other rights and promoting the free flow of information.[168]

The bill takes the form of a general information protection statute which gives effect to internationally recognised core information protection principles. The information protection principles as set out in the report require that information must be: obtained fairly and lawfully; used only for the specified purpose for which it was intended; adequate, relevant and not excessive to purpose; accurate and up to date; accessible to the subject; kept secure; and destroyed after its purpose is completed.[169] The intention is that sector-specific statutes and codes of conduct for the various sectors may be developed at a later stage. The savings clause in the bill provides that it does not affect the operation of any other personal information protection statute which is not in conflict with it.[170] The report acknowledges the negative consequences of inadequate information protection in the area of genomic research.[171] The list of consequences includes stigmatization, insurance discrimination, and employment discrimination.

Sections 25 and 30 are relevant for the purposes of this discussion. Section 25 makes provision for inter alia the special protection of health information privacy. The section reads as follows:

> '25. Unless specifically permitted by this Part, a responsible party may not process personal information -
> a) concerning a child who is subject to parental control in terms of the law; or
> b) concerning a data subject's religious or philosophical beliefs, race or ethnic origin, trade union membership, political opinions, health, sexual life, or criminal behaviour.

Section 30 of the draft Bill provides the following exemptions to the prohibition on the processing of personal information concerning health:

> '30.(1) The prohibition on processing personal information concerning a data subject's health or sexual life, as referred to in section 25, does not apply to the processing by -
> (a) medical professionals, healthcare institutions or facilities or social services, if this is necessary for the proper treatment and care of the data subject, or for the administration of the institution or professional practice concerned;
> (b) insurance companies, medical aid schemes, medical scheme administrators and managed healthcare organisations, provided that this is necessary for -

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168 Ibid s 2.
169 Supra note 164 at 9.
170 Supra note 167 at s 5(1).
171 Supra note 6 at 110.

(i) assessing the risk to be insured by the insurance company or covered by the medical aid scheme and the data subject has not objected to the processing;
(ii) the performance of an insurance or medical aid agreement; or
(iii) the enforcement of any contractual rights and obligations.
(c) schools, if this is necessary to provide special support for pupils or making special arrangements in connection with their health or sexual life;
(d) institutions for probation, child protection or guardianship, if this is necessary for the performance of their legal duties;
(e) the Ministers for Justice and Constitutional Development and of Correctional Services, if this is necessary in connection with the implementation of prison sentences or detention measures; or
(f) administrative bodies, pension funds, employers or institutions working for them, if this is necessary for –
(i) the implementation of the provisions of laws, pension regulations or collective agreements which create rights dependent on the health or sexual life of the data subject; or
(ii) the reintegration of or support for workers or persons entitled to benefit in connection with sickness or work incapacity.
(2) In the cases referred to under subsection (1), the information may only be processed by responsible parties subject to an obligation of confidentiality by virtue of office, employment, profession or legal provision, or established by a written agreement between the responsible party and the data subject.
(3) Responsible parties that are permitted to process information concerning a data subject's health or sexual life in terms of this section and are not subject to an obligation of confidentiality by virtue of office, profession or legal provision, are required to treat the information as confidential, unless they are required by law or in connection with their duties to communicate the information to other parties who are authorised to process such information in accordance with subsection (1).
(4) The prohibition on processing any of the categories of personal information referred to in section 26, does not apply if it is necessary to supplement the processing of personal information concerning a data subject's health, as referred to under subsection (1)(a), with a view to the proper treatment or care of the data subject.
(5) Personal information concerning inherited characteristics may not be processed in respect of a data subject from whom the information concerned has been obtained, unless-
(a) a serious medical interest prevails; or
(b) the processing is necessary for the purpose of scientific research or statistics.
(6) More detailed rules may be prescribed concerning the application of subsection (1)(b) and (f).'

The Bill has been described as procedural and not substantive.[172] The drafters have indicated that the Bill is about attaining good data management and not about addressing all privacy issues.[173] This may explain why the Bill has limited reference to substantive issues pertaining to genetic privacy.

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[172] Parliamentary Monitoring Group 'Protection of Personal Information Bill B9-2009: Deliberations (4 November 2009) available at http://www.pmg.org.za accessed on 12 November 2009.
[173] Ibid 2.

There is no attempt made in the Bill to address specific concerns relating to the privacy of genetic information or even to define genetic privacy. This may be due to the claim that the Bill is procedural, it is not intended to address specific privacy concerns and it envisages the promulgation of other legislation to deal with other areas of privacy. Sections 25, 30(1), 30(2), 30(3), 30(4) and 30(6) of the bill deal with information relating to health. Section 30(5) deals with genetic information as it refers specifically to 'personal information concerning inherited characteristics'. It is clear that a distinction is being drawn between genetic information and other health information. This interpretation is further justified upon a reading of s 30(6) which provides that more detailed rules may be prescribed in respect of the processing of health information by insurers[174] and employers.[175]

Section 30(5) permits the processing of genetic information only where a serious medical interest prevails or where the processing is necessary for the purpose of scientific research or statistics. It follows that the processing of genetic information by employers and insurers is prohibited without exception. This is different from the position regarding other health information and is cause for concern as it fails to recognise the interests of employers and insurance companies. There are circumstances where employers and insurance companies should have the right to process genetic information. For example, employers who offer services to the public will need to ensure that their employees don't pose a threat to the safety of the public. Insurers need certain information for risk assessment and in order to prevent adverse selection.[176] The type of genetic information that may be processed and the circumstances in which such processing may take place, need to be specified. A blanket prohibition on the processing of genetic information by insurers and employers is not reflective of a balancing of interests. It is unlikely that such a provision will pass constitutional muster.

The commission acknowledges that information privacy is closely linked to other privacy concerns and proposed legislation would have to be closely linked to legislation in such other areas. A further observation made by the commission is that proposed

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[174] Supra note 167 at s 30(1)(b).
[175] Ibid s 30(1)(f).
[176] Adverse selection refers to the phenomenon whereby individuals make insurance purchase decisions on risks known to them but unknown to the insurer.

legislation would have to address problems in areas which are not yet regulated.[177] Based on the savings clause[178] in the Bill, it must be accepted that all other legislation dealing with the protection of information privacy must be compatible with the bill or risk being invalidated. Insofar as s 30(5) is concerned, the problem is that it prohibits the processing of genetic information by insurers and employers thereby preventing other legislation from providing to the contrary. A contrary provision in other legislation will have the effect of diminishing rather than extending the protection afforded by s 30(5) of the Bill. For this reason such contrary provision will not prevail. A genetic privacy protection statute will have to be in harmony with the bill, which means that it cannot make provision for the processing of genetic information by insurers and employers even in specially prescribed circumstances. This will result in that statute also falling foul of the constitution.

The second problem with s 30(5) is that it provides for the processing of genetic information in general terms with no further provision for the prescribing of detailed rules concerning the application of the subsection. Section 30(6) clearly provides for the prescribing of more detailed rules in respect of the processing of health information by insurers and employers. There is no consent requirement for the processing of genetic information in the research context. A balance needs to be struck between access to genetic information for research purposes and the research subject's right to privacy. Section 30(5)(b) in its current form is vague, wide and not balanced. As far as health information is concerned, there is a requirement that the processing of information may take place if the individual has not objected thereto. These points illustrate the inconsistencies between the treatment of genetic information and other health information.

The consequences of s 30(5) of the Bill do not augur well for the protection of genetic privacy. The resultant restriction on any planned genetic privacy legislation insofar as the processing of genetic information by employers and insurers is concerned is subject to constitutional attack. The consequences for genetic research and the privacy rights of research subjects are also untenable. The subsection will have to be deleted in its entirety

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[177] Supra note 6 at 140.
[178] Supra note 167 s 5.

or couched in less restrictive terms in order for the Bill to survive constitutional scrutiny. The cursory manner in which the bill deals with genetic privacy is clearly indicative of the need for a specific genetic privacy protection statute.

4.5 THE RIGHT TO GENETIC PRIVACY

The concept of genetic privacy has not received adequate attention from academic commentators, lawyers, judicial officers, lawmakers or policymakers in South Africa. Two noteworthy attempts by Slabbert in 2007[179] and 2008[180] to introduce the debate into South African law are worth mentioning here. Slabbert undertook a brief comparative study of the state of genetic privacy protection in the United Kingdom, Germany, Switzerland and South Africa. She concludes that genetic privacy in South Africa is 'protected in a multi-layered, piecemeal fashion'[181] and that there is a need for specific protection of genetic information 'due to its unique and complex nature'.[182] She does not, however, propose a specific genetic privacy protection statute. No similar specific commentary on genetic privacy in South Africa has been found. Due to the dearth of South African literature on the issue of genetic privacy, much reliance is placed here on the writings and views of international commentators. Much work has been done in this field in other countries. Genetic privacy is important as it promotes medical research, encourages people to seek medical help in the form of genetic testing, and encourages genetic screening for preventable disorders. The benefits of human genomics can only be fully realised if people are guaranteed protection of their right to privacy.

The reasons for the requirement of genetic privacy protection are multifarious.[183] These include inter alia the uniqueness of genetic information, capacity of information technology to link genetic information to an individual, predictive nature of genetic information, and uses to which genetic information can be put. Gostin proposes the following justification for the protection of genetic information:

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[179] M Nöthling Slabbert 'Genetic privacy in South Africa and Europe: A comparative perspective (Part1)' (2007) 70 *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 622.

[180] M Nöthling Slabbert 'Genetic privacy in South Africa and Europe: A comparative perspective (Part 2)' (2008) 71 *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 81.

[181] Ibid 97.

[182] Ibid 98.

[183] As discussed in ch 1.

> 'Genomic data are qualitatively different from other health data because they are inherently linked to one person. While non-genetic descriptions of any given patient's disease and treatment could apply to many other individuals, genomic data are unique. But, although the ability to identify a named individual in a large population simply from genetic material is unlikely, the capacity of computers to search multiple databases provides a potential for linking genomic information to that person. It follows that non-linked genomic data do not assure anonymity and that privacy and security safeguards must attach to any form of genetic material.'[184]

Laurie states that 'the history of privacy has been beleaguered by obscanturism and imprecision'[185] Like the right to privacy, the concept of genetic privacy poses definitional difficulties. Laurie views genetic privacy as a 'contemporary exemplar of the crisis that has dogged the protection of personal privacy for many years.'[186] He observes that the concept of genetic privacy raises the same concerns and creates the same difficulties as those posed by the general concept of privacy. Allen, in the same vein, observes that the concept of genetic privacy is riddled with the same difficulties that continue to plague the concept of privacy.[187]

Laurie's legal exposition of genetic privacy is an accurate reflection of the difficult legal issues created by the concept. The aspect of definition is just one such issue but it has major consequences for the protection of genetic privacy in general. This is due to the fact that a sound definition forms the cornerstone of an effective protection framework. It is difficult, if not impossible, to carve out rules for the protection of an ill-defined concept. It follows that the first step in genetic privacy protection would be to define genetic information. This would be followed by a proposed definition of genetic privacy which would in essence be the protection of genetic information privacy.

Allen adopts the approach that the old concept of privacy applied to genetic information, constitutes genetic privacy. She also observes that genetic privacy originally entailed information privacy but the concept has become four-dimensional. The four dimensions are informational, physical, decisional, and proprietary privacy. Informational privacy deals with access to information; physical privacy with access to individuals and personal spaces; decisional privacy with the right to make personal choices based on genetic information; and proprietary privacy with the individual's

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184 L O Gostin 'Genetic privacy' (1995) 23 *Journal of Law, Medicine and Ethics* 320 at 322.
185 Graeme Laurie *Genetic Privacy – A Challenge to Medico-Legal Norms* (2002) 26.
186 Ibid 25.
187 Anita L Allen 'Genetic privacy: Emerging concepts and values' in Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 31.

ownership interest in his or her genes.[188] Allen correctly notes that the informational dimension of genetic privacy is addressed by means of legislation, policy guidelines, and codes of professional ethics whilst the other three dimensions usually receive less attention.[189] This is not an untenable situation since a breach of informational privacy has the potential to cause the kind of harm which the law seeks to prevent. It is thus understandable why, in a privacy discourse, the focus would be on the informational dimension of genetic privacy.

The protection of genetic privacy in South Africa should focus on informational privacy since this aspect of genetic privacy bears the risk of harm to individuals. The threat of such harm has to be minimised in order to protect the constitutionally entrenched right to privacy.

4.6 CONCLUSIONS

The right to privacy is protected by the common law and the Constitution. Since the advent of the Constitution the common law has been developed in a manner which amounts to a balancing of rights. This, in effect, reflects a permeation of the common law with constitutional values, as intended by the drafters of the Constitution. Recognition of the right to privacy in South Africa has undergone positive change in recent times as illustrated by the court decisions discussed above. The courts have progressed from viewing privacy as an aspect of dignitas to recognising it as a separate right of personality within the concept of dignitas. The Constitution recognises the right to privacy as a fundamental right in the Bill of Rights, thereby affording the right the highest level of protection against infringement. This is indicative of the changing societal perceptions of privacy and the increasing level of importance being attached to the right. The investigation conducted by the South African Law Reform Commission, which culminated in the recommendation of a Protection of Personal Privacy Bill, is also a reflection of changing needs of society insofar as the processing of personal information is concerned.

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188 Ibid 33-4.
189 Ibid.

Genetic privacy is a modern concept which also demands specific protection against infringement. As discussed above, human genomics is an area which holds untold promise for modern medicine insofar as hereditary conditions are concerned. Its full potential has yet to be realised. The realisation of this positive potential is threatened by the negative potential for stigmatisation and unfair discrimination which can arise from the unauthorised disclosure of an individual's genetic information. These threats have to be minimised in order to ensure that a science which holds such promise for the human race can continue to flourish. The law has a pivotal role to play in this regard. It can promote the science by protecting individual privacy, thereby benefiting mankind and medicine as a whole.

On the basis of the discussion above, the following conclusions have been reached:

(1) The current legal framework does not provide adequate protection to genetic information privacy.

(2) The common law does not provide adequate protection against invasion of privacy. There is no scope for relief under the actio injuriarum in cases of negligent invasions of privacy.

(3) The common law should be developed to introduce negligence as a form of fault for negligent invasions of genetic privacy by the media as well as by ordinary citizens. In genetic privacy cases, the introduction of a negligence criterion can be justified on the basis that the information is sensitive and the patient has a reasonable expectation of privacy. It would also take care of situations where medical staff who are not necessarily bound by ethical rules or confidentiality agreements, are legally obliged to exercise caution when dealing with genetic information.

(4) The incremental approach to common law development as adopted by the courts is not adequate for the purposes of dealing with genetic privacy. Law reform which occurs on a case-by-case basis cannot be expected to keep pace with the rapidly expanding science of human genomics. This leaves loopholes in the law which can be exploited by insurance companies and employers to the detriment of the individual.

(5) The Protection of Personal Information Bill does not adequately protect genetic information as its treatment of genetic privacy is merely cursory. There are no substantive provisions dealing with genetic privacy.

(6) The relevant provisions of the Protection of Personal Information Bill are too wide to pass constitutional muster. The bill does not reflect a proper balancing of interests as it fails to take cognizance of employers' and insurers' interest in genetic information.

(7) The protection of genetic privacy requires specific legislative intervention. Even though the right to privacy enjoys common law and constitutional protection, the challenges posed by a combination of genetic technology and information technology cannot be adequately addressed through these mechanisms.

(8) The savings clause in the Protection of Personal Information Bill does not affect the operation of any other personal information protection statute which is not in conflict with it. The bill specifically provides that if more extensive safeguards for the protection of personal information are provided by other statutes, the more extensive safeguards will prevail.[190] A genetic privacy protection statute will not conflict with the provisions of the bill and will provide more protection to genetic information than that which is anticipated by the bill.

(9) Difficulties concerning the definition of genetic information and the right to genetic privacy do not constitute adequate justification for not legislating for the protection of genetic information.

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[190] Supra note 167, s 5(2).

CHAPTER V

PRIVILEGE

5.1 INTRODUCTION

> 'The protection of privacy afforded by the privilege is…not a means to the end of assuring competent medical or therapeutic treatment; protection of privacy is an end in itself. An individual's right of privacy is a fundamental tenet of the…legal tradition, protected by common law, statutory provisions, and the Constitution. To be sure, the legal protections currently afforded privacy in these contexts….make it clear that privacy is a widely recognised legal interest – an interest that courts and legislatures should accord considerable weight when deciding whether to recognize or establish…a privilege.'[1]

Privilege refers to the right of an individual to refuse to disclose admissible evidence in judicial proceedings. Confidential communications are not automatically protected by the common law. In South Africa privilege only applies to confidential communications between lawyer and client. Confidential communications between doctor and patient are not subject to any protection from disclosure in judicial proceedings. Genetic information, which, although bearing its own unique characteristics, falls within the realm of medical information, would be protected by ethical rules of confidentiality but would not be subject to any privilege in law.

Since the study of human genomics is still relatively new, it is necessary for researchers to earn the trust of potential research subjects, without whose co-operation genetic research would not be possible. The benefits that genetic research may yield for society and governments in terms of healthcare, are significant enough to warrant protection of genetic information from disclosure. In addition, due to limited understanding of the science of human genetics, there is potential for ostracism and discrimination on the basis of genetic information, which provides further motivation for protection from disclosure. A concept of 'genetic information privilege' as a means of protecting genetic privacy is therefore worth investigating.

This chapter accordingly explores the possible introduction of a statutory genetic information privilege. It is acknowledged at the outset, though, that a statutory genetic privilege cannot be

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[1] The Harvard Law Review Association 'Developments in the law: Privileged communications' (1985) 98:7 *Harvard Law Review* 1449 at 1544.

absolute as it must accommodate the interests of vulnerable individuals as well as those of society as a whole. Examples would be children and the interest of society in combating crime. A statutorily recognised judicial discretion to excuse a witness from giving evidence in breach of a social or ethical value is also considered. This, in turn, necessitates an understanding of the historical background of the privilege as well as an examination of recent developments pertaining to the privilege. An analysis of legal professional privilege is undertaken in an attempt to determine why confidential communications between lawyer and client are deemed worthy of protection from disclosure in judicial proceedings whilst confidential communications made to other professionals do not enjoy the same protection. The aim is to establish whether the rationale behind legal professional privilege is the only rationale which can be used to justify the introduction of new privileges and if so, why.

In examining the law on this topic, emphasis is placed on developments in English law since South African rules on privilege originate in English law.[2] English cases are discussed because South African courts have been guided by such decisions in regard to rules of privilege. Where necessary, developments in other jurisdictions are briefly considered as these can prove useful and their use is encouraged by the South African Constitution.[3] The emphasis on English law is, however, dominant and this is due to the influence that English law has had on South African rules relating to privilege.

Section 14 of the National Health Act[4] provides that health information is confidential. One of the exceptions to this rule occurs when health information is required to be disclosed in terms of a court order.[5] Health information, unlike legal information, is not fully protected from disclosure.

5.2 HISTORICAL BACKGROUND

The origin of testimonial privilege can be traced back to Roman law.[6] [7] Although Radin found

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2 *General Accident, Fire and Life Assurance Corporation v Goldberg* 1912 TPD 494.
3 The Constitution of the Republic of South Africa Act 108 of 1996.
4 Act 61of 2003.
5 Ibid s 14(2)(b).
6 Max Radin 'The privilege of confidential communication between lawyer and client' (1928) 16 *California Law Review* 487 at 487-9.
7 H L Ho 'History and judicial theories of legal professional privilege' (1995) *Singapore Journal of Legal Studies* 558 at 556.

no proof that the Roman law gave rise to or influenced the development of the privilege in English law, he does not rule out the possibility that it may have done so.[8] Ho's view is that the influence of Roman law on the development of the privilege in English law was minimal.[9]

Wigmore's treatise on privilege[10] features most prominently in writings on this topic. According to Wigmore, legal professional privilege is the oldest privilege in respect of confidential communications.[11] Despite the wide acceptance of the treatise, it has attracted thought-provoking criticsm. Auburn draws attention to what he considers to be an inconsistency relating to the dating of the origin of privilege.[12] Wigmore[13] claims that the privilege arose in the sixteenth century in response to the advent of testimonial compulsion via the Perjury Act, 1562,[14] thus implying, according to Auburn, that the privilege has 'always been an important part of the law of testimonial compulsion'.[15] Auburn observes that testimonial compulsion existed in the Chancery Courts since the fourteenth century but privilege was only introduced in such courts after its introduction in the common law courts in the sixteenth century.[16] He accordingly finds it difficult to reconcile this with Wigmore's assertion that the rule relating to legal professional privilege 'appears to have commended itself at the very outset as a natural exception to the then novel right of testimonial compulsion.' He attributes this inconsistency to the failure to draw a distinction between Chancery and common law courts. The origin of testimonial privilege is clearly not a settled issue.

The earliest relevant court decision made after the promulgation of the Perjury Act[17] is *Berd v Lovelace*[18] where the court found that a solicitor could not be called as a witness in a case where he was engaged as a legal representative. Tapper[19] observes that the modern concept of privilege is usually ascribed to the judgment of Lord Brougham in *Greenough v Gaskell*[20] in

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8 Op cit note 6 at 489.
9 Op cit note 7.
10 JH Wigmore *Evidence in Trials at Common Law* (Vol. 8) 3 ed (1940).
11 Ibid 547.
12 Jonathan Auburn *Legal Professional Privilege: Law and Theory* (2000) 2.
13 Op cit note 11.
14 5 Eliz c. 9, §12.
15 Op cit note 12.
16 Ibid 3.
17 Supra note 14.
18 (1577) Cary 62, 21 ER 33.
19 Colin Tapper 'Prosecution and privilege' (1997) 1 *The International Journal of Evidence and Proof* 5 at 11.
20 (1833) 1 My & K 98.

1833. In *R v Derby Magistrate's Courts*[21] the court acknowledged that the law relating to privilege has been established since the *Greenough* decision.[22] According to Tapper, this case resolved many uncertainties regarding the privilege, including the question as to what purpose is served by the privilege.

Respect for the confidentiality of communications between doctor and patient was recognised in Roman-Dutch law.[23] However, even at that stage no testimonial privilege in respect of medical information existed. De Villiers notes that doctors were bound to secrecy unless required by a court of law to disclose medical information relating to a patient.[24] This legal position still prevails in South Africa.

5.3 THE RATIONALE BEHIND LEGAL PROFESSIONAL PRIVILEGE

A cursory view of the subject may create the impression that protection of confidentiality is the rationale behind privilege. That is not entirely correct. Whilst it is acknowledged that 'confidence lies at the very heart of legal professional privilege'[25] it is accepted that confidentiality itself has never amounted to sufficient justification for recognition of a privilege. This is borne out by Auburn's observation that '…privilege is not a branch or variant of any over-arching doctrine of confidentiality…'[26]

Two rationales for the introduction of rules of legal privilege become evident from a study of the relevant literature. The first is that of 'honor among gentlemen.' Wigmore observes that this was accepted as sufficient justification for a witness's refusal to testify, which was evident from the trials that took place in the seventeenth century.[27] This obligation of honor was originally considered to be the rationale behind legal privilege since most lawyers were gentlemen and were bound by an obligation to respect confidential communications made to them. Radin indicates that this was the position insofar as barristers were concerned.[28] Attorneys, however, were not gentlemen but were regarded as servants and therefore bound to keep their masters'

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21 *R v Derby Magistrate's Courts, Ex Parte B & another* [1995] 4 All ER 526.
22 Supra note 20.
23 M. De Villiers *The Roman and Roman-Dutch Law of Injuries* (1899) 108.
24 Ibid.
25 Colin Tapper *Cross and Tapper on Evidence* 10 ed (2004) 468.
26 Op cit note 12 at 1.
27 Op cit note 11.
28 Op cit note 6.

secrets.[29] This obligation stemmed from the duty of loyalty owed by a servant to his master. Radin regards this position as comparable to that of a slave in Roman law, who was not allowed to testify for or against his master because he was considered to be part of his master's family and bound by a duty of fidelity.

Radin observes that from the eighteenth century onwards the attorney's duty of loyalty to the client began to overshadow the notion of honor as the rationale of the privilege.[30] The evolution of the rationale for the privilege became evident in the English cases of *Greenough*[31] and *Bolton v Liverpool Corporation*[32] where Lord Brougham emphasised the foundation of the rule as being the right of the client to obtain legal advice in confidence. The second rationale behind the privilege is the promotion of the smooth administration of justice. In this respect, the court in *Greenough* stated as follows:

> 'The foundation of the rule is not difficult to discover. It is not (as has sometimes been said) on account of any particular importance which the law attributes to the business of legal advisers, or any particular disposition to afford them protection,…But it is out of regard to the interests of justice, which cannot be upholden, and to the administration of justice, which cannot go on, without the aid of men skilled in jurisprudence, in the practice of the Courts, and in those matters affecting rights and obligations which form the subject of all judicial proceedings.'[33]

The above approach was followed in *Derby* which provides an authoritative, yet somewhat controversial, exposition of the rationale behind legal professional privilege.[34] Lord Taylor observed that 'legal professional privilege…is a fundamental condition on which the administration of justice as a whole rests'[35] and suggested that legal professional privilege might even be a human right protected by the European Convention of Human Rights.[36] This judgment has been criticised for its uncompromising approach. It failed to recognise a public interest that was even greater than the smooth administration of justice.[37] In a later judgment the Privy Council observed that 'the public interest could scarcely have been higher than it was' in this case.[38] Even then the court in *Derby* refused to accept that any other interest could be strong enough to override legal professional privilege.

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29 Ibid.
30 Op cit note 6 at 488.
31 Supra note 20.
32 (1833) 1 My & K 88.
33 Supra note 20 para 103.
34 Supra note 21.
35 Ibid 540-541.
36 Ibid 507 European Convention for the Protection of Human Rights and Fundamental Freedoms (1950).
37 *B & others v Auckland District Law Society* [2003] UKPC 38, [2004] 4 All ER 269.
38 Ibid.

The position described in *Derby* is a reflection of the common law position. It is an uncompromising, rigid approach which seeks to portray the lawyer-client relationship as inviolate. The approach prevails even in cases where doing so would result in grave injustice to a litigant, thereby defeating the ends of justice. From a constitutional perspective the restrictive common law position can clearly never be justified in South Africa. It is encouraging to note that South African commentators are aware of the shortcomings of the common law approach as well as the fact that such position is unlikely to pass constitutional muster. In 2003 Zeffert et al[39] anticipated that the common law situation is likely to change in view of the new constitutional dispensation which recognises the right of all individuals 'not to have the privacy of their communications infringed'.[40] They indicate that 'an assault on the old position may thus be anticipated since the common law undoubtedly constitutes a limitation of this right.'[41] This prediction is well-founded and will soon be realised. An extension of the common law will then be required and if that is not forthcoming, alternative means of protecting other privileged communications will have to be investigated.

5.4 CRITICISM OF THE PRIVILEGE

'Attacked as impediments to the truth, praised as guarantors of individual privacy'[42] privileges have always been controversial in all jurisdictions. It is understandably difficult to reconcile the concept of privilege with the necessity for all available evidence to be placed before court. Privilege may be viewed as a curtailment of the opportunity to place all admissible evidence before the court. Hence it may be considered to be nothing more than an exclusionary rule. A further complication is caused by the fact that even if the privilege is viewed as an exclusionary rule, it would fall into the category of extrinsically exclusionary rules rather than intrinsically exclusionary rules. The latter are more easily justifiable due to the fact that they exclude evidence which may be regarded as 'unreliable' or 'diluted'. Examples of such evidence would be hearsay and opinion evidence. Extrinsically exclusionary rules prove difficult to rationalise because they result in the exclusion of reliable evidence on the basis of extrinsic factors such as

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39 DT Zeffert, AP Paizes & A St Q Skeen *The South African Law of Evidence* (2003) 589.
40 Section 14 of the Constitution.
41 Op cit note 39.
42 Supra note 1 at 1453.

public policy. These extrinsic factors have no bearing on the quality or the value of the evidence sought to be adduced. The exclusion of good, valuable evidence in a judicial system which aims to uncover the truth at almost any cost, is hard to justify. It is therefore imperative that the calls for new privileges be theoretically and constitutionally sound as the privilege itself appears to go against the grain of the judicial truth-seeking mandate.

The argument that all evidence must be made available to the court, must be balanced against the view that the pursuit of truth may cost too much.'[43] The privilege can be viewed either as an aid or as a threat to fact-finding in litigation. It can be seen as an aid since it prevents perjury whilst the threat lies in its ability to prevent the disclosure of pertinent information. A privilege does result in the exclusion of evidence but such exclusion is a consequence, not an objective, of the privilege. Louisell observes that:

> '…to conceive of the privileges merely as exclusionary rules is to start out on the wrong road and, except by happy accident, to reach the wrong destination. They are, or rather by the chance of litigation may become, exclusionary rules; but this is incidental and secondary. Primarily they are a right to be let alone, a right to unfettered freedom, in certain narrowly prescribed relationships, from the state's coercive or supervisory powers and from the nuisance of its eavesdropping.'[44]

The justification for legal professional privilege has been attacked by Tapper[45] who sees no reason why it deserves such an elevated status as was accorded to it by the court in *Derby*.[46] Tapper questions why confidential communications between lawyer and client should be deserving of protection from disclosure when other confidential communications arising in the course of other professional relationships are not so protected.[47] He states that:

> '…it is not self-evident why the prosecution of disputes, especially perhaps those which a lawyer's client instigates, is so much more deserving of being fostered than say, the receipt of treatment or psychological counseling which a medical practitioner's patient needs ….if anything most people would probably expect communications with their advisers about their private medical and financial affairs to be more resistant to disclosure than those relating to legal disputes.'[48]

The cause of the anomaly described above by Tapper can be attributed directly to Wigmore's four-part test which sets out the following four requirements that must be satisfied in order to establish a privilege against the disclosure of communications:

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43 *Pearse v Pearse* (1846) 63 ER 950 at 957.

44 David W. Louisell 'Confidentiality, conformity and confusion: Privileges in Federal Court today' (1956) 31 *Tulane Law Review* 101 at 110.

45 Op cit 19 at 12-15.

46 Supra note 21.

47 Op cit note 45 at 12-13.

48 Ibid.

(1) The communications must originate in a confidence that they will not be disclosed.

(2) This element of confidentiality must be essential to the full and satisfactory maintenance of the relations between the parties.

(3) The relation must be one which in the opinion of the community ought to be sedulously fostered.

(4) The injury that would inure to the relation by the disclosure of the communications must be greater than the benefit thereby gained for the correct disposal of litigation.[49]

Only a few types of confidential communications have been able to pass the test in order to qualify for a privilege. According to Wigmore himself, confidential communications between doctors and patients do not satisfy all of the requirements. This argument is most often used to reject calls for a medical privilege. In spite of Wigmore's approach, the United States of America has wide medical privilege protection. Those American States which have granted statutory recognition to medical privilege have used confidentiality and the right to privacy as justification for such recognition. This has been the approach since 1828 when New York became the first American state to recognise medical privilege. McHale observes that in the United States of America Wigmore's approach is being overtaken by the privacy approach,[50] which is in keeping with the recognition of a constitutional right to privacy. It is foreseeable that South Africa will follow the same route by virtue of the fact that the right to privacy is a constitutionally entrenched right here.

In *Derby* the court emphasised the absolute nature of legal professional privilege.[51] In *S v Safatsa*, Botha JA cautioned that 'any claim to a relaxation of the privilege... must be approached with the greatest circumspection.'[52] The exercise of caution is wise but as pointed out by Zeffert et al 'it is unlikely that the South African Courts would follow the highly conservative approach of the House of Lords.'[53] The human rights ethos which permeates all aspects of South African law will not permit the kind of absolutism or rigidity displayed by the House of Lords in *Derby*.[54]

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49 Wigmore op cit note 11 at 531.
50 Jean V. McHale *Medical Confidentiality and Legal Privilege* (1993) 29.
51 Supra note 21 at 542.
52 1988 (1) SA 868 at 886.
53 Op cit note 39 at 576.
54 Supra note 21.

5.5 ALTERNATIVES TO THE COMMON LAW PRIVILEGE

The history of privilege and its rationale indicate that its extension to the medical profession under the common law is not likely. In the unlikely event of such an extension taking place, it is still anticipated that such development will not occur in time to deal with the challenges posed by the rapidly advancing science of human genomics. This, together with the fact that certain categories of medical information are highly confidential, demand that alternative means of protecting such information be investigated. The following alternatives have already been canvassed in certain other jurisdictions, namely, the Unites States, United Kingdom, Canada, Australia, and New Zealand. The reception has not always been positive but the idea has been brought to the fore for consideration.

(a) Statutory recognition

The creation of privilege by statute provides a solution to the non-recognition of medical privilege by the common law. Three reasons for this can be identified. First, a statutory privilege will be able to circumvent the common law rationale for privilege, which is that of promoting the smooth administration of justice. Confidentiality and the constitutional right to privacy can be used to justify a statutory medical privilege but not a common law privilege. Secondly, a statutory privilege will allow for all aspects of the privilege to be clearly set out immediately without having to wait for the rules to be settled by the judiciary over long periods of time as has happened with the common law legal professional privilege. Thirdly, court cases involving human genetics are bound to revolve around highly technical information. Due to the fact that the impact of human genetics on law is a relatively new and highly technical area, a statutory privilege will assist the judiciary in dealing with cases involving genetic information in a consistent and reasonably predictable manner.

(b) Public policy exclusionary rule

In South African law,[55] as in English law, communications are not automatically protected by virtue of their confidentiality. The stance of the English law was reiterated by the court *D v*

[55] *Parkes v Parkes* 1916 CPD 702; *Botha v Botha* 1972 (2) SA 559 (N).

NSPCC.[56] In the Court of Appeal, Lord Denning emphasized the value of confidentiality. In what may be seen as an attempt to circumvent the fact that no privilege automatically attaches to confidential communications, Lord Denning suggested a presumption against disclosure unless the disclosure was in the public interest. Unfortunately this approach was rejected in the House of Lords. The judges did not find any public interest in protecting confidentiality itself but were open to the idea that confidential information may be protected if there is a sufficiently strong public interest for doing so. The relevant point made in this case is that the categories of public interest can change according to social conditions.[57] This statement opens the door to the recognition of a public policy exclusionary rule for medical information.

Mc Hale observes that to date there has been only one English case where the courts have attempted to move towards the recognition of such a rule. She accordingly questions whether it is wise to wait for the courts to develop a public policy exclusionary rule. In support of her argument she refers to the following quote from *Malone v MPC*[58]: 'It is no function of the courts to legislate in a new field. The extension of existing laws and principles is one thing. The creation of an altogether different right, another. At times judges must, and do, legislate; but as Holmes J once said, they do so intentionally and with molecular rather than molar motions.'[59] McHale argues that even if it does happen, the public policy exclusionary rule may not be the solution as it 'lacks the precise definition that a specific statutory defined privilege may provide'.[60] She suggests that 'any privilege should…contain a considered response to the problem posed by the variable levels of confidentiality which exist in medical practice.'[61] This is a significant argument as the different levels of confidentiality attaching to the various categories of medical information is one that is frequently used to reject medical privilege.

There is scope for a public-policy exclusionary rule in respect of genetic information. A comparison can be drawn between genetic information, which by its very nature is sensitive, and other sensitive medical information. The Appellate Division and the Constitutional Court have already acknowledged the need to protect the confidentiality of communications relating to

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56 *D v National Society for the Prevention of Cruelty to Children* [1978] AC 171.
57 Ibid 230.
58 [1979] 2 All ER 620 at 642.
59 Op cit note 50 endnote 34 at 144.
60 Ibid 22-23.
61 Ibid.

HIV/AIDS[62] in *Jansen Van Vuuren v Kruger*[63] and *NM v Smith*[64] respectively. This was done in an attempt to encourage individuals to seek medical care when afflicted by diseases of a sensitive nature. It is undoubtedly in the public interest for diseases such as HIV/AIDS to be treated and it is equally important for research into these diseases to be encouraged by protecting the privacy of infected persons. Another important argument is that by protecting confidential communications made in the course of confidential relationships, the law of privilege will be giving due recognition to the right to privacy.[65]

(c) Judicial discretion

English cases are not clear as to whether a judge has a judicial discretion to exclude evidence where a confidential relationship exists and where such disclosure would be in breach of a social or ethical value involving public interest. The Law Reform Committee in England indicated that a judge has a discretion to exclude evidence where disclosure would be a breach of some ethical or social value and non-disclosure would be unlikely to result in serious injustice in the particular case.[66] This view was later challenged by the Criminal Law Revision Committee. The committee's view was that a judge does not have the discretion to exclude relevant evidence merely on the basis of confidentiality.[67]

In *Trust Sentrum v Zevenburg* doubt was expressed as to whether a judge in South Africa is vested with a wide discretion to permit a witness (or any other person) to refuse to disclose information where disclosure would be a breach of some ethical or social value.[68] South African courts have acknowledged the existence of a judicial discretion to exclude evidence in criminal cases if such admission would be unfair[69] or prejudicial.[70] However, in *Botha,* Leon J expressed doubts as to whether a judge in civil proceedings has any discretion to exclude admissible evidence.[71]

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62 Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome.
63 *Jansen Van Vuuren & another NNO v Kruger* 1993 (4) SA 842 (A).
64 *NM & others v Smith & others (Freedom of Expression Institute as Amicus Curiae)* 2007 (5) SA 250 (CC).
65 The Australian Law Reform Commission Report (ALRC 38) *Report on Evidence* (1987).
66 Law Reform Committee, Sixteenth Report , *Law of Evidence in Civil Proceedings* (1967) Cmnd 3472.
67 Criminal Law Revision Committee, Eleventh Report, *Evidence (General)* (1972) Cmnd 4991 at 158-9.
68 *Trust Sentrum (Kaapstad) (Edms) Bpk v Zevenburg* 1989 (1) SA 145 (C) at 150B-C.
69 *S v Mushimba* 1977 (2) SA 829 (A); *S v Basson* 2007 (3) SA 582 (CC).
70 *S v Roets* 1954 (3) SA 512 (A).
71 Supra note 55.

A discretionary rule is not advisable as it does not promote certainty. This is more so the case in respect of information based on new technologies and science.

5.6 PHYSICIAN-PATIENT PRIVILEGE

As early as in 1776, the House of Lords, in the Duchess of Kingston's case, rejected the claim of physician-patient privilege.[72] Calls for the introduction of such a privilege have often been rejected on the basis that confidentiality itself does not constitute a valid justification for the existence of a privilege. Another reason given is that not all medical information is deserving of the same level of confidentiality, which makes it difficult to devise a statutory privilege.

The concept of medical privilege has always been non-existent in the common law. This may be attributed to the fact that in English law confidentiality is not considered to be a separate head of privilege.[73] Confidential communications are therefore not automatically protected.[74] McHale's view is that there is no inconsistency between allowing legal professional privilege and denying medical privilege since the former is protected '…not because of its inherent confidentiality, but rather because of considerations of the smooth administration of justice.'[75] It is generally accepted that since confidentiality cannot be established as the rationale behind legal professional privilege, these views must be correct. Once accepted, the possibility that confidentiality may be used as justification for the extension of privilege to other confidential communications, must be rejected. It follows that calls for the introduction of new privileges would have to be motivated on other grounds except confidentiality.

According to Wigmore, a privilege should be recognised only if it satisfies all of the requirements of his test.[76] Wigmore's view has always been that medical privilege does not satisfy such requirements and that it can therefore never qualify as a privilege. Insofar as the recognition of medical privilege by American states is concerned, Wigmore evaluates the privilege for compliance with his four-part test and concludes that there is none. He concedes

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72 (1776) 20 How. St. Tr. 355; [1775–1802] All ER 623.
73 *Alfred Crompton Amusement Machines v Commissioners of Customs and Excise* (No.2) [1973] 2 All ER 1169 at 1184.
74 *Attorney-General v Clough* [1963] 1 QB 773.
75 Op cit note 50 at 17.
76 At 133 above.

that the medical privilege meets the third requirement but is generally quite scathing in his criticism of such a privilege.[77]

With regard to the first requirement, Wigmore argues that only a few facts that are communicated to a doctor are ever truly confidential. He accepts that there are certain medical conditions which may require confidentiality but argues that a blanket privilege cannot be justified. With regard to the second requirement he argues that the absence of a privilege would not deter patients from seeking medical attention. In support of this argument he points out that even in those jurisdictions where no medical privilege exists, patients continue to seek medical care. It is interesting to note that legal professional privilege has been justified on the grounds that it is required for the full and frank disclosure by clients to their legal representatives. As stated in *Greenough*, 'if the privilege did not exist at all, everyone would be thrown upon his own legal resources; deprived of all professional assistance, a man would not venture to consult any skilful person, or would only dare to tell his counselor half his case.'[78] In respect of the fourth requirement, Wigmore argues that conditions which are most often the subject of litigation are those that are usually 'disclosable without shame' and matters of public knowledge. The injury, he argues, lies in the withholding of this information from the courts and not in its disclosure to the courts.

Legal professional privilege, to which medical privilege is often compared, is not based on confidentiality but on the interests of the smooth administration of justice. After a critical analysis of relevant cases, McHale found that all of the exclusionary rules of privilege and public interest are based on considerations of the administration of justice rather than on confidentiality.[79] This makes it difficult to argue for a medical privilege based on the confidentiality of the communications between doctor and patient. However, as will be argued later, confidentiality supported by a right to privacy, is a new matter for consideration.

Van Dokkum argues that 'a patient's privacy interest is therefore constitutionally protected and this should be accorded significant weight in the decision whether to establish a doctor-patient testimonial privilege.'[80] He also argues that the approaches adopted by the courts in

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77 Wigmore op cit note 11 at 811-813.
78 Supra note 20 at 101.
79 Op cit note 50 at 24.
80 Neil Van Dokkum 'Medical evidential privilege' (1996) 9 *South African Journal of Criminal Justice* 14 at 21.

recent cases[81] have 'swung the pendulum quite markedly in the direction of privilege attaching to medical confidentiality being regarded prima facie in the public interest rather than against it, whatever the nature of the proceedings.'[82]

McHale observes that in jurisdictions where medical privilege is recognised 'two strands of ethical reasoning' justifying such recognition have emerged, namely, utilitarianism and a human rights based justification.[83] The utilitarian approach is based on a comparison of the costs and benefits of a particular privilege on a societal level. It is thus an empirical approach. It has received much criticism because of the difficulty in calculating costs and benefits which, in the case of a privilege, are intangible. McHale suggests that it would be extremely difficult, if not impossible to obtain empirical data to determine how the existence or absence of a privilege will affect communications between doctor and patient.[84] The criticism relating to the empirical aspect of utilitarianism has been countered by Green and Nesson who point out that laws do not require empirical justification as they are usually based on behavioural assumptions.[85] In concluding her critical analysis of the utilitarian approach, McHale objectively sums up the position as follows:

> 'The fact that the utilitarian approach has been extensively criticized does not mean it should necessarily be abandoned: there are many uncertainties in ethical analysis. But neither does the inherent uncertainty which accompanies any excursion into the realms of ethics justify our unquestioning acceptance of the theory on the grounds that uncertainty is an inevitable price to pay. The flaws in utilitarianism are manifold: not least is the problem of the calculation of which interests are and which are not maximized by utility.'[86]

Wigmore's approach is regarded as utilitarian and it has been described as 'the most influential rationale for privilege law'.[87] It emphasises the interests of society as a whole over the rights of individuals. Although Wigmore's approach is regarded as utilitarian and utilitarianism has been used to justify the recognition of medical privilege in certain jurisdictions, Wigmore argues that medical privilege does not satisfy all the requirements of his utilitarian-based test. McHale attributes Wigmore's stance to a flawed application of the test and not to any possibility that utilitarianism may not be able to justify a medical privilege. Traces of utilitarianism can even be found in Roman-Dutch law. De Villiers notes that even though 'the

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81 Supra note 63; *Castell v De Greeff* 1994 (4) SA 408 (C).
82 Op cit note 80 at 20.
83 Op cit note 50 at 38 – 48.
84 Op cit note 50 at 44.
85 Eric D. Green & Charles R. Nesson *Problems, Cases and Materials on Evidence* (1994) 526.
86 Op cit note 50 at 48.
87 Supra note 1 at 1472.

medical man' is bound to secrecy, this secrecy must take second place 'where his obligations to society would be of greater weight than his obligations to the individual.'[88] This is clearly a utilitarian approach.

The human rights approach focuses on the rights of individuals and not on societal benefits. For this reason it is often thought that utilitarianism and human rights are opposing concepts which cannot be reconciled but I would argue otherwise. It is possible to reconcile human rights and utilitarianism using rule utilitarianism. Human rights are clearly based on values which society finds to be of paramount importance. All rules and policies which are aligned with these values must surely then be in the interests of society as a whole, thereby leading to a greater good. I would therefore argue that adopting a human rights based justification for the introduction of a new privilege is not entirely in conflict with Wigmore's rationale for the privilege. There is no bar to the right to privacy being used to justify the introduction of a genetic information privilege.

McHale observes that doctors owe certain fundamental obligations to their patients in terms of patients' human rights.[89] Her view is that reliance upon a fundamental right provides a strong justification for a privilege. The difficulty, however, lies in identifying the right that is to be relied upon in claiming such a privilege.[90] McHale suggests that if the right is one that is already recognised in law then such recognition may be used to bolster the argument for the introduction of a privilege intended to protect the right in question.[91] I would argue that the right to privacy as enshrined in the South African Constitution provides ample justification for the introduction of a privilege. More specifically, I would rely on s 14(d) which provides that 'everyone has the right to privacy, which includes the right not to have the privacy of their communications infringed.' Although subject to limitation, this right paves the way for the recognition of a privilege. The confidentiality of a particular communication strengthens the argument in favour of the introduction of a privilege. The argument is further strengthened when one party is bound by an ethical obligation not to disclose communications made to him or her in confidence.

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88 Op cit note 23.
89 Op cit note 50 at 49.
90 Ibid 52.
91 Ibid 53.

According to Peiris there are three basic approaches to the recognition of medical privilege; namely, the category approach, the discretionary approach, and the principle approach.[92] The category approach recognises specific categories of relationships as being subject to privilege, to the exclusion of all others. For example, confidential communications between lawyer and client are subject to legal professional privilege whilst all other professional relationships are denied such privilege. This seems to be the dominant approach in the common law. It is a rigid approach which lacks the ability to accommodate changing circumstances and new challenges. For this reason, amongst others, it is far from satisfactory. Peiris submits that the disadvantages of this approach 'outweigh the merits of precision and stability'.[93] This approach is unable to accommodate change and that reason alone is sufficient justification for its rejection.

The discretionary approach as described by the English Law Reform Committee 'accords to the judge a wide discretion to permit a witness, whether a party to the proceedings or not, to refuse to disclose information where disclosure would be a breach of some ethical or social value, and non-disclosure would be unlikely to result in serious injustice in the particular case in which it is claimed.'[94] This approach is more flexible in allowing the courts to decide on a case-by-case basis whether certain communications should be privileged or not. In *Trust Sentrum* doubt was expressed as to whether a judge in South Africa is vested with a wide discretion to permit a witness (or any other person) to refuse to disclose information where disclosure would be a breach of some ethical or social value.[95] South African courts have acknowledged the existence of a judicial discretion to exclude evidence in criminal cases if such admission would be unfair[96] or prejudicial.[97] However, in *Botha*, Leon J expressed doubt as to whether a judge in civil proceedings has any discretion to exclude admissible evidence.[98]

The principle approach is based on Wigmore's exposition of privilege. Peiris observes that 'the fullest scope of judicial creativity' is allowed by this approach[99] and that the core of this approach 'consists of recognition of the incompleteness of existing categories, and the emphasis

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92 Op cit note 99 at 327.
93 Ibid 328.
94 Law Reform Committee of England 16th Report (1967) Cmnd. 3472 para 1.
95 Supra note 68 at 150B-C.
96 *S v Mushimba* 1977 (2) SA 829 (A); *S v Basson* 2007 (3) SA 582 (CC).
97 *S v Roets* 1954(3) SA 512 (A).
98 Supra note 55.
99 GL Peiris 'Medical professional privilege in Commonwealth law' (1984) 33:2 *The International and Comparative Law Quarterly* 301 at 327.

on malleability and resilience as prime requisites of the judicial attitude to the problem.'[100] Van Dokkum,[101] writing from the South African perspective, notes the difficulty in satisfying Wigmore's fourth requirement. However, he observes that two fairly recent decisions by our courts indicate that the protection of medical confidentiality is in the public interest.[102] In the course of this research it will be argued that the protection of genetic information from disclosure is clearly in the public interest due to the implications for family members as well as entire ethnic groups.

English courts have attempted to find a compromise between unqualified privilege and compulsory disclosure of confidential communications. The approach adopted by the English courts amounts to a combination of the category approach and the discretionary approach. As observed by Pereis 'the traditional view espoused by the courts in England has favoured an extensive judicial discretion which enables a case-by-case evaluation of the propriety of disclosure, in competition with the ethical or social value which is transgressed by reception of the evidence.'[103] The Law Reform Committee of England considered the issue of privilege and declined to extend a statutory privilege to communications between doctor and patient.[104] The committee's view was that the courts were coping well enough and there was therefore no need for an extension of the privilege. The Committee rejected the idea that a statutory privilege would afford more protection than judicial discretion would. The discretionary approach was favoured for its ability to accommodate changing needs and priorities of the law. This is an attractive alternative insofar as new technologies are concerned.

Although the discretionary approach is appealing in the context of new technologies, its success depends on progressive thinking by judicial officers. It is crucial for judicial officers to be willing to reassess the legal position in the light of the implications of the absence of a privilege for genetic information. This would require sensitisation around the concerns that are peculiar to genetic information; namely, the heightened potential for economic and social harm, the implications for families, communities, and even entire populations, the adverse impact on future genetic research, and the impact on the individual's health in terms of utilising genetic health services. The required progressive thinking is unlikely to take place if genetic information

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100 Ibid 328.
101 Op cit note 80 at 20.
102 *Jansen van Vuuren & another NNO v Kruger* 1993 (4) SA 842 (A); *Castell v De Greeff* 1994 (4) SA 408 (C).
103 Op cit note 99 at 309.
104 Supra note 94 paras 46-52.

is viewed merely as an extension of medical information or if it is viewed as information shared only between medical practitioners and patients. It is therefore crucial for genetic information to be clearly defined.

It is expected that genetic information will be treated like other medical information unless it is clearly defined. Even so, the fate of genetic privacy cannot be left to the discretion of judicial officers because their decisions will have irreversible consequences for individuals, families, communities, and entire populations. Judicial officers are not keen to recognise new privileges. It is anticipated that the general lack of progressive thinking will hamper efforts to protect genetic privacy. For this reason it is recommended in this research that a statutory genetic information privilege be introduced

Based on the general approach of South African courts towards privilege, the likelihood of the extension of privilege to other professions seems remote. Notwithstanding this attitude, this research supports the idea of attaching a privilege to all confidential communications involving genetic information in an attempt to protect genetic privacy. It is argued that in view of the current South African constitutional dispensation, which regards privacy as a fundamental human right, the protection of confidential medical information from disclosure in judicial proceedings is obligatory. Such privilege may be based specifically on the relationship within which the genetic information is shared or on the nature of the information sought to be protected from disclosure. For the purpose of privilege, it is argued that genetic information should be treated as a category of protected medical information, based entirely on its nature and not on any relationship. No argument is made here for a blanket medical privilege because such a privilege would be based on the relationship between doctor and patient. History has shown that there is almost no possibility of the recognition of a general medical professional privilege in the near future. Genetic information, unlike traditional medical information, has characteristics which justify the need for added protection. Hence, the argument for a genetic information privilege.

5.7 THE SOUTH AFRICAN APPROACH TO PRIVILEGE

South African rules on privilege are based on the relevant English rules in this regard. This was acknowledged by the court in 1912 in the case of *General Accident, Fire and Life Assurance*

Corporation v Goldberg.[105] Smith J observed '.... that our Rules, are taken directly from the English Rules on the subject, and that we should be guided by the decisions which the English Courts have given upon these Rules.'[106] In South Africa, like in the United Kingdom, professional privilege applies only to the lawyer-client relationship. Zeffert et al[107] observe that the South African position is likely to change in view of the new constitutional dispensation which recognises the right of all individuals 'not to have the privacy of their communications infringed'.[108] They state that 'an assault on the old position may thus be anticipated since the common law undoubtedly constitutes a limitation of this right.'[109]

The right to privacy is protected by the Constitution.[110] The Constitution recognises the right to privacy as a fundamental right in the Bill of Rights. Section 14 of the Constitution provides as follows:

> 'Everyone has the right to privacy, which includes the right not to have -
> (e) their person or home searched;
> (f) their property searched;
> (g) their possessions seized; or
> (h) the privacy of their communications infringed.'

Section 14(d) is relevant for the purposes of the current discussion as it clearly protects private communications. Confidential communications would undoubtedly fall into this category. This right can be used to rationalise the privilege. Every right is, however, subject to limitation in terms of section 33 of the Constitution.

The Appellate Division judgment in *Jansen Van Vuuren*[111] was delivered during the period of the interim Constitution.[112] This case dealt with the unauthorised disclosure of the HIV status of the deceased by his medical practitioner. The court placed great emphasis on the protection of confidentiality in cases involving HIV/AIDS due to social consequences for infected persons. The court found that in the case of HIV/AIDS there are 'special circumstances justifying the protection of confidentiality'.[113] Harms AJA went so far as to state as follows:

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105 Supra note 2.
106 Ibid 500.
107 Op cit note 39 at 589.
108 Section 14 of the Constitution of the Republic of South Africa Act 108 of 1996.
109 Op cit note 39.
110 Constitution of the Republic of South Africa Act 108 of 1996.
111 Supra note 63.
112 Constitution of the Republic of South Africa Act 200 of 1993.
113 Supra note 63 at 854H-J.

> 'AIDS is a dangerous condition. That on its own does not detract from the right of privacy of the afflicted person, especially if that right is founded in the doctor-patient relationship. A patient has the right to expect due compliance by the practitioner with his professional ethical standards…'[114]

In awarding damages, the court took the view that the amount awarded should reflect the importance of the right to privacy. The fact that professional ethical standards had not been adhered to by the medical practitioner was considered to be an aggravating factor.

NM v Smith[115] dealt with the unauthorised disclosure of identities of HIV-positive volunteers who were participating in certain clinical trials. The volunteers claimed that disclosure without their consent amounted to a violation of, inter alia, their right to privacy. Madala J noted that 'there are in the case of HIV/AIDS special circumstances which justify the protection of confidentiality bearing in mind that the disclosure of the condition has serious personal and social consequences for the sufferer.'[116]

The abovementioned cases, as decided by the highest courts in South Africa, reveal that the courts have taken cognisance of the link between medical confidentiality and the right to privacy, which is a constitutionally entrenched right. Although the facts of these cases do not pertain to disclosure of medical information in judicial proceedings, the attitude of the courts towards medical confidentiality and its effect on the valuable right to privacy, is encouraging. It indicates that courts are taking medical confidentiality seriously and are willing to see it as an extension of the patient's right to privacy. This ultimately means that confidential communications should be protected. It is, however, also important to remember that the right to privacy is not absolute so not all confidential communications will enjoy the same level of protection from disclosure. It is reasonable to assume that the more sensitive information demands a higher level of confidentiality.

5.8 GENETIC INFORMATION PRIVILEGE

> 'Human genomic information is invested with enormous power in a scientifically motivated society. Genomic information has the capacity to produce a great deal of good for society. It can help identify and understand the etiology and pathophysiology of disease. In so doing, medicine and science can expand the ability to prevent and ameliorate human malady through genetic

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114 Supra note 63 at 856E-F.
115 Supra note 64.
116 Supra note 64 at 267G.

> testing, treatment, and reproductive counseling. Genomic information can just as powerfully serve less beneficent ends. Information can be used to discover deeply personal attributes of an individual's life. That information can be used to invade a person's private sphere, to alter a person's sense of self- and family identity, and to affect adversely opportunities in education, employment, and insurance. Genomic information can also affect families and ethnic groups that share genetic similarities.'[117]

The above note is a succinct explanation of the benefits and the dangers posed by genetic information, as given by Gostin. He also establishes a justification for genetic privacy protection. Tapper notes that there must be 'good cause… for the existence of any privilege' and 'the crucial question is whether there is some interest protected by the privilege which is at least as significant as the proper administration of justice.'[118] In a similar vein, Mueller and Kirkpatrick suggest that requests for the introduction of new privileges be approached with caution.[119] They suggest that the following factors be considered when evaluating requests for the introduction of new privileges:

> '(1) The importance to the community of the information sought to be protected;
> (2) whether community values would be offended by governmental intrusion into the privacy of the relationship;
> (3) the extent to which societal traditions and professional standards create a reasonable expectation of confidentiality in such a relationship;
> (4) whether the purpose of the relationship depends upon full and open communication;
> (5) the extent to which such communication would be impeded by non-recognition of a privilege; and
> (6) the direct and indirect benefits to the public from encouraging the communication and protecting the privacy of the relationship in comparison to the cost to the litigation process resulting from the loss of evidence.'[120]

A brief comparison with Wigmore's four-part test[121] reveals certain deficiencies in his test which will always lead to the rejection of medical privilege. The first requirement of his test is that the communications in respect of which privilege is being claimed, must originate in a confidence that they will not be disclosed. In the case of genetic disorders this is presumed because of the highly sensitive and familial nature of the information. The second requirement that the element of confidentiality must be essential to the full and satisfactory maintenance of the relations between the parties, is also satisfied in the case of genetic disorders. It is neither fair nor reasonable to compare genetic disorders with other common illnesses. Unlike the

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117 Lawrence O. Gostin 'Genetic privacy' (1995) 23 *Journal of Law, Medicine & Ethics* 320 at 323.
118 Op cit note 25 at 445.
119 Christopher B. Mueller & Laird C. Kirkpatrick *Evidence: practice under the rules* (1999) 404.
120 Ibid.
121 At 138 above.

situation in respect of other ailments, individuals who suspect that they have genetic disorders are unlikely to seek medical help and testing if they do not have the assurance of confidentiality. This is due to fears of stigmatisation and discrimination. South African courts have acknowledged the need for confidentiality in cases relating to HIV/AIDS because of the potential for stigmatisation, ostracism, and discrimination.[122] There is no reason why the same approach cannot be adopted in respect of genetic disorders. McHale describes Wigmore's view on confidentiality as simplistic.[123]

Wigmore's fourth requirement demands special attention. The requirement is that the injury caused by disclosure must be greater than the benefit thereby gained for the correct disposal of litigation. In the course of his argument on this point, Wigmore relies on the remarks made by Owen J in *Maine v. Maryland Casualty Co.*[124] The following remarks by Owen J can be described as judgmental, outdated, presumptuous and one-dimensional to the point that the objectivity of the maker thereof is compromised:

> 'In all the range of human affliction that one can think of but one class of diseases that he would hide from his friends and neighbours, and that is venereal diseases. No other diseases, nor class of diseases, bring shame or humiliation or disgrace to the sufferer. He who has acquired venereal disease by clandestine liaison has scant claim upon legislative consideration for protection from the shame which he has deliberately invited…this statute must be said to have been enacted to save from shame and disgrace those who by their own acts have forfeited their honor.'[125]

Wigmore asserts a two-pronged argument in respect of the fourth requirement. First, he asserts that no medical information, except that relating to venereal disease, is so confidential as to be subject to a privilege. Secondly, he argues that only diseases which 'bring humiliation or shame or disgrace to the sufferer' may require confidentiality but where such diseases have been acquired by 'clandestine liaison' such desire for confidentiality should not prejudice innocent persons who may benefit from disclosure. As remarked by Owen J: 'The innocent should not be thus deprived of justice and made to pay the cost of the protection which this statute would afford to those who have forfeited all right to protection.'[126]

This approach to medical privilege is problematic for three reasons. First, it assumes that every person who is infected with a venereal disease has acquired the disease by 'clandestine liaison'. This fails to take cognisance of the reality that sexually transmitted diseases can be

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122 Supra notes 63 and 64.
123 Op cit note 50 at 47.
124 172 Wis. 350, 178 N.W. 749 (1920).
125 Ibid
126 Supra note 124.

acquired otherwise than by clandestine liaison, for example, through acts of sexual assault. Secondly, it suggests that people who engage in morally unacceptable conduct should forfeit their right to protection from the law. This argument must be rejected in South Africa due to our constitutional dispensation which guarantees certain fundamental rights to all citizens regardless of moral considerations. It is not possible to deprive individuals of their constitutional rights, as enshrined in the Bill of Rights, purely on the basis that they have engaged in conduct which others may find morally reprehensible. Thirdly, the approach is restrictive as it confines conditions demanding confidentiality to those which 'bring humiliation or shame or disgrace to the sufferer'. Other conditions such as genetic disorders do not satisfy this description but communications relating to such disorders are highly confidential and deserving of protection.

The general acceptance of Wigmore's four-part test as the dominant test for determining whether certain communications should be subject to a common law privilege, is clearly problematic. None of Wigmore's arguments against the recognition of privilege are valid in the case of genetic information. His approach is too outdated to deal with developments in modern medicine and related technology. The case for genetic information privilege has to follow a different path as it cannot be moulded to fit an inappropriate test.

Since Wigmore himself always maintained that the introduction of a medical privilege would not be possible under his test because it does not satisfy all of the criteria for recognition of a privilege, it is necessary to look at alternatives. Any unquestioning acceptance of Wigmore's rejection of medical privilege would not augur well for a proposed genetic information privilege. It may be useful to consider the requirements proposed by Mueller and Kirkpatrick, not merely because Wigmore's test is not favourable to medical privilege, but because of the comprehensive, more objective nature of their requirements. They also refer specifically to societal traditions and professional standards. The ethical rules which medical professional are bound by will clearly be given due consideration.

I would argue for a genetic information privilege on the basis of the constitutional right to privacy. Louisell argues that the right to be left alone is such an important aspect of human liberty that it can take precedence over the need for accuracy in adjudication.[127] He observes that 'privileges are a right to be let alone, a right to unfettered freedom, in certain narrowly prescribed relationships, from the state's coercive or supervisory powers and from the nuisance of its

[127] Op cit note 44.

eavesdropping.'[128] He acknowledges the need for accuracy in the litigation process as well as the need to maintain confidentiality in certain relationships.[129]

Three important uses would be served by the introduction of a genetic information privilege. First, a genetic information privilege would serve to prevent courts from compelling disclosure of genetic information, including genetic research information. This is important because genetic research requires the participation of vulnerable research participants. In order to avoid stigmatisation or discrimination, potential crucial subjects may decline involvement in research. This would serve only to hinder research in a rapidly expanding field which has the potential to revolutionise healthcare. In the interests of ongoing research and protection of vulnerable participants it is imperative that research participants be guaranteed protection against disclosure of their personal genetic information. Secondly, respect for private medical information may yield benefits for the improvement of health policies and healthcare systems. Madala J, in *NM v Smith,*[130] made the point in respect of HIV/AIDS policies but it should be equally applicable to genetic conditions. Thirdly, the adverse impact of the disclosure of one person's genetic information on families and entire communities can be limited via a genetic information privilege. Gostin describes the long reach of genetic information in the following passage:

> 'It is thus possible to conceive of a genetic information system that contains a robust account of the past, present, and future health of each individual, ranging from genetic fetal abnormalities and neonate carrier states, to current and future genetic conditions at different points in one's life. Genetic data can even explain causes of morbidity and mortality after death; …such genetic explanations of morbidity and mortality provide an expansive understanding not only of the individual, but also of her family (ancestors as well as current and future generations) and possibly of whole populations.'[131]

Doctors are ethically bound, not only to treat as confidential those communications made verbally by their patients, but also information gained from tests.[132] The latter category is especially relevant to human genetics where much of the information is gained through genetic testing. The difficulty lies in the fact that genetic information passes through the hands of many individuals. A doctor-patient privilege will serve to prevent only doctors from disclosing genetic information in judicial proceedings. Other individuals who have knowledge of the patient's genetic information may be obliged to keep the information confidential but will not be

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128 Ibid.
129 Ibid 109.
130 Supra note 64 at 263E.
131 Op cit note 117 at 321.
132 Op cit note 11 at 823.

prohibited by law from disclosing it in judicial proceedings. It follows that the introduction of a doctor-patient privilege will not solve the problem insofar as the disclosure of genetic information by other individuals is concerned. The new position will simply be akin to the current one.

Not all communications between doctor and patient are deserving of protection from disclosure in judicial proceedings. To argue otherwise would result in such communications being privileged purely on the basis of the doctor's profession. This would amount to recognition of a professional privilege. Some communications are more confidential than others because of the medical condition involved and therefore deserving of protection not merely on the basis of confidentiality but due to the sensitivity of the matter. McHale points out that the levels of confidentiality or sensitivity may differ due to, inter alia, the nature of the ailment, age of the patient, culture, and ethnicity.[133] In *Jansen Van Vuuren*,[134] the Appellate Division was fully aware of such factors and adopted an approach which was appropriate for dealing with HIV and AIDS. There is no reason why a similar approach cannot be adopted with regard to other types of medical information where there are 'special circumstances justifying the protection of confidentiality.'

It is acknowledged that powerful arguments are required to justify the existence of any privilege.[135] The justification of a privilege is a daunting task, especially as the trend now appears to be moving towards the limitation rather than extension of privileges. The following observations by Tapper tend to balance the scales so that new privileges do not appear impossible to justify:

> 'It is also important not to exclude the possibility that the law is defective by failing to recognize legitimate claims to privilege, and not merely by protecting interests which do not deserve it. The influence of public opinion should not be ignored. The proper administration of justice…includes the notion of the rejection of relevant evidence because its reception would be unduly offensive to contemporary public opinion. It follows that that which was the subject of privilege in one generation should not necessarily be privileged in the next, and vice versa.'[136]

The creation of a genetic information privilege will not amount to an unreasonable or unjustifiable extension of the rules of privilege. Statutory recognition will promote certainty and consistency in the application of the privilege. In other jurisdictions there are already other

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133 Op cit note 50 at 76.
134 Ibid note 114.
135 Op cit note 25 at 443.
136 Ibid 445.

privileges which have been established either at common law or by statute. All American States have introduced a statutory psychotherapist privilege.[137] Gostin observes that, unlike traditional medicine which aims to benefit the individual patient, genetic applications can benefit entire communities and ethnic groups.[138] He argues that 'there is considerable utility in using population-based data to promote community health.'[139] Here he refers to research which has identified a predisposition to breast and ovarian cancer in women of Eastern European Jewish descent as well as the discovery of the predominance of Tay-Sachs syndrome in Ashkenazi Jews and sickle cell trait in African Americans. A similar view of the social utility of psychotherapy has resulted in the introduction of a psychotherapist-patient privilege in the United States of America. The privilege was first recognised in Illinois in 1952 in the case of *Binder v Ruvell*.[140] In 1996 the United States Supreme Court introduced the psychotherapist patient privilege in *Jaffee v Redmond.*[141] The court found that the overall mental health of citizens creates a net benefit to society which justifies the occasional loss of probative evidence.

Privileges may be based on the nature of the relationship within which the information has been communicated or on the nature of the information sought to be protected from disclosure. A genetic information privilege should be based on the nature of the information sought to be disclosed, and not on the nature of the relationship within which the confidential information was communicated. This is important because genetic information may be found in the possession of various individuals, ranging from researchers to entire healthcare teams and administrative

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137 Ala. Code § 34-26-2 (1975); Alaska Rule Evid. 504; Ariz. Rev. Stat. Ann. § 32-2085 (1992); Ark. Rule Evid. 503; Cal. Evid. Code Ann. § 1010, 1012, 1014 (1995); Colo. Rev. Stat. § 13-90-107(g) (1995); Conn. Gen. Stat. § 52-146c (1995); Del. Uniform Rule Evid. 503; D.C. Code Ann. § 14-307 (1995); Fla. Stat. § 90.503 (Supp. 1992); Ga. Code Ann. § 24-9-21 (1995); Haw. Rules Evid. 504, 504.1; Idaho Rule Evid. 503; Il Comp. Stat., ch. 225, §15/5 (1994); Ind. Code §25-33-1-17 (1993); Iowa Code §622.10 (1987); Kan. Stat. Ann. §74-5323; Ky. Rule Evid. 507; La. Code Evid. Ann., Art. 510 (995); Me. Rule Evid. 503; Md. Cts. & Jud. Proc. Code Ann. §9-109 (1995); Mass. Gen. Laws §233:20B (1995); Mich. Comp. Laws Ann. §333.18237 (West Supp. 1996); Minn. Stat. §595.02 (1988 and Supp. 1996); Miss. Rule Evid. 503; Mo. Rev. Stat. §491.060 (1994); Mont. Code Ann. §26-1-807 (1994); Neb. Rev. Stat. §27-504 (1995); Nev. Rev. Stat. §49.215 (1993); N.H. Rule Evid. 503; N.J. Stat. Ann. §45:1413-28 (West 1995); N.M. Rule Evid. 11-504; N.Y. Civ. Prac. Law §4507 (McKinney 1992); N.C. Gen. Stat. §8-53.3 (Supp. 1995); N.D. Rule Evid. §503; Ohio Rev. Code Ann. §2317.02 (1995); Okla. Stat., Tit. 12, §2503 (1991); Ore. Rules Evid. 504, 504.1; 42 Pa. Cons. Stat. §5944 (1982); R.I. Gen. Laws §§5-37.3-3, 5-37.3-4 (1995); S.C. Code Ann. §19-11-95 (Supp. 1995); S.D. Codified Laws §§ 19-13-6 to 19-13-11 (1995); Tenn. Code Ann. §24-1-207 (1980); Tex. Rules Civ. Evid. 509, 510; Utah Rule Evid. 506; Vt. Rule Evid. 503; Va. Code Ann. §8.01-400.2 (1992); Wash. Rev. Code §18.83.110 (1994); W. Va. Code §27-3-1 (1992); Wis. Stat. §905.04 (1993-1994); Wyo. Stat. §33-27-123 (Supp. 1995).

138 Op cit note 117 at 323.

139 Ibid.

140 Civil Docket 52C2535, Circuit Court of Cook County, Illinois, June 24, 1952.

141 518 U.S. 1 (1996).

personnel, not all of whom are bound by professional ethical rules. A privilege that is dependent on the nature of a relationship would cover communications made to certain categories of persons only. Since matters covered by a privilege can be proved by the evidence of persons falling outside of the protected categories, the purpose of a genetic information privilege will be defeated if it is based on a particular relationship.

A genetic privacy protection statute must also provide for exclusions to the privilege. These would ordinarily apply to cases which concern the welfare of children and criminal cases. In such cases the evidence should be heard in camera so as to prevent harm to the patient, family, community or population group.

5.9 CONCLUSIONS

It is evident that the call for the introduction of a new privilege will meet with resistance. Much of this resistance may be attributed to Wigmore's test. It has, however, been shown that Wigmore's test is no longer the ideal or superior test. There are other approaches which are more current and therefore more suitable for the purpose of addressing new challenges to privacy. The current approach to the development of privilege law is inappropriate for the protection of genetic information privacy. The ad hoc development of the law relating to privilege is neither appropriate nor advisable for the protection of genetic information due to the sensitivity of genetic information and its wide-ranging implications. Genetic privacy protection requires immediate attention so that the law can keep pace with the science of genetics. A statutory judicial discretion to refuse to compel disclosure is also inadequate because it cannot guarantee consistency or certainty in the application of the discretion. Even guiding principles may not be sufficient.

The constitutional right to privacy, high level of confidentiality of genetic information, social utility of genetic applications, and other special circumstances surrounding genetic information justify the introduction of a statutory genetic information privilege in South Africa. Such a statutory genetic information privilege should be based on the nature of the genetic information and vulnerability of individuals/populations but not on any professional relationship within which confidential communications are made. In order to be totally effective the privilege must

cover documentary evidence in the form of genetic test results. The privilege must also be subject to specific exceptions since the constitutional right to privacy is not absolute.

As mentioned above, the possibility of a new privilege being introduced is remote.[142] It is therefore important to explore alternative avenues for genetic privacy protection. This is one of the reasons for the cross-jurisdictional review which is undertaken in the next chapter.

[142] At 143 above.

CHAPTER VI

CROSS-JURISDICTIONAL REVIEW: DEVELOPMENTS IN SELECTED FOREIGN JURISDICTIONS

6.1 INTRODUCTION

The issue of genetic privacy affects the entire human species regardless of race, sex, or geographical location. It has national, regional, and international significance due to globalisation, cross-border sharing of information, collaborative research initiatives, advances in information technology, and the proliferation of genetic databases. Many countries are proactively attempting to address the legal and ethical issues posed by developments in the area of genetic testing and genetic research involving human participants. In this chapter the developments in five countries will be discussed. These are the United Kingdom (UK), the United States of America (USA), Australia, Canada, and the Netherlands.

The UK and Australia are considered for the insight they can provide through the research that they have already undertaken into genetic privacy and the reform recommendations that they have proposed. In the UK the Human Genetics Commission (HGC) has conducted two relevant inquiries into genetic information. One dealt with the forensic use of genetic information[1] and the other with the balancing of competing interests in the use of personal genetic data.[2] The work of the HGC is ongoing and provides valuable insight into public attitudes and concerns relating to genetic information. Due to the intensive public consultations that are undertaken by the HGC prior to compiling reports, its recommendations are based on actual public concerns and not just on perceptions of policymakers and legislators. The influence of the European Data Protection Directive[3] on the rest of the world, including South Africa, necessitates a discussion of this instrument. It has been observed that, in addition to harmonising data protection

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[1] Human Genetics Commission Report *Nothing to Hide, Nothing to Fear?* (2009) available at http://www.hgc.gov.uk/Client/document.asp?DocId=226&CAtegoryId=10 accessed on 24 February 2012.

[2] Human Genetics Commission Report *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (2002) available at http://www.hgc.gov.uk/Client/document.asp?DocId=131&CAtegoryId=10 accessed on 24 February 2012.

[3] 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 available at http://eur-ex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML accessed on 29 September 2011.

principles within Europe, the Directive 'can also be credited with creating one of the world's leading paradigms for privacy protection, which has served as an inspiration to legal regimes outside Europe.'[4] The UK also has the world's largest forensic DNA database per head of the population as well as various other non-forensic human genetic databases, including the UK Biobank. The forensic DNA database, although legally flawed in its operation, has influenced the development of forensic databases in other countries and for this reason it warrants attention in this chapter.

The Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council undertook a joint inquiry into the protection of human genetic samples and information.[5] The project has been referred to as 'the most comprehensive consideration of the ethical, legal and social implications of the 'New Genetics' ever undertaken'.[6] The report contains 144 recommendations for reform, most of which have since been accepted by the Australian government.

Canadian developments are based largely on the work of the Canadian Biotechnology Advisory Committee and the application of the Personal Information Protection and Electronic Documents Act (PIPEDA)[7] to genetic information. An analysis of the Canadian position is intended to demonstrate how general privacy legislation, such as PIPEDA, may be used to protect genetic privacy in the absence of other more suitable legal and regulatory instruments. The Netherlands has been included in this discussion because it differs from the other jurisdictions under review to the extent that it has legislation aimed at protecting genetic privacy together with a moratorium on the use of genetic information by insurance companies. It therefore provides a unique alternative for consideration. The American position, which is based on an anti-discrimination paradigm, is considered here because it helps to demonstrate why a privacy approach has been favoured over an anti-discrimination approach in this research.

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4 Neil Robinson, Hans Graux, Maarten Botterman, Lorenzo Valeri *Review of the European Data Protection Directive* (2009) available at http://www.ico.gov.uk/~/media/documents/library/Data_Protection/Detailed_specialist_guides/REVIEW_OF_EU_DP_DIRECTIVE.ashx accessed on 5 October 2011.

5 Australian Law Reform Commission *The Protection of Human Genetic Information in Australia* (2001).

6 Australian Law Reform Commission Report 96 *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003) at 33, available at http://www.alrc.gov.au/publications/report-96 accessed on 24 February 2012.

7 S.C 2000, C.5.

6.2 CROSS-JURISDICTIONAL REVIEW

6.2.1 THE UNITED KINGDOM

The UK has been and still is a key contributor to developments in the field of human genetics. In 1953 Watson and Crick discovered the double-helical structure of deoxyribonucleic acid (DNA) whilst working together at the University of Cambridge. DNA fingerprinting was developed by Professor Sir Alec Jeffreys and his colleagues at the University of Leicester in 1984. The UK also made a significant contribution to the Human Genome Project through the involvement of the Wellcome Trust Sanger Institute. The UK continues to monitor developments in human genetics so as to respond to the consequent ethical, legal, and social challenges. Much work has been done in this area by various bodies including the House of Commons and House of Lords Select Committees on Science and Technology, Genetics and Insurance Committee, Human Genetics Advisory Commission, Human Genetics Commission, Information Commissioner, the Department of Health, and the National Health Service.

There is no written Constitution or national Bill of Rights in the UK. The UK ratified the European Convention on Human Rights (ECHR)[8] in 1951. The ECHR recognises privacy as a fundamental human right.[9] The Charter of Fundamental Rights (CFR)[10] was signed and proclaimed in December 2000.[11] It was the first formal European Union (EU) document to consolidate existing civil, political, social, and economic rights of EU citizens into one instrument but it was not a legally binding instrument. It merely reflected a political commitment to the respect for certain fundamental rights. The Lisbon Treaty,[12] which entered into force in December 2009, made the CFR legally binding. This was achieved through article 6(1) which provides that 'The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union, which shall have the same legal value as

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[8] Council of Europe *Convention for the Protection of Human Rights and Fundamental Freedoms* (1950) available at http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=005&CM=8&DF=07/10/2011&CL=ENG accessed on 7 October 2011.

[9] Ibid Article 8.

[10] *Charter of Fundamental Rights of the European Union* (2000) available at http://www.europarl.europa.eu/charter/pdf/text_en.pdf accessed on 8 October 2011.

[11] The European Parliament, Council of the European Union, and the European Commission *Charter of Fundamental Rights of the European Union* 2000 Official Journal of the European Union (C 364) 1 (December 7, 2000) (Nice) available at http://www1.umn.edu/humanrts/instree/europeanunion2.html accessed on 8 April 2012.

[12] *Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community* 2007 Official Journal of the European Union (C306) 50 (December 17, 2007) available at http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2007:306:SOM:EN:HTML, accessed on 7 October 2011.

the Treaties.' The significance of article 6(1) lies in the fact that a treaty is a binding agreement between EU member countries. According to Barnard this means that the CFR now forms part of the primary law of the EU and its provisions can be enforced by the national courts and by the European Court of Justice.[13]

Article 7 of the CFR provides for the protection of privacy and article 21 of the CFR prohibits discrimination on 'any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation.' For the purposes of this discussion it is important to take note of the prohibition based on genetic features. It is also important to note that even though the CFR has acquired legal status in the EU by virtue of the signing of the Lisbon Treaty, the protection that is afforded by the CFR is limited in the UK. This has been achieved by the inclusion of an opt-out Protocol[14] in the Lisbon Treaty which provides that the CFR will not create additional enforceable rights over and above those already provided for in UK national legislation. It has been suggested that the 'Protocol adds a regrettable and unnecessary layer of complexity and confusion to an already complicated EU legal landscape in relation to fundamental rights.'[15] As discussed below, the application of the opt-out Protocol in practice remains uncertain.[16]

(a) Genetic Databases

(i) Forensic DNA Databases

In 1991 the Royal Commission on Criminal Justice (Runciman Commission) was established in response to a string of miscarriages of justice.[17] The Commission was tasked with reviewing the criminal justice system with the aim of inter alia preventing wrongful convictions. In 1995 the

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[13] Catherine Barnard 'The Opt-Out for the UK and Poland from the Charter of Fundamental Rights: Triumph of Rhetoric over Reality?' in Stefan Griller & Jacques Ziller (eds) *The Lisbon Treaty – EU Constitutionalism without a Constitutional Treaty?* (2008) 260.

[14] Ibid Protocol 7 on the application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom.

[15] Maria Fletcher 'Schengen, the European Court of Justice and flexibility under the Lisbon Treaty: Balancing the United Kingdom's 'ins' and 'outs' ' (2009) 5 *European Constitutional Law Review* 71 at 95.

[16] At 23-24.

[17] Birmingham Six, Guildford Four, Tottenham Three, Cardiff Three, Taylor Sisters, and the Maguires.

NDNAD was established[18] pursuant to a recommendation of the Runciman Commission. The NDNAD is operated by the Forensic Science Service and is currently the world's largest forensic DNA database per head of the population.[19]

There is no specific statutory provision governing the operation of the NDNAD. The Criminal Justice and Public Order Act 1994[20] created a framework for DNA sample collection and profiling. It extended police powers even further by permitting speculative searching,[21] widening the category of non-intimate samples to include mouth swabs,[22] and permitting the taking of non-intimate samples without consent from individuals arrested for any recordable offence. The Act provided for the removal from the database of profiles of persons acquitted of a crime. A number of cases followed, challenging the legality of identification using DNA profiles which should have been removed from the database. Two such cases are *R v B*[23] and *R v Weir,*[24] both of which have been discussed in chapter two.

In 2001 The Criminal Justice and Police Act[25] amended the Police and Criminal Evidence Act[26] to allow for the indefinite retention of DNA samples collected from individuals regardless of whether such individuals are acquitted. The Criminal Justice Act[27] was amended in 2003 to authorise the taking of samples in any arrest for a recordable offence even if the person is not charged with an offence. Such samples can also be retained indefinitely. This statutory provision was challenged in the European Court of Human Rights in the case of *Marper v The United Kingdom*.[28] The applicants in this case argued that the retention of DNA samples and profiles of unconvicted persons is not proportionate to the aim of detecting and preventing crime. Whilst acknowledging the importance of DNA evidence in combating crime, the court found that

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[18] Established in England and Wales. Scotland and Northern Ireland have their own DNA databases which submit profiles to the National DNA Database. See Parliamentary Office of Science and Technology 'The National DNA Database' (February 2006) 258 *Postnote* available at http://www.parliament.uk/documents/post/postpn258.pdf accessed on 6 March 2012.

[19] Privacy International 'United Kingdom Privacy Profile' (January 26, 2011) available at https://www.privacyinternational.org/article/united-kingdom-privacy-profile, accessed on 6 March 2012.

[20] 1994 c. 33.

[21] Section 63A.

[22] Sections 58(2) and (3).

[23] Attorney General's Reference (No. 3 of 1999); [2000] 2 Cr. App. R.416.

[24] [2001] 2 Cr. App. R.9.

[25] 2001 c. 16.

[26] 1984 c. 60.

[27] 2003 c. 44.

[28] *S. and Marper v The United Kingdom* Applications nos. 30562/04 and 30566/04 (4 December 2008).

the retention of profiles of unconvicted persons violated their right to privacy and could not be justified.

On 18 May 2011 the findings of the European Court of Human Rights (ECtHR) in *Marper*[29] were echoed by the UK Supreme Court in *R v Commissioner of Police*.[30] The appellants in this case had DNA samples taken from them upon arrest. They were subsequently acquitted of all charges and they applied for judicial review of the retention of their data. In so doing they relied on the decision of the ECtHR in *Marper*.[31] Their applications were dismissed by the lower court on the basis that there were no exceptional circumstances, within the meaning of the guidelines issued by the Association of Chief Police Officers (ACPO Guidelines), which could justify destruction of their DNA samples. On appeal, the majority in the UK Supreme Court accepted that '[i]t is common ground that, in the light of *Marper ECtHR*, the indefinite retention of the appellants' data is an interference with their rights to respect for private life protected by article 8 of the ECHR, which for reasons given by the ECtHR, is not justified under article 8(2).'[32] The court accordingly granted a declaration that the present ACPO Guidelines are unlawful because they are incompatible with the ECHR. In the majority judgment, Lord Dyson pointed out that '[i]f Parliament does not produce revised guidelines within a reasonable time, then the appellants will be able to seek judicial review of the continuing retention of their data under the unlawful ACPO guidelines and their claims will be likely to succeed.'[33] The majority also adopted the stance that since the scheme for retention of DNA is currently being reviewed in the course of deliberations on the Protection of Freedoms Bill,[34] it is 'neither just nor appropriate to make an order requiring a change to the legislative scheme within a specified period.'[35]

In *Goggins & others v The United Kingdom*,[36] the government indicated its acceptance of the decision by the ECtHR in *Marper*.[37] The government declared that it 'is in the process of implementing the decision of the Court in *Marper*, which will be done by introducing new

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29 Ibid.
30 *R (GC) v The Commissioner of Police of the Metropolis; R(C) v The Commissioner of Police of the Metropolis* [2011] UKSC 21.
31 Supra note 28.
32 Supra note 30 para 15.
33 Ibid para 49.
34 Bill 146 (2010-2011).
35 Supra note 30 para 46.
36 Applications nos. 30089/04, 14449/06, 24968/07, 13870/08, 36363/08, 23499/09, 43852/09 and 64027/09 (19 July 2011) Strasbourg.
37 Ibid para 57.

legislation to ensure that the provisions governing the retention of such data are proportionate in light of the rights of the individuals under Article 8.'[38] The court accepted the government's undertaking but did indicate that it will revisit the applications if the legislation before Parliament is not enacted.[39]

The Protection of Freedoms Bill[40] was presented to Parliament on 11 February 2011. It introduces a new framework for police retention of DNA and fingerprint data in England and Wales. The new framework is based on the Scottish model. In *Marper* the court observed that the Scottish model was 'notably consistent with the Committee of Ministers' Recommendation R(91)1, which stresses the need for an approach which discriminates between different kinds of cases and for the application of strictly defined storage periods of data, even in more serious cases' unlike arrangements in force in the rest of the UK.'[41] The Bill went through the report stage and third reading in the House of Commons on 11 October 2011. It is currently awaiting consideration by the House of Lords.

The NDNAD in the UK has served as a model for forensic databases in other countries. A major difference though is that other countries do not permit the indefinite retention of DNA profiles. Even though the UK is a pioneer in the field of forensic DNA databases, the legislative position is unsatisfactory. This has been proven by the decision of the ECtHR in *Marper*[42] as well as the subsequent decision of the Supreme Court of the UK in *Goggins.*[43] The position between the privacy rights of individuals and that of the State is unbalanced with the State being in a much more favourable position. The role of the State in preventing and detecting crime is considered to be of paramount importance thus resulting in an unjustifiable limitation of the right to privacy. Based on the comments made by the ECtHRin *Marper,*[44] it is fair to conclude that the current regulatory framework has not succeeded in fostering a culture of respect for privacy rights. A landmark review[45] of the protection of human rights in Britain was recently concluded by the Equality and Human Rights Commission. The review concluded that there are ten areas

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38 Ibid para 59.
39 Ibid para 78.
40 Supra note 34.
41 Supra note 28 para 110.
42 Supra note 28.
43 Supra note 36.
44 Supra note 28.
45 Equality and Human Rights Commission Human Rights Review *How fair is Britain? An assessment of how well public authorities protect human rights* (2012) 260-261 available at http://www.equalityhumanrights.com/uploaded_files/humanrights/ehrc_hrr_full.pdf accessed on 13 March 2012.

where public authorities can improve the way they protect fundamental rights.[46] These include the protection of the right to privacy.

There is clearly a need for change especially after the signing of the Lisbon Treaty[47] which accorded legal status to the CFR.[48] The report notes that '…the long running debate about the effectiveness of the HRA, lack of leadership and insufficient guidance about human rights has encouraged uncertainty and criticism about the remit of the Act. This led first the Labour Government, and now the Coalition Government, to consider whether it should be replaced by a Bill of Rights.'[49] Because of problems with the implementation of the HRA, in March 2011 the government established a Commission on a Bill of Rights to investigate the creation of a UK Bill of Rights.[50] The Commission is expected to report by the end of 2012.

(ii) Genetic Research Databases

The UK has received much media and academic attention as a result of its development of a population-based biobank.[51] The UK Biobank is a large prospective research resource aimed at facilitating an understanding of the interaction between genetic, environmental, and lifestyle factors in the development of various diseases.[52] It accordingly set out to collect lifestyle and environmental information, medical history, physical measurements, and biological samples from about 500 000 people aged 40-69. The target number of volunteers has since been met.[53] The health of participants will be monitored over a long period by accessing their medical and health records with their consent. Biological samples will be stored for future use in biochemical and genetic analyses. It is intended that this biobank resource will facilitate research which can aid in disease prevention, diagnosis, and treatment. An Ethics and Governance Framework (EGF) has been put in place and continued funding of the project is conditional upon compliance

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46 Ibid Executive Summary 9-23 available at http://www.equalityhumanrights.com/uploaded_files/humanrights/hrr2012_executive_summary.pdf accessed on 13 March 2012.

47 Supra note 12.

48 Supra note 10.

49 Supra note 45 at 18.

50 Ibid.

51 See http://www.ukbiobank.ac.uk/ accessed on 15 March 2012.

52 UK Biobank Protocol available at http://www.ukbiobank.ac.uk/wp-content/uploads/2011/11/UK-Biobank-Protocol.pdf accessed on 15 March 2012.

53 See http://www.ukbiobank.ac.uk/2011/11/following-health/ accessed on 15 March 2012.

with this framework.[54] The EGF operates as a core reference document against which all policies and activities of the UK Biobank are judged. An Ethics and Governance Council (EGC) has also been established. This is an independent body that advises the UK Biobank on the revision of the EGF, monitors and reports publicly on compliance with the EGF, and advises generally on the interests of research participants and the general public.[55]

The UK Biobank is not governed by specific legislation but is subject to the existing legislative framework consisting of the Human Tissue Act,[56] and the Data Protection Act.[57] In 2000 the House of Lords' Science and Technology Committee launched an inquiry into the factual position of non-forensic human genetic databases in the UK. The aims of the inquiry were to:

> '(a) investigate how issues of privacy, ownership, distribution and anonymisation of individuals' genetic and related health information were dealt with in relation to currently available and planned use of human genetic databases;
> (b) take stock of developments which might be expected not only in genetic and database technologies but also in knowledge about genetics and gene function – together with their consequences for medical practice; and
> (c) report, drawing attention to the areas where current practice and regulation seemed likely to need development, taking into account the opportunities and the challenges of changing technology and knowledge.'[58]

The committee concluded that the Data Protection Act[59] adequately protects information contained in genetic databases and there is therefore no need for a new regulatory framework.[60] As discussed below, it is debatable whether this conclusion is still valid.[61] Gibbons notes that 'no purpose-designed legal framework or dedicated legal instrument applies to genetic databases in the UK.'[62] It appears that the committee's conclusion has not settled the issue. A report commissioned by the Wellcome Trust and the EGC on public attitudes towards access to data contained in the UK Biobank reveals uncertainty about the adequacy of the DPA in relation to

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54 UK Biobank Ethics and Governance Framework available at http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf accessed on 15 March 2012.

55 See http://www.egcukbiobank.org.uk/ accessed on 15 March 2012.

56 2004 c. 30.

57 1998 c. 29.

58 House of Lords Select Committee on Science and Technology Fourth Report *'Human Genetic Databases: Challenges and Opportunities'* (2001) para 2.10, available at http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/57/5701.htm accessed on 11 November 2011.

59 1998 (c. 29).

60 Supra note 58 para 3.17.

61 At 182.

62 Susan MC Gibbons 'Are UK genetic databases governed adequately? A comparative legal analysis' (2007) 27:2 *Legal Studies* 312 at 318.

biobanks.[63] The first observation is that since the DPA applies only to data of living individuals it will obviously not apply to data of biobank participants after their death. This is a major concern in the genetic arena because indiscriminate disclosure of data of deceased participants can have adverse consequences for surviving biological relatives who share the genetic characteristics of deceased relatives. The second observation is that since the DPA applies to identifiable data it will not apply to biobank data which is usually de-identified before being passed on to researchers. The ensuing research would therefore not be covered by the DPA. These are clearly concerns which must be addressed. Based on these observations, the conclusions reached by the House of Lords' Science and Technology Committee[64] need to be revisited.

Genetic database governance strategies in the UK have been aptly summed up as 'piecemeal, pragmatic, and largely reactive.'[65] Gibbons observes that '[t]he UK patchwork, with its lack of any specific, formal legislative framework and reliance on general-purpose instruments and informal techniques, suffers from several significant shortcomings.'[66] She identifies the key problems as 'inconsistent legal standards, ambiguities, disadvantages associated with informality and gaps.'[67] These are the very same problems that have been identified in the discussion above. There is clearly scope for intervention and reform.

(b) Genetic discrimination

(i) Insurance

The UK has a universal health care system so the threat of genetic discrimination in health insurance is not significant for a discussion on discrimination. This, together with the fact that life insurance is required for mortgages, has confined the debate surrounding genetics and insurance to life insurance. No formal prohibition on the use of genetic information by insurers exists in the United Kingdom. Instead, a system of voluntary regulation is in place. In 1997 the

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63 The University of York Science and Technology Studies Unit (Final Report) *Public attitudes to third party access and benefit sharing: their application to UK Biobank* (30 June 2008) at 58.

64 Supra note 58 .

65 Gibbons op cit 62 at 316.

66 Ibid 319-320.

67 Ibid.

Association of British Insurers (ABI) issued a policy statement on the use of genetic test results for underwriting purposes. The statement indicated that applicants would not be requested to undergo genetic testing when applying for life insurance. Insurers agreed not to use genetic test results for life insurance policies below £100,000. It has been pointed out that this action was prompted by a perceived threat of statutory regulation.[68] In 1999 the ABI introduced a Code of Practice [69] which governs the use of predictive genetic test results by its members. Compliance with the code is mandatory for all members of the ABI. The code has been revised in order to keep up with developments in the field of genetic testing and its impact on the insurance industry. In 2001 the government and the ABI agreed on a five-year moratorium on the use of predictive genetic tests in insurance underwriting. This moratorium has since been extended a few times. The latest extension was announced in 2011 and is valid until 2017.[70]

Currently the moratorium applies to life insurance policies valued under £500,000; critical illness policies under £300,000; and income protection policies which pay annual benefits under £30,000. Insurers may not request results of genetic tests that are done for research purposes.[71] Furthermore, only results of those tests which have been approved by the Genetics and Insurance Committee (GAIC) may be considered in the underwriting of policies which are not subject to the moratorium. The only test which has been approved for use by insurers thus far is the test for Huntington's Disease. The GAIC was disbanded in 2009[72] and its oversight function was transferred to the Human Genetics Commission's Monitoring Group on Genetics and Insurance.[73] This function entails monitoring compliance with the Code and the Concordat as well as identifying developments which may have implications for the use of predictive genetic test results by insurers.[74]

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[68] Julia Black 'Regulation as facilitation: Negotiating the genetic revolution' (1998) 61:5 *Modern Law Review* 621 at 638.

[69] Association of British Insurers Code of Practice for Genetic Tests (2008) available at http://www.abi.org.uk/consumer2/disclosure.htm accessed on 19 October 2011.

[70] ABI News Release 'Insurance Genetics Moratorium extended to 2017' (5 April 2011) available at http://www.abi.org.uk/Media/Releases/2011/04/Insurance_Genetics_Moratorium_extended_to_2017.aspx accessed on 15 March 2012.

[71] Ibid clause 16(iii).

[72] See http://www.dh.gov.uk/ab/Archive/GAIC/index.htm accessed on 15 March 2012.

[73] See http://www.hgc.gov.uk/Client/Content.asp?ContentId=856 accessed on 15 March 2012.

[74] Ibid.

In 2005 a Concordat and Moratorium between the government and the ABI was introduced[75] to address the concern that patients might be deterred from taking predictive genetic tests due to the fear that the results may be used by insurers to discriminate against them. It creates a policy framework for cooperation that provides for the fair and transparent use of genetic information by insurers.[76] It applies to predictive genetic tests only and is restricted to life, critical illness, and income protection insurance.[77] The agreement is, however, a statement of intent only and not legally binding.

Even though the system of voluntary regulation is working well, it is merely a temporary solution.[78] It serves the purpose of giving the government and the insurance industry time to reflect on the matter before taking permanent steps. The main disadvantage of the system is that it lacks certainty. The obvious question to be asked is what will happen when the moratorium ends. A specific concern relates to the possible retrospective use of genetic test results.[79] In response to this concern, the House of Lords' Science and Technology Committee recommended that the government should negotiate with the ABI for the inclusion of a new clause in the ABI Code of Practice and Concordat to prevent insurers from requesting results of genetic tests which were taken during the moratorium period. Another point to note is that the ABI is only a trade association and membership thereof is not compulsory. Those insurers who are not members of the ABI are therefore not bound by the ABI Code of Practice or by the Concordat and Moratorium, thus creating a gap in protection for consumers. It is clear that the matter is far from settled and the government of the UK needs to address public concerns in a more certain and binding manner.

(ii) Employment

There is no specific statute prohibiting genetic discrimination in employment in the UK even though Article 21 of the CFR prohibits discrimination on the basis of genetic features. As briefly

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75 Concordat and Moratorium on Genetics and Insurance (2005) available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4106050.pdf accessed on 19 October 2011.

76 Ibid clause 2.

77 Ibid clause 18(ii).

78 House of Lords Science and Technology Committee Second Report *Genomic Medicine* (2009) paras 6.44 and 6.46 available at http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf accessed on 19 October 2011.

79 Ibid para 6.44.

mentioned above[80] and discussed further below[81] it is uncertain whether such a prohibition will be directly enforceable in the UK due to the opt-out Protocol in the Lisbon Treaty[82] which provides that the CFR will not create additional enforceable rights over and above those already provided for in UK national legislation. In February 2005 the government launched the Discrimination Law Review with the aim of developing a more streamlined legislative framework for dealing with discrimination. At that stage much of the protective mechanisms were scattered amongst various pieces of legislation.[83]

As a result of the Discrimination Law Review, the government developed proposals for a Single Equality Act which would consolidate the individual pieces of legislation and update the provisions where necessary. The government then invited public comment on the proposals. The HGC commented specifically with regard to genetic discrimination. The HGC maintained their view[84] that genetic discrimination should be dealt with separately from disability discrimination. The government agreed and stated that '[p]eople with a pre-symptomatic genetic predisposition do not have a mental or physical impairment which affects their normal day-to-day activities, and there is no certainty that they will go on to develop a health problem. Extending disability discrimination protection to cover people who are not disabled would change the very nature of disability discrimination law and risk being seen as a dilution of disabled people's rights.'[85] The view of the HGC was that the Single Equality Act provided 'a clear opportunity to resolve the dilemma by treating genetic discrimination under a separate heading.'[86] This point has merit since the Equality Act deals with various grounds of discrimination and it would have been able to accommodate discrimination on the basis of genetic characteristics.

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80 At 157.

81 At 176.

82 Supra note 14.

83 Equal Pay Act 1970 c. 41; Sex Discrimination Act 1975 c. 65; Race Relations Act 1976 c. 74; Disability Discrimination Act 1995 c. 50 ; Employment Equality (Religion or Belief) Regulations 2003 No. 2520; Employment Equality (Sexual Orientation) Regulations 2003 No. 2519; Employment Equality (Age) Regulations 2006 No. 1031; Equality Act 2006 c.3; Equality Act (Sexual Orientation) Regulations 2007 No. 1263.

84 Supra note 2 para 6.31.

85 Department of Communities and Local Government Discrimination Law Review Consultation *A Framework for Fairness: Proposals for a Singe Equality Bill for Great Britain* (June 2007) available at http://www.communities.gov.uk/publications/communities/frameworkforfairnessconsultation accessed on 25 October 2011.

86 Human Genetics Commission Response to the Discrimination Law Review Consultation *A Framework for Fairness: Proposals for a Single Equality Bill for Great Britain* (14 September 2007) at 4, available at http://www.hgc.gov.uk/Client/document.asp?DocId=134&CAtegoryId=4 accessed on 25 October 2011.

Unfortunately the government did not agree that there was a need to legislate against genetic discrimination due to insufficient evidence of such discrimination in the UK.[87] The UK government was of the view that genetic discrimination could be addressed by non-legislative means such as moratoria and industry codes.[88] It is interesting to note the response of the HGC to these arguments. First, the HGC pointed out that there was evidence of genetic discrimination although such evidence has not been collected systematically.[89] Secondly, the HGC pointed out that only legislation may be able to provide individuals with the reassurance required in the insurance context.[90]

The Equality Act[91] was passed in April 2010. It has consolidated various pieces of anti-discrimination legislation, including the Disability Discrimination Act,[92] into a single Act. It prohibits direct and indirect discrimination on the basis of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.[93] These are referred to in the Act as 'protected characteristics'. The Act does not refer to genetic discrimination either under the disability provisions or on its own. It is not yet clear how the Equality Act is going to be used to prevent genetic discrimination in the employment setting. A job applicant may be able to resist disclosure of genetic information since section 60 limits the questions that may be asked regarding health status in the pre-employment situation. An employee may only be asked health-related questions which will assist the employer in determining whether 'reasonable adjustments' need to be made to accommodate the employee in the work environment or to assist the employee in performing his or her job. It is possible that job applicants and employees can rely on such provisions to keep their genetic information confidential.

The Information Commissioner issued the Employment Practices Data Protection Code[94] under s 51 of the Data Protection Act 1998. The aim of the Code is to assist employers in complying with the Data Protection Act and to promote good practice by employers. The Code

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87 Supra note 85 para 8.29.
88 Ibid para 8.31.
89 Supra note 55 at 3.
90 Ibid 5.
91 2010 c. 15.
92 1995 c.50. This Act still applies in Northern Ireland.
93 Supra note 91, s 4.
94 Available at http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/employment_practices_code.pdf accessed on 26 October 2011.

does not impose new legal obligations. It applies to job applicants, employees, agency staff, casual staff, and contract staff. The Code covers inter alia the use of genetic testing in employment. Employers are advised not to request workers to undergo genetic testing or to disclose results of previous genetic tests. Good Practice Recommendations relating to genetic information are set out in Part 4 of the Code, which provides as follows:

(i) 'Do not use genetic testing in an effort to obtain information that is predictive of a worker's future general health.
(ii) Do not insist that a worker discloses the results of a previous genetic test.
(iii) Only use genetic testing to obtain information where it is clear that a worker with a particular, detectable genetic condition is likely to pose a serious safety risk to others or where it is known that a specific working environment or practice might pose specific risks to workers with particular genetic variations.
(iv) If a genetic test is used to obtain information for employment purposes ensure that it is valid and is subject to assured levels of accuracy and reliability.'[95]

It is important to bear in mind that the Code applies to the processing of data in terms of the Data Protection Act, 1998. 'Processing' includes the initial obtaining of personal information, the retention and use of it, access and disclosure, and final disposal.[96] Employers generally may be able to access information in two ways: they may seek access to the results of previous genetic tests or they may require employees to undergo genetic testing as a condition of employment. The Code would be applicable in the second scenario. It provides guidance to employers on how to 'process' genetic information without breaching the provisions of the Data Protection Act. The aims of the Code are laudable but it does nothing more than reiterate the intentions of the Data Protection Act. The recommendations relating to the processing of genetic information merely ensure compliance with the requirements of the Data Protection Act insofar as it relates to the processing of sensitive information. There is clearly a need for an alternative option to effectively deal with situations where employers may try other avenues to access genetic information of employees. Unfortunately, in 2009 the House of Lords' Science and Technology Committee indicated that it did not consider it necessary to legislate against genetic discrimination in employment due to insufficient evidence of genetic discrimination.[97]

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95 Supra note 94, s 4.5.
96 Supra note 94 at 7.
97 Supra note 78 para 6.3.9.

(iii) Genetic research

There are various statutes, conventions, and directives which govern and regulate medical research in the UK. These include the Data Protection Act 1998,[98] National Health Service Act 2006,[99] Human Tissue Act 2004,[100] Mental Capacity Act 2005,[101] Health Service (Control of Patient Information) Regulations 2002,[102] Medicines for Human Use (Clinical Trials) Regulations 2004,[103] European Union Clinical Trials Directive,[104] Council of Europe Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data,[105] European Convention on Human Rights,[106] and Research Governance Framework for Health and Social Care 2005.[107] Research governance is recognised as one of the core standards of health care in the UK.[108]

All research in the National Health Service (NHS) which involves human participants must be reviewed and approved by an ethics committee. Various bodies are involved in ethics review. The nature of the research determines which body will conduct the review. There are NHS Research Ethics Committees, a Social Care Research Ethics Committee, independent ethics committees which review phase I clinical trials of medicines that are conducted outside of the NHS, a Gene Therapy Advisory Committee which reviews research on gene and stem cell therapies, the Ministry of Defence Research Ethics Committee which reviews studies involving their personnel, and University ethics committees.[109]

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98 Supra note 59.
99 2006 c. 41.
100 2004 c. 30.
101 2005 c. 9.
102 2002 No. 1438.
103 2004 No. 1031.
104 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use.
105 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.
106 Supra note 8.
107 Department of Health *Research Governance Framework for Health and Social Care* 2ed. (2005) available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 accessed on 24 April 2012.
108 Department of Health *Standards for Better Health* (21 July 2004) available at http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4132991.pdf accessed on 9 November 2011.
109 Academy of Medical Sciences *A New Pathway for the Rregulation and Governance of Health Research* (2011) available at http://www.acmedsci.ac.uk/index.php?pid=99&puid=209 accessed on 24 February 2012.

The EU Clinical Trials Directive[110] aims to harmonise the rules governing clinical trials with human participants involving medicinal products. Member States were required to adopt the necessary regulations and administrative provisions for purposes of compliance with the Directive before 1 May 2003 and to implement these before 1 May 2004.[111] In the UK the directive was accordingly transposed into law by the Medicines for Human Use (Clinical Trials) Regulations 2004.[112] The directive obliges Member States to establish and operate research ethics committees. It provides further that no clinical research involving investigational medicinal products may commence without a favourable opinion from a research ethics committee.[113] The incorporation of this requirement in the Medicines for Human Use (Clinical Trials) Regulations 2004 makes it legally binding.

Research Ethics Committees no longer operate under separate policies in the four countries which make up the UK. A harmonised edition of the policy on Governance Arrangements for Research Ethics Committees has been issued by the Department of Health and came into effect on 1 September 2011.[114] The position throughout the UK has been harmonised via this policy. The Research Governance Framework for Health and Social Care[115] contains general principles of good practice aimed at improving the quality of research in the UK. It applies to all research that falls within the jurisdiction of the Secretary of State for Health. It sets out the responsibilities of the various roleplayers in research.

There are concerns that the regulatory and governance framework is too complex and cumbersome which has the effect of hampering rather than promoting research in the UK.[116] As a result, in March 2010 the Department of Health (DOH) decided to review the regulation and governance of medical research in the UK. This was prompted by an earlier publication by the Academy of Medical Sciences (AMS) which drew attention to the need for such a review.[117] The government commissioned the Academy of Medical Sciences to conduct such an independent

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110 Supra note 104.
111 Ibid Article 22.
112 Supra note 103.
113 Ibid Article 9.
114 Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474 accessed on 24 February 2012.
115 Department of Health (2005) 2ed. *Research Governance Framework for Health and Social Care.*
116 Supra note 109 at 81; supra note 78 at 26-27.
117 Academy of Medical Sciences *Reaping the Rewards: a vision for UK medical science* (2010) available at http://www.acmedsci.ac.uk/index.php?pid=99&puid=172 accessed on 1 November 2011.

review with a focus on research involving human participants, their tissue, and data. The aims of the review were to:

> '1. Review the regulatory and governance environment for medical research in the United Kingdom, with a particular focus on clinical trials.
> 2. Identify key problems and their causes, including unnecessary process steps, delays, barriers, costs, complexity, reporting requirements and data collection.
> 3. Make recommendations with respect to the regulatory and governance framework that will: increase the speed of decision-making; reduce complexity; and eliminate unnecessary bureaucracy and costs.'[118]

The AMS released its report in January 2011.[119] The report contains a number of recommendations aimed at streamlining the current system so as to enhance efficiency, reduce complexity, and eliminate unnecessary bureaucracy. The recommendations include the urgent establishment of a new independent Health Research Agency as a single regulator of health research. It is envisaged that the Health Research Agency would work with all countries in the UK to develop an integrated system for the whole of the UK.[120] The report also notes that a few of the submissions received highlighted the importance of specialist expertise on research ethics committees. Reference was made to the existing specialist research ethics committees and the suggestion was put forward that this system should be extended to other areas which would benefit from specialist expertise. It is encouraging to note that specific mention is made of genomics as an area in which developments need to be monitored so as to decide if and when a specialist research ethics committee may need to be established to review genomic research proposals.[121] This is a practical and reasonable approach.

(c) Privacy

As mentioned above,[122] there is no formal constitutional right to privacy in the UK. There is no separate action for invasion of privacy either.[123] Claims based on invasions of privacy have been dealt with under the umbrella of breach of confidence which requires the existence of a prior

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[118] Academy of Medical Sciences First Call for Evidence *Review of the Regulation and Governance of Medical Research* (2010) at 1, available at http://www.acmedsci.ac.uk/p47prid88.html accessed on 24 February 2012.
[119] *A New Pathway for the Regulation and Governance of Medical Research* available at http://www.acmedsci.ac.uk/download.php?file=/images/project/130734957423.pdf accessed on 15 March 2012.
[120] Supra note 109 at 85.
[121] Ibid 78.
[122] At 158.
[123] *Wainwright v Home Office* [2003] 3 WLR 1137; *Campbell v MGN Limited* [2004] UKHL 22.

agreement or relationship of confidence between the parties to an action. Invasions of privacy, however, do not necessarily arise out of confidential relationships or agreements. This makes it impossible to use the breach of confidence action in cases based on invasions of privacy where no prior relationship of confidence can be established. In *Campbell v MGN Limited*[124] Lord Nicholls observed that the requirement of a confidential relationship had been found to be irrelevant by the UK courts in the case of *Attorney-General v Guardian Newspapers Ltd (No 2)*[125] and that this position had been accepted by the European Court of Human Rights in the case of *Earl Spencer v United Kingdom.*[126] According to Lord Nicholls, the newly stated principle which no longer includes a requirement of a prior confidential relationship is firmly established in the UK.[127]

Phillipson is not convinced that the new position as described by Lord Nicholls is being correctly implemented by the courts.[128] He uses the case of *A v B plc*[129] to illustrate this and concludes that '…while the court in *A* v *B plc* appeared to sweep away the requirement of an obligation of confidentiality based on a pre-existing relationship, or agreement of confidentiality, the reasoning employed to resolve the actual case in front of it displayed a continuing attachment to just such notions.'[130] In analysing similar decisions he observes that '[w]hile the decisions ...open up the potential for the transformation of confidence by the values of privacy, in many cases the actual decisions made are…rooted firmly not in such values, but in very traditional common law principles.'[131] As a possible solution Phillipson notes that if an obligation of confidentiality could be imposed on the basis of the private nature of information and not on the nature of the relationship, there would be room for claims of invasion of privacy within the action for breach of confidence.[132]

Unfortunately the courts still appear to be forcing actions for invasion of privacy into the mould of the breach of confidence action. As noted by Lord Phillips in the *Douglas* appeal case, '[t]he Government has made it clear that it does not intend to introduce legislation in relation to

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124 [2004] UKHL 22 para 48.
125 [1990] 1 AC 109.
126 (1998) 25 EHRR CD 105.
127 Supra note 124.
128 Gavin Phillipson 'Transforming Breach of Confidence? Towards a Common Law Right of Privacy under the Human Rights Act' (2003) 66:5 *The Modern Law Review* 726.
129 [2002] 3 WLR 542.
130 Phillipson op cit note 128 at 748.
131 Ibid.
132 Ibid 744.

this area of the law, but anticipates that the judges will develop the law appropriately, having regard to the requirements of the convention…The courts have not accepted this role with whole-hearted enthusiasm.'[133] Phillipson similarly notes a 'deep ambivalence towards the reception of privacy into English law.'[134] It can only be concluded that the common law action for breach of confidence is not suited to dealing with privacy and that attempts to do so thus far have been unsatisfactory. The position regarding the protection of the right to privacy is complicated further in the light of the Human Rights Act[135] as discussed below.[136] One overarching positive aspect of the UK position as noted by Lord Nicholls in the case of *Campbell v MGN Limited*[137] is that the 'protection of various aspects of privacy is a fast developing area of the law…' This bodes well for the protection of genetic privacy and for privacy in general.

The law in the UK respects medical confidentiality. The importance of medical privacy within the European Union was clearly stated in the case of *Z* v *Finland.*[138] The court stated that 'Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general.'[139] In *Campbell* Lord Nicholls acknowledged the privacy interest attached to medical data including data which is not strictly in the form of medical records.[140] In this particular case the medical data related to drug addiction for which Naomi Campbell, an internationally known fashion model, was receiving therapy. In an earlier judgment the Court of Appeal did not consider the information to be in the category of medical records[141] but the House of Lords found otherwise. The judgment of the House of Lords is progressive and indicates a willingness to depart from rigid applications of the law in the interest of advancing medical privacy. Phillipson highlights the degree of importance to be attached to medical data by pointing out that it is considered to be sensitive personal data for the purposes of data

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133 *Michael Douglas, Catherine Zeta-Jones, Northern & Shell Plc AND Hello Limited, Hola S.A., Eduardo Sanchez Junco* [2005] EWCA Civ 595 para 46.
134 Phillipson op cit note 128 at 748.
135 1998 c. 42.
136 At 178.
137 [2004] UKHL 22 para 11.
138 (1997) 25 EHRR 371 para 95.
139 Ibid.
140 Supra note 124 paras 144 -147.
141 [2003] QB 633 CA.

protection in the UK.[142] That being the case, Phillipson rightly criticises the reasoning of the Court of Appeal[143] and concludes that 'For the Court thus to find that information that would be treated as of an especially private nature under a European Directive, and the Act of Parliament implementing it, is too trivial to merit protection at common law, seems incongruous, to say the very least.'[144]

The rapidly advancing field of privacy law in the UK, coupled with the progressive attitude of the House of Lords towards the protection of medical data, is very encouraging. Claims for the protection of genetic data and genetic information privacy are likely to be thoroughly investigated by the courts if and when they are called upon to deal with the issue. The system is not so rigid as to automatically preclude the recognition of genetic privacy in the absence of specific statutory intervention. The various instruments which play a role in privacy protection are discussed below.

(1) European Convention on Human Rights[145]

The European Convention on Human Rights (ECHR), which was ratified by the UK in 1951, recognises privacy as a fundamental human right. Article 8 of the ECHR provides as follows:

> '1. Everyone has the right to respect for his private and family life, his home and his correspondence.
> 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 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.'

In view of the wording of Article 8(2), there has been much debate about whether the convention requires member states to apply Article 8 horizontally. Lord Phillips, in the *Douglas* appeal case, pointed out that the matter had been settled by the European Court of Human Rights in the case of *Von Hannover v Germany.*[146] In *Von Hannover* the European Court of Human Rights had stated that:

> '… although the object of Article 8 is essentially that of protecting the individual against arbitrary interference by the public authorities, it does not merely compel the State to abstain from such interference: in addition to this primarily negative undertaking, there may be positive obligations

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142 Phillipson op cit note 128 at 735.
143 Supra note 141.
144 Ibid.
145 Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms (1950) available at http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=005&CM=8&DF=07/10/2011&CL=ENG accessed on 7 October 2011.
146 Application No. 59320/00 [2004] ECHR 294 (24 June 2004) para 57.

> inherent in an effective respect for private or family life. These obligations may involve the adoption of measures designed to secure respect for private life even in the sphere of the relations of individuals between themselves…'[147]

Based on the above statement, the court in the *Douglas* appeal case was convinced that States are obliged to protect the right to private life against invasion by individuals as well.[148]

(2) Charter of Fundamental Rights of the European Union[149]

The Charter of Fundamental Rights (CFR), which was signed and proclaimed in December 2000, acquired legal status via the Lisbon Treaty[150] which entered into force in December 2009. Article 7 of the CFR provides that 'Everyone has the right to respect for his or her private and family life, home and communications.' Article 8 provides for the protection of personal data. It states as follows:

> '1. Everyone has the right to the protection of personal data concerning him or her.
> 2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
> 3. Compliance with these rules shall be subject to control by an independent authority.'

Article 21 of the CFR prohibits inter alia discrimination based on genetic features. The CFR is more comprehensive than the ECHR. In addition to civil and political rights covered by the ECHR, the CFR also covers economic, social, cultural, and third generation rights. It also deals with modern-day issues such as data protection. The wider reaching and more encompassing nature of the CFR may be attributed to the fact that the CFR was drafted relatively recently as compared to the ECHR which was drafted in 1950. The CFR is accordingly a more current document. Two points must be noted insofar as the application of the CFR to the UK is concerned. First, the Charter only applies to Member States when Member States act within the scope of EU law.[151] Secondly, the status of the CFR in the UK is unclear due to an 'opt-out' Protocol[152] included in the Lisbon Treaty. The Protocol provides as follows:

> '*Article 1*
> 1. The Charter does not extend the ability of the Court of Justice of the European Union, or any court or tribunal of Poland or of the United Kingdom, to find that the laws, regulations or

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147 Ibid.
148 Supra note 133 para 49.
149 Supra note 10.
150 Supra note 12.
151 Supra note 10 Article 51.
152 Supra note 12. Protocol 7 on the application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom.

administrative provisions, practices or action of Poland or of the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that it reaffirms.

2. In particular, and for the avoidance of doubt, nothing in Title IV of the Charter creates justiciable rights applicable to Poland or the United Kingdom except in so far as Poland or the United Kingdom has provided for such rights in its national law.

Article 2

To the extent that a provision of the Charter refers to national laws and practices, it shall only apply to Poland or the United Kingdom to the extent that the rights or principles that it contains are recognised in the law or practices of Poland or of the United Kingdom.'

The Protocol has been and continues to be the subject of much debate.[153] The controversy relates to the effect of the Protocol on the application of the CFR to the UK. The question is whether the Protocol is an opt-out provision or merely a clarification of the Lisbon Treaty insofar as the application of the CFR is concerned.[154] This question has yet to be answered. It is likely that such answer will only come from the courts in litigation involving the relevant provisions.

(3) The European Union Data Protection Directive[155]

The aim of the Directive is to protect the right to privacy in the processing of personal data whilst promoting the free flow of information within the European Union (EU).[156] The Directive is binding on member States.[157] Implementation of the Directive by member States is intended to harmonise their relevant laws, thereby facilitating the cross-border flow of data within the EU. The Directive also prohibits the transfer of data to countries outside the EU which do not provide an adequate level of protection.[158] Provision is made for a prohibition on processing of sensitive data which includes personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.[159] This is not, however, an unqualified prohibition. The Directive authorises Member States to derogate from the prohibition when it is in the public interest to do so in areas such as public health, social protection, scientific research, and government statistics. In doing so, member States are obliged to provide adequate safeguards for the protection of the fundamental rights and the privacy of individuals.[160]

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153 Supra note 13 at 258.
154 Ibid.
155 Supra note 3.
156 Ibid Article 1.
157 Ibid Article 32.
158 Ibid Preamble, clause 57.
159 Ibid Article 8.
160 Ibid Preamble, clause 34.

The Directive has recently come under scrutiny in the UK. The adequacy of the Directive in the light of technological and other advancements has been questioned. It has been observed by the Information Commissioner's Office that: '[t]here is a growing feeling that the EU Directive on data protection is becoming increasingly outdated and is more bureaucratic and burdensome than it needs to be.'[161] Based on this observation the Information Commissioner commissioned a review of EU data protection law in 2008. A report was issued in 2009 indicating inter alia the strengths and weaknesses of the Directive.[162] The report concludes that the Directive serves as a good foundation for data protection in the EU but that it needs to be updated. The overall conclusion is stated as follows:

> 'Overall, we found that as we move toward a globally networked society, the Directive as it stands will not suffice in the long term. While the widely applauded principles of the Directive will remain as a useful front-end, they will need to be supported by a harms-based back-end in order to cope with the growing challenge of globalisation and international data flows. However, it was also widely recognised that more value can still be extracted from current arrangements. A lot can be achieved by better implementation of the current rules, for instance by establishing consensus over the interpretation of several key concepts and a possible shift in emphasis in the interpretation of others. Abandoning the Directive as it currently stands is widely (although not unanimously) seen as the worst option, as it has served, and continues to serve, as a stimulus to taking data protection seriously.'[163]

The conclusion made in the report is understandable in view of the fact that the Directive came into force as long ago as 1995. In the fast-paced science and technology arena this is a long period of time and it explains why the Directive may now be considered to be outdated.

The European Commission also launched a review of the current data protection legal framework in May 2009. This review was in keeping with the Commission's main policy objectives which have been stated as follows:

> '1. Modernise the EU legal system for the protection of personal data, in particular to meet the challenges resulting from globalisation and the use of new technologies.
> 2. Strengthen individuals' rights, and at the same time reduce administrative formalities to ensure a free flow of personal data within the EU and beyond.

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[161] Iain Bourne, Head of Data Protection Projects at the ICO (14 April 2008) available at http://www.ico.gov.uk/upload/documents/pressreleases/2008/invitation_to_tender_1404081.pdf accessed on 5 October 2011.

[162] Neil Robinson, Hans Graux, Maarten Botterman, Lorenzo Valeri *Review of the European Data Protection Directive* (May 2009) at viii available at http://www.ico.gov.uk/~/media/documents/library/Data_Protection/Detailed_specialist_guides/REVIEW_OF_EU_DP_DIRECTIVE.ashx accessed on 5 October 2011.

[163] Ibid vii.

3. Improve the clarity and coherence of the EU rules for personal data protection and achieve a consistent and effective implementation and application of the fundamental right to the protection of personal data in all areas of the Union's activities.'[164]

The review entailed inter alia a comparative study on different approaches to new privacy challenges in the light of technological developments.[165] The aim of the review was to consider whether the legal framework of the Directive is still adequate and if not, whether amendments should be considered. This would serve as a basis for discussions with other EU institutions as well as the development of legislative and non-legislative data protection measures.[166] The review concluded that the core principles of the Directive are still relevant and necessary. A few areas were identified as being in need of development or reform. For the purposes of the protection of genetic information, it is important to note the finding that the provision on sensitive data needs to be reconsidered 'in the light of technological and other societal developments.'[167] It is indicated that the category of sensitive data may have to be expanded to include genetic data. If that happens, the necessary conditions for the processing of genetic data, as a subcategory of sensitive data, will have to be developed.[168] Another issue which the Commission intends to revisit is that of making sanctions and remedies more effective.[169] This includes considering imposing criminal sanctions in cases of serious data protection violations.

(*4) Human Rights Act*[170]

The Human Rights Act came into effect on 2 October 2000. It incorporated most of the rights of the ECHR into domestic law. A qualified right to privacy is included in the Act as follows.

'1 Everyone has the right to respect for his private and family life, his home and his correspondence.

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 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.'[171]

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164 Available at http://ec.europa.eu/cgi-bin/etal.pl accessed on 11 October 2011.

165 Comparative Study on Different Approaches to New Privacy Challenges in the Light of Technological Developments (20 January 2010) available at http://ec.europa.eu/justice/policies/privacy/docs/studies/new_privacy_challenges/final_report_working_paper_2_en.pdf accessed on 5 October 2011.

166 Ibid Item 3 at 18-19.

167 Ibid Item 2.1.6 at 9.

168 Ibid Item 2.1.6 at 9.

169 Ibid Item 2.1.7.

170 Supra note 135.

171 Ibid Schedule 1, Article 8.

Section 6 provides that the Act applies only to public authorities performing public acts. In view of this provision it is not clear whether the Act can be applied horizontally or not. This aspect of the Act has come under scrutiny by the courts[172] and by academics.[173] Phillipson observes that the courts appear to have settled on an indirect horizontal effect according to which courts must apply the ECHR in private law cases involving existing causes of action.[174]

(5) Data Protection Act[175]

The main piece of legislation dealing with the protection of personal information in the United Kingdom is the Data Protection Act, which was passed in July 1998 and came into force on 1 March 2000. This Act implements the European Union Data Protection Directive.[176] It creates eight data protection principles which aim to ensure that personal data is processed fairly, lawfully and with due respect for the rights of data subjects. [177]

The Act also created the office of the Information Commissioner[178] who is responsible inter alia for promoting good practice in the handling of personal data and for enforcing compliance with the Act. Section 2(e) of the Data Protection Act provides for medical information to be treated as sensitive personal data. Schedule 3 provides special conditions for the processing of sensitive personal data. According to the information commissioner these are over and above those conditions specified in schedule 2.[179] Further Schedule 3 conditions are set out in The Data Protection (Processing of Sensitive Personal Data) Order.[180] These conditions enhance the protection that is afforded by the Act to sensitive personal data. It may be concluded that if genetic information is to be classified as medical data in the UK, it will be treated as sensitive personal data and will benefit from the relevant provisions of the Data Protection Act. In

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172 *Glaser v UK* [2000] 3 FCR 193 Ect HR; *Venables and another v News Group Newspapers* [2001] 1 All ER 908; *Douglas and Zeta Jones and others v Hello!* [2001] QB 967.

173 Supra note 128 fn 31, 32 and 33.

174 Ibid 729.

175 Supra note 59.

176 European Parliament and Council Directive 95/46/EC 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 (1995) 38 L281*Official Journal of the European Communities* 31.

177 Ibid Schedule 1, Part 1.

178 Ibid s 6.

179 Information Commissioner 'Data Protection Act 1998 Legal Guidance' available at http://www.ico.gov.uk/~/media/documents/library/data_protection/detailed_specialist_guides/data_protection_act_legal_guidance.pdf accessed on 29 November 2011.

180 (2000) S.I. No. 417.

practice the Data Protection Act has proven to be a challenging piece of legislation. The courts have criticised the Act as being 'inelegant and cumbersome.'[181] It has also been referred to as 'a notoriously unwieldy and confusing piece of legislation.'[182] In addition to these criticisms the Act may be criticised for containing a large number of exemptions which serve only to dilute the protection expected from such an Act.[183]

(d) Privilege

In English law communications are not automatically protected by virtue of their confidentiality.[184] The consistent refusal to recognise a medical professional privilege on the basis of confidentiality is proof of this. This position can be traced back to the *Duchess of Kingston's case* in 1776[185] and continues to this day. It is thus apparent that any argument for the protection of genetic information from disclosure will meet the same fate if it is based on confidentiality. McHale notes that at first glance there may appear to be an inconsistency in the approach of the courts to medical information and other types of confidential information.[186] She observes, however, that those confidential communications which have received protection from disclosure have received it on the basis of public policy and not because of any inherent confidentiality.[187] This observation leads her to conclude that there is no inconsistency in the approach of the courts towards medical information and other confidential information.[188]

In the case of *D v National Society for the Prevention of Cruelty to Children*[189] the court adopted the stance that public interest did not require that confidentiality per se had to be protected. The court did accept that the protection of confidential information could be in the public interest. This would obviously depend on the circumstances of each case. Although there is no scope for the introduction of a medical privilege based on confidentiality, such information can be protected from disclosure if the courts find that it is in the public interest to do so. It is

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181 *Naomi Campbell v Mirror Group Newspapers* 2002 [EWCA] Civ. 1373 para 72.
182 The Academy of Medical Sciences *Personal Data for Public Good: using health information in medical research* (January 2006) at 22.
183 Supra note 59, schedule 7.
184 *Attorney-General v Clough* [1963] 1 QB 773.
185 (1776) 20 State Trials 355.
186 Jean V. McHale *Medical Confidentiality and Legal Privilege* (1993) 16-17.
187 Ibid.
188 Ibid.
189 [1978] AC 171.

equally possible that courts may find the protection of genetic information from disclosure to be in the public interest.

English courts have attempted to find a compromise between unqualified privilege and compulsory disclosure of confidential communications. This has resulted in a discretionary approach which 'accords to the judge a wide discretion to permit a witness, whether a party to the proceedings or not, to refuse to disclose information where disclosure would be a breach of some ethical or social value, and non-disclosure would be unlikely to result in serious injustice in the particular case in which it is claimed.'[190] As observed by Pereis '[t]he traditional view espoused by the courts in England has favoured an extensive judicial discretion which enables a case-by-case evaluation of the propriety of disclosure, in competition with the ethical or social value which is transgressed by reception of the evidence.'[191] In 1967 the Law Reform Committee of England considered the issue and declined to introduce a statutory medical privilege.[192] The discretionary approached was favoured for its ability to accommodate changing needs and priorities of the law. The committee took the view that there was no need for their intervention as the courts were handling the situation well enough.

The discretionary approach clearly has advantages and disadvantages. The main advantage is that it is flexible in allowing the courts to decide on a case-by-case basis whether certain communications should be privileged or not. It allows the courts to consider and weigh up the various interests that may be at stake. This is a useful approach when dealing with new technologies and scientific advances which have new public interest ramifications. The flexibility of this approach is also a disadvantage as it does not create certainty. It does not provide any guarantee as to the protection of confidential communications since there is no certainty as to how the discretion will be exercised. In an area as new as human genetics, lack of certainty can prove detrimental to the uptake of clinical genetic testing by patients as well as to the voluntary participation in genetic research. The benefits which were anticipated by the Human Genome Project and large-scale population studies such as the UK Biobank may be jeopardised if individuals do not have some assurance that they will not be compelled to disclose their genetic information in court. A statutory judicial discretion may therefore prove more

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[190] Law Reform Committee of England 16th Report (1967) Cmnd. 3472 para 1.

[191] GL Peiris 'Medical Professional Privilege in Commonwealth Law' (1984) 33:2 *International and Comparative Law Quarterly* 309.

[192] Supra note 190 paras 46-52.

suitable than the common-law judicial discretion since it creates more certainty and could provide the reassurance that is required in the area of genetic privacy protection. Since genetic privacy is a relatively new concept, a statutory judicial discretion may be accompanied by pertinent guiding principles which can assist judicial officers in exercising the discretion. This will promote uniformity and certainty

Since confidentiality has not been accepted as a basis for the introduction of a medical privilege, McHale investigates the introduction of a public policy exclusionary rule to protect the confidentiality of medical information.[193] She refers to a statement by Lord Hailsham in *D v National Society for the Prevention of Cruelty to Children*[194] to the effect that the categories of public interest are constantly changing due to changing social conditions. This statement holds promise for the protection of genetic privacy. It conveys a positive attitude insofar as developing sciences and technologies are concerned. In conclusion McHale states as follows:

> 'It is perhaps questionable whether the most satisfactory solution to the problem is to let the courts evolve the public-policy rule over time and hope that perhaps one day an enlightened judiciary may extend it to protect medical confidentiality. Even if the other judges were willing to follow Mann LJ's lead, it is doubtful if the public policy exclusionary rule is the best method of excluding medical information. It lacks the precise definition that a specific statutory defined privilege may provide. Any privilege should, I suggest, contain a considered response to the problem posed by the variable levels of confidentiality which exist in medical practice.'[195]

The concerns raised here by McHale have already been raised above in respect of judicial discretion. There is, however, no doubt that there is room for the protection of confidential genetic information from disclosure but the attitude of the courts towards such a claim has yet to be tested. There are four obvious options: common-law judicial discretion, statutory judicial discretion, public policy exclusionary rule, and a statutory genetic information privilege. The first three options have obvious flaws which may only be exacerbated by courts in the course of dealing with a new and rapidly advancing science. In order to promote certainty it is advisable to introduce a statutory genetic information privilege. This privilege may be a qualified one similar to the statutory journalistic privilege contained in section 10 of the Contempt of Court Act.[196]

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193 McHale op cit note 186.
194 Ibid 230.
195 Ibid 23.
196 1981 c. 49.

6.2.2 THE UNITED STATES OF AMERICA

In the United States of America (USA) most of the relevant legislation has been developed within an anti-discrimination paradigm. Individual States have adopted divergent approaches to the protection of genetic information with emphasis on preventing improper use of information. At federal level the relevant statutes are the Health Information Portability and Accountability Act 1996 (HIPAA);[197] the Americans with Disabilities Act 1990 (ADA);[198] and the Genetic Information Non-Discrimination Act 2008 (GINA).[199] The positions in the various states cannot be dealt with comprehensively within the parameters of this chapter. Due to this constraint as well as the fact that federal legislation provides a baseline level of protection, the federal position will receive attention in the discussion that follows.

GINA was signed into law on 21 May 2008. Its purpose is to 'establish a national and uniform basic standard that is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.'[200] In pursuance of this objective it prohibits genetic discrimination in health insurance and employment. It provides that the sections of the law relating to health coverage (Title I) would take effect twelve months after enactment[201] and the sections relating to employment (Title II) would take effect eighteen months after enactment.[202] GINA required regulations pertaining to both titles to be completed by May 2009. GINA defines genetic information as information about:

> 'an individual's genetic tests (including genetic tests done as part of a research study);
> genetic tests of the individual's family members (defined as dependents and up to and including 4th degree relatives);
> genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
> the manifestation of a disease or disorder in family members (family history);
> any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or family member.'[203]

GINA defines a genetic test as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.[204] GINA does not apply

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197 42 U.S.C. § 300gg.
198 42 U.S.C. § 12101 et seq.
199 (P.L. 110-233, 122 Stat. 881).
200 Ibid s 2(5).
201 Ibid Title I ss101(f)(2); 102(d)(2); 103(f)(2); 104(c); 105(b)(2).
202 Ibid Title II s 213.
203 Ibid Title I s 101(d) and Title II s 201(4).

to life insurance, disability insurance and long-term care insurance. In the employment sphere GINA does not apply to employers with fewer than 15 employees. As federal legislation, it provides the minimum level of protection against genetic discrimination. States may adopt more stringent laws.[205]

(a) Genetic Databases

(i) Forensic DNA Databases

The Combined DNA Index System (CODIS) was developed by the Federal Bureau of Investigation (FBI) in 1990. CODIS is a computer software program that operates databases of DNA profiles from convicted offenders, arrestees, detainees, unsolved crime scene evidence, and missing persons. It is implemented as a three-tiered database consisting of DNA profiles at local, state and national levels. CODIS software thus enables local, state, and national law enforcement crime laboratories to share and compare DNA profiles electronically. The Local DNA Index System (LDIS) which is installed at crime laboratories is operated at local level by police departments or sheriffs' offices. DNA profiles originating at the local level can be transmitted to the state and national levels. Each State has a designated laboratory that operates the State DNA Index System (SDIS). SDIS allows local laboratories within a particular State to compare DNA profiles. The National DNA Index System (NDIS) is the highest level of the CODIS hierarchy and enables state laboratories to compare DNA profiles. The NDIS is maintained by the FBI.

The DNA Identification Act of 1994[206] authorised the director of the FBI to establish an index such as the NDIS and specified the following types of data for inclusion in such index:

'(1) DNA identification records of -
(A) persons convicted of crimes;
(B) persons who have been charged in an indictment or information with a crime; and
(C) other persons whose DNA samples are collected under applicable legal authorities, provided that DNA samples that are voluntarily submitted solely for elimination purposes shall not be included in the National DNA Index System;

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[204] Supra note 199 Title I s101(d) and Title II s 201(7).
[205] Supra note 199 s 209(a).
[206] Contained within the Violent Crime Control and Law Enforcement Act 42 U.S.C. §14132; Pub. L. No. 103-322, Title XXI §210304.

(2) analyses of DNA samples recovered from crime scenes;
(3) analyses of DNA samples recovered from unidentified human remains; and
(4) analyses of DNA samples voluntarily contributed from relatives of missing persons.'[207]

The Act also contains privacy protection standards.[208] It provides that 'the results of DNA tests performed for a Federal law enforcement agency for law enforcement purposes may be disclosed only-

'(A) to criminal justice agencies for law enforcement identification purposes;
(B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules; and
(C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged.'[209]

The exception to the above is that de-identified test results may be disclosed for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.[210] The Act provides that a fine may be imposed upon any employee or official who intentionally discloses individually identifiable DNA information, which has been indexed in a database, to any other person or agency which is not authorised to receive such information.[211] In a similar vein it provides that a fine or a period of imprisonment may be imposed upon the recipient of the information.'[212]

The DNA Identification Act[213] does not, however, provide for the collection of DNA samples from individuals. This gap was filled through the promulgation of the DNA Analysis Backlog Elimination Act 2000[214] which authorises the collection of DNA samples from persons convicted of certain federal offences.[215] All States subsequently passed legislation compelling all persons convicted of certain offences to provide DNA samples for inclusion in CODIS. The DNA Fingerprint Act 2005[216] amended the DNA Analysis Backlog Elimination Act[217] to authorise the collection of DNA samples from arrestees and detainees for inclusion in CODIS. It authorised

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207 42 U.S.C. §14132(a)
208 42 U.S.C. §14133(b).
209 Ibid §14133(b)(1).
210 Ibid §14133(b)(2).
211 Ibid §14133(c)(1)
212 Ibid §14133(c)(2).
213 Supra note 206.
214 42 U.S.C. §14135a, Pub. L. No. 106-546 §3.
215 Ibid, §14135a(d) lists felonies, sexual offences, violent crimes, and any attempts or conspiracy to commit any of these crimes as qualifying offences for purposes of the Act.
216 Pub. Law No. 109-162 §1004.
217 Supra note 214.

the Attorney General or his delegate to collect DNA samples from arrestees and detainees.[218] The DNA Fingerprint Act[219] also amended the DNA Identification Act[220] to provide for the prompt expungement from CODIS of the DNA profiles of persons who are acquitted or against whom charges are dismissed. This applies at national and state[221] levels. Whether this approach is legally sound or not can only be determined in the context of a constitutional challenge to the Act. The previous legislative approach of taking DNA samples from convicted persons passed constitutional muster in the case of *Landry v Attorney General.*[222] The Massachusetts Supreme Court upheld a statute[223] requiring those convicted of thirty three specified offences[224] or an attempt or conspiracy to commit any of the specified offences, to submit to the taking of DNA samples and the storage of their profiles in a database.

The DNA Fingerprint Act[225] extended the reach of law enforcement authorities far beyond that permitted by any previous legislation. To the extent that it permitted the taking of DNA samples from arrestees, it brought the American position in line with the unsatisfactory approach that existed in the United Kingdom prior to the *Marper*[226] judgment. The only positive aspect of the American approach is that it allows for the expungement of profiles upon acquittal or upon the dismissal of charges.

All States have laws compelling all convicted felons to provide DNA samples for inclusion in the national database. In March 2011 Idaho became the last remaining state to amend its laws to make such a provision. Previously Idaho required only those felons who were convicted of violent or sexual crimes to submit DNA samples for inclusion in its database. The amendments to Idaho's legislation will come into effect on or after 1 July 2013. Thirty eight States also

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218 Supra note 216 §1004.
219 Ibid §1002.
220 Supra note 206 §14132(d).
221 Ibid §14132(d)(2).
222 709 N.E.2d 1085, 1092 (Mass. 1999).
223 DNA Seizure and Dissemination Act, M.G.L. c. 22E §§ 1-15
224 The Act applies to the following offences: murder, manslaughter, indecent assault and battery on a mentally retarded person, indecent assault and battery on a person over 14, mayhem, assault with intent to murder, attempt to murder by poisoning, armed robbery, armed assault with intent to rob, armed assault in a dwelling, use of a firearm during commission of a felony, home invasion, rape, rape of a child under 16, statutory rape, assault with intent to rape, assault with intent to rape a child under 16, kidnapping, armed burglary in the nighttime with intent to commit a felony, unarmed burglary in the nighttime, abduction for the purpose of prostitution, administering drugs with intent to rape, inducing a minor to become a prostitute, deriving support from child prostitution, open and gross lewdness, incest, dissemination of obscenity, solicitation of child pornography, dissemination of child pornography, unnatural and lascivious acts, unnatural and lascivious acts with a child under 16, and prostitution.
225 Supra note 216.
226 Supra note 28.

collect DNA samples from persons convicted of misdemeanors.[227] Twenty five States collect DNA samples from persons arrested for certain offences such as murder, sex crimes, and burglary.[228]

The laws governing the collection of DNA samples in the different States vary considerably in many respects including the criteria for inclusion in a database, retention periods for samples and profiles, and provisions on third party access to databases. The adoption of the same approach by all fifty States towards the collection of DNA from convicted felons, goes a long way towards creating cohesion in the overall system but there are further divisive elements that must be borne in mind. For example, at federal level felonies are divided into five classes which carry penalties ranging from imprisonment of more than one year to the death penalty[229] whilst the position at state level varies with each state having its own statutory definition of a felony. Some definitions are aligned to the federal definition but others differ considerably. An extreme example is that of the State of Louisiana which defines a felony as a crime which is punishable by death or imprisonment with hard labour.[230] Issues such as these, although beyond the scope of this research, must be given due consideration in the future in order to create a cohesive DNA collection system in the USA.

(ii) Genetic Research Databases

The USA has a large number of human genetic research databases[231] and biorepositories.[232] The world's largest tissue and blood sample collection is based in the USA at the National Pathology Repository of the Armed Forces Institute of Pathology.[233] It has been estimated that the

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[227] National Conference of State Legislatures (2010) available at http://www.ncsl.org accessed on 17 December 2011.

[228] Ibid.

[229] U.S. Code §3559(a).

[230] Louisiana Code Title 14 RS14:2 §2(4).

[231] Women's Health Initiative, Framingham Heart Study, National Health and Nutrition Examination Survey, National Cancer Institute Multiethnic/Minority Cohort Study of Diet and Cancer, National Children's Study, Veterans Administration Genomic Medicine Program, Genes and Environment Initiative, Genetic Association Information Network, Human Genome Epidemiology Network; *Report of the Secretary's Advisory Committee on Genetics, Health, and Society* 'Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease (March 2007) 17, available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_LPS_report.pdf accessed on 29 January 2012.

[232] Over 150 have been listed at http://specimencentral.com/biobank-directory.ashx accessed on 27 January 2012.

[233] Yael Bregman-Eschet 'Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?' (February 5, 2006) *Bepress Legal Series* Working Paper 934 at 14, available at http://law.bepress.com/expresso/eps/934 accessed on 29 January 2012.

repository holds more than 90 million specimens dating back to 1864.[234] Although the repository was officially closed on 15 September 2011, the specimens are being accommodated until the Institute of Medicine makes its recommendations on their future use.[235] The recommendations are due in June 2012 and are expected to cover issues such as the potential use of specimens, which were originally collected for clinical use, in research.[236]

Marshfield Clinic's Personalised Medicine Research Project which, like the UK Biobank, is used inter alia to study gene-environment interaction, is the largest population-based genetic research project in the USA. It commenced in August 2002 and is expected to run for a period of twenty years. The Personalised Medicine Research Database contains genetic, medical, environmental, background, and family information from twenty thousand participants. The genetic information is derived from analysis of blood samples, medical information is derived from medical records; and environmental, background, and family information, is obtained through a questionnaire. The purpose of the database is to provide a resource for studying 'which genes cause disease, which genes predict reactions to drugs, and how environment and genes work together to cause disease.'[237] The ultimate aim is for medical practitioners to be able to use a patient's genetic profile to decide what treatment would work best for the particular individual. This concept of personalised medicine holds much promise for improved healthcare as well as a reduction in healthcare costs. It will save time in obtaining diagnoses and save costs by ensuring that the most effective medication is prescribed for the individual.

Despite the large number of biobanks and research databases in the USA there is no federal legislation specifically governing research databases or biobank activity. There are, however, three federal rules which govern research involving human participants and which may also be used to protect research data. The Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule),[238] issued under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996,[239] provides national standards

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234 Ibid; Alison McCook 'Death of a pathology centre: Shelved' (18 August 2011) 476 *Nature* 270.
235 Ibid McCook at 272.
236 Institute of Medicine *Review of the Appropriate use of AFIP's Tissue Repository Following its Transfer to the Joint Pathology Center* available at http://www8.nationalacademies.org/cp/projectview.aspx?key=IOM-BSP-10-03 accessed on 29 January 2012.
237 Available at http://www.marshfieldclinic.org/chg/pages/default.aspx?page=chg_pers_med_res_prj accessed on 27 January 2012.
238 45 CFR Parts 160 and 164.
239 P.L. 104-191 Title 11 Subtitle F.

for the protection of privacy of health information, including genetic information. It regulates inter alia the use and disclosure of protected health information by covered entities for research.[240] The rule is subject to two crucial limitations which may result in it being inapplicable to biobanks and genetic research databases.[241] First, covered entities are limited to health care providers that conduct certain transactions in electronic form; healthcare clearinghouses; and health plans.[242] Research databases and biobanks are not covered entities under the Privacy Rule. This means that disclosure of information contained in the databases and biobanks does not have to comply with the standards of the HIPAA Privacy Rule. Secondly, the Privacy Rule only applies to identifiable data. De-identified data contained in databases does not fall within the definition of protected health information under the Privacy Rule and is therefore not protected by it.

The second relevant rule is the Department of Health and Human Services Regulations for Protection of Human Research Subjects (Common Rule)[243] which requires researchers to obtain informed consent from research participants before collecting and storing their tissue for research purposes. Only identifiable tissue specimens are subject to the Common Rule. The main limitations of the Common Rule are that it only governs 18 federal departments and agencies[244] and it has not been adopted by all agencies that fund research. This implies that research that is not funded by any of the 18 departments or agencies does not have to comply with the Common Rule.

As discussed in chapter two, the absence of a regulatory framework for research databases and biobanks is a challenge for genetic research which relies heavily on such resources. The HIPAA Privacy Rule and the Common Rule leave regulatory gaps which must be filled due to a rapid proliferation of research databases, the ever-increasing demand for resources for genetic

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240 Ibid §164.502.

241 M B Kapp 'Ethical and legal issues in research involving human subjects: do you want a piece of me?' (2006) 59 *Journal of Clinical Pathology* 335 at 338.

242 45 CFR 164.103.

243 45 CFR Part 46 Subpart A.

244 The following departments have adopted the rule: Department of Health and Human Services; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Defence; Consumer Product Safety Commission; International Development Cooperation Agency; Department of Housing and Urban Development,; Department of Justice; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; and Department of Transportation. The Rule applies to the Central Intelligence Agency (by Executive Order 12333), and the Social Security Administration (by P.L. 103- 296). The Office of Science and Technology Policy signed but did not codify the Rule because it does not conduct clinical research.

research purposes; and the fact that the US is a member of the Organisation for Economic Co-Operation and Development (OECD). On 22 October 2009 the OECD Council adopted the Recommendation on Human Biobanks and Genetic Research Databases which 'aims to provide guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases…'[245] Although the Recommendation is not a legally binding instrument 'it represents an important political commitment on the part of the member countries.'

The Recommendation contains principles, best practices, and comprehensive guidelines, which also require filling of the gaps left by the HIPAA Privacy Rule and the Common Rule. It provides that biobanks and research databases 'should be established, governed, managed, operated, accessed, used and discontinued in accordance with applicable legal frameworks and ethical principles.'[246] As indicated above, the existing legal framework in the US is inadequate for these purposes. The Recommendation also provides that operators and users of biobanks and databases should always 'respect human rights and freedoms and secure the protection of participants' privacy and the confidentiality of data and information.[247] Once again, due to gaps in the regulatory framework, these protections cannot be guaranteed in the USA.

The guidelines take cognisance of the potential harm that may arise from genetic research. This is evident from the following statement:

> 'Research pertaining to a large portion of a population, especially amongst those sharing common characteristics, may raise issues of potential discrimination and stigmatisation. For example, an association between a specific heritage and a particular disease may lead to discrimination from insurers or employers. The initiators and operators of the HBGRD [Human Biobanks and Genetic Research Databases] should take into consideration potential consequences not only for participants but also individuals, families and groups who may not have participated in the HBGRD. In addition, the HBGRD should make information publicly available about the possibility that research results generated from population-based human genetic data may have repercussions for individuals, participants, their family, groups to which they belong and the community as a whole. Examples of repercussions may include loss of dignity or community stigmatisation.'[248]

The guidelines should prove useful for the regulation of genetic research databases in any country. It provides ample guidance on how to operate genetic research databases in a manner which protects human rights. It also indicates where the gaps in protection lie. This is a useful

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[245] Recommendation available at http://www.oecd.org/dataoecd/41/47/44054609.pdf, accessed on 16 March 2012.
[246] Ibid clause 1.A.
[247] Ibid clause 1.D.
[248] Ibid Part II para 10 at 23-24.

instrument which, if implemented in the USA, can help to close the existing gaps in the protection of human genetic information.

(b) Genetic Discrimination

There are decided cases of genetic discrimination in the USA.[249] Anti-discrimination legislation has been and continues to be used to prevent the misuse of genetic information at federal and state levels. Even before the passage of the Genetic Information Nondiscrimination Act (GINA)[250] it was observed that '[i]ronically, the most important law regulating the privacy and confidentiality of employee medical information is not a privacy law at all but an anti-discrimination law.'[251] The laws at state level vary widely in terms of content and purpose. A review of such laws is therefore not particularly useful therefore only federal legislation will be considered.

(i) Insurance

The USA has federal laws prohibiting discrimination in health coverage based on genetic information. Such laws are the HIPAA,[252] GINA,[253] and the HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).[254] Since the provisions of these laws do not extend to life insurance, a comprehensive discussion of the relevant provisions would serve no useful purpose in the context of this research. However, insofar as health coverage is concerned, two developments are interesting to note. First, GINA[255] requires that the definition of 'health information' as contained in the HIPAA Privacy Rule[256] be amended to clearly indicate that genetic information is health information under the Rule and to prohibit health plans from using or disclosing genetic information for underwriting purposes. It must be borne in mind, however, that genetic

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249 *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* 135 F. 3d 1260 (9th Cir. 1998). *; Echazabal v Chevron USA 213* F.3d 1098 (9th Cir.2000); *Bentivegna v United States Dept of Labour* 694 F.2d 619 (9th Cir. 1982).

250 (P.L. 110-233, 122 Stat. 881).

251 Mark A Rothstein (ed) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997) 287.

252 Supra note 197.

253 Supra note 199.

254 45 CFR Parts 160 and 164.

255 Supra note 199 s 105(a).

256 Supra note 254 s 160.103.

information will only be protected under the HIPAA Privacy Rule if it is individually identifiable and maintained by a covered entity or business associate of a HIPAA covered entity.[257] The second point of interest is that GINA[258] includes a research exception to allow health insurers or group health plans engaged in research to request (but not require) that an individual undergo a genetic test. This aspect is discussed more fully below under the topic relating to research.[259]

(ii) Employment

It has been observed that '[u]nlike in most other countries, there is considerable anecdotal evidence of genetic discrimination by employers in the USA.'[260] Crosbie attributes this to the fact that the majority of Americans depend on their employers for health insurance. The main legislative attempts by the USA to curb genetic discrimination by employers are accordingly discussed below.

(1) The Americans with Disabilities Act (ADA)[261]

The ADA was promulgated in 1990. It prohibits inter alia discrimination against disabled individuals in employment but applies only to employers who employ fifteen or more employees.[262] It defines disability as '(a) a physical or mental impairment that substantially limits one or more of the major life activities of an individual; (b) a record of such an impairment; or (c) being regarded as having such an impairment.'[263] Although the ADA[264] does not contain specific provisions relating to genetic discrimination, it has been interpreted by the Equal Employment Opportunity Commission (EEOC)[265] to include a prohibition of discrimination in cases where genetic information relating to illness causes an individual to be regarded as having a disability.[266] This interpretation is based on part (c) of the abovementioned definition of 'disability'.

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257 Ibid.
258 Supra note 199 ss 102(a); 102(b); 103(b); 104(b).
259 At 198 -199.
260 Deborah Crosbie 'Protection of Genetic Information: An international Comparison' *Report to the Human Genetics Commission* (2000) at 42.
261 42 U.S.C. §12101.
262 Ibid § 12111(5).
263 Ibid § 12102.
264 Ibid.
265 Established by the Civil Rights Act 1964 (Pub. L. 88-352 Title VII section 705) to prevent unlawful employment practices in the USA.
266 Equal Employment Opportunity Commission *Compliance Manual* (1995) 2 at 32.

The EEOC has acknowledged that the protection offered by the ADA against genetic discrimination is limited.[267] The ADA prohibits pre-employment medical examinations and disability-related inquiries[268] but it does not prohibit employers from requiring employees to disclose such information after commencing employment. The application of the ADA to genetic disease will clearly prove challenging in a court of law for two reasons. First, the definition of disability has to be found to include genetic disease. It is important to note here that the stance of the EEOC has not been confirmed by courts in the USA.[269] Secondly, the onus of proving discrimination is difficult to discharge due to its subjective nature. Proving that an employee is being treated differently may not be difficult but the challenge lies in proving that such differential treatment is due to or because of a disability. Such proof would require an examination of the employer's state of mind. This is clearly an unsatisfactory situation which does not create certainty for disabled employees. There is no guarantee that the ADA can be successfully used to protect employees who have or are predisposed to genetic disease.

(2) The Genetic Information Nondiscrimination Act 2008 (GINA)[270]

GINA prohibits discrimination in employment based on genetic information. The prohibition applies to employers, employment agencies, labour organizations, and joint labour-management committees, all of whom are referred to as 'covered entities'.[271] The section relating to employment (Title II) came into effect on 21 November 2009. GINA required the EEOC to issue regulations not later than one year after the date of enactment of Title II. Such regulations were issued on 9 November 2010 and came into effect on 10 January 2011. Unlike the ADA[272] which prohibits only pre-employment inquiries relating to disability, GINA applies to applicants as well as employees. This means that the protections afforded by GINA are applicable in the pre-employment phase as well as during the period of employment.

GINA protects the privacy of employees in two ways. First, it prohibits the acquisition of employees' genetic information by employers and other covered entities except in certain limited

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267 Paul Steven Miller, US Equal Employment Opportunity Commission *Statement before the Senate Committee on Health, Education, Labor and Pensions* (July 20, 2000).

268 Supra note 261 §12112(d)(2).

269 *Bragdon v Abbott* 524 U.S. 624 (1998); *Sutton v United Airlines* 527 U.S. 471 (1999); *Murphy v United Parcel Service, Inc*. 527 U.S. 516 (1999); *Albertsons Inc. v Kirkingburg* 527 U.S. 555 (1999).

270 Supra note 199.

271 Regulations Under the Genetic Information Nondiscrimination Act of 2008, 29 CFR Part 1635.

272 Supra note 261.

circumstances.[273] It states that 'it shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee.'[274] The acquisition of genetic information by employers will not amount to a contravention of GINA where -

(a) an employer acquires the information inadvertently;

(b) an employer acquires the information as part of health or genetic services or a wellness programme with authorisation from the employee;

(c) an employer requests or requires family medical history from the employee to comply with requirements in terms of other laws;

(d) an employer acquires the information through the media;

(e) the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace; or

(f) an employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification, for quality control or to detect sample contamination.[275]

Secondly, GINA provides for the protection of confidentiality of genetic information.[276] It provides that genetic information about employees must be maintained on separate forms and in separate medical files and be treated as a confidential medical record of the employee. Employers are prohibited from disclosing genetic information of employees except -

(a) at the written request of the employee;

(b) to a researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;

(c) in response to a court order;

(d) to government officials who are investigating compliance with this law prohibiting genetic discrimination in employment;

(e) in connection with the employee's compliance with certain laws; or

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273 Supra note 199 ss 202(b); 203(b); 204(b).
274 Ibid s 202(b).
275 Ibid s 202(b).
276 Ibid s 206(a).

(f) to a Federal, State, or local public health agency with regard to certain prescribed health information.[277]

GINA also provides enforcement mechanisms and remedies for violations of Title II.[278] These are amplified in the Regulations.[279] The preamble to the regulations notes that 'in crafting GINA's enforcement and remedies section, Congress recognised the advisability of using the existing mechanisms in place for redress of other forms of employment discrimination.' The specific remedies provided for violations of Title II are compensatory and punitive damages, reasonable attorney's fees, and injunctive relief including reinstatement, hiring, back pay, and other equitable remedies.[280]

It has been suggested that GINA be thought of as 'a new layer in the scheme of overlapping protections provided by existing antidiscrimination laws.'[281] Even though the title of GINA suggests that it is primarily an anti-discrimination statute, it is an improvement on the ADA in a few crucial respects. First, GINA is aimed directly at genetic information so there is no need for it to be liberally interpreted to include genetic information as is the case with the ADA. Secondly, it offers protection to applicants as well as employees insofar as the acquisition of employee's genetic information by employers is concerned, thereby closing a major gap in the protection afforded by the ADA. Finally, in attempting to prevent discrimination, GINA also protects privacy, thus taking it beyond the limits of a pure anti-discrimination statute. GINA is complemented by a comprehensive set of regulations which implement Title II of the statute. The regulations assist in clarifying many aspects of GINA.

Rothstein has suggested that GINA will be ineffective in protecting genetic privacy[282]because of its limited coverage and the fact that it does not differ markedly from existing laws, the shortcomings of which it was intended to address. Kim is of the opinion that the experience of Title VII of the Civil Rights Act 1964[283] 'suggests that the traditional antidiscrimination model is unlikely to eliminate genetic discrimination in employment if

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277 Ibid s 206(b).
278 Ibid s 207.
279 Supra note 271
280 Ibid s 1635.10(b).
281 Elizabeth Pendo 'Race, sex, and genes at work: Uncovering the lessons of *Norman-Bloodsaw* (2010) 10 *Houston Journal of Health Law & Policy* 227 at 254.
282 Rothstein, Mark A. 'Keeping your genes private' (2008) 299:3 *Scientific American* 64 at 65.
283 42 U.S.C. §2000e-2.

employers gain ready access to genetic information.'[284] This conclusion is reached after an examination of how the Civil Rights Act[285] works in practice and the difficulty of proving intentional discrimination.[286] Since GINA is a relatively new piece of legislation, its practical shortcomings are yet to be discovered. It will be only through the actual implementation of the various provisions of the Act, that the gaps and flaws will be detected. This should be closely monitored to remedy defects in the Act as well as to ensure that the Act keeps pace with the rapid developments in genetic science. Despite these negative comments, it must be concluded that GINA, as the first and long-awaited federal statute to address genetic discrimination, holds promise for the protection of genetic privacy in the USA.

(iii) Genetic Research

Research involving human participants is governed by ethical guidelines and federal regulations. The ethical guidelines are the Belmont Report,[287] Declaration of Helsinki,[288] and the International Ethical Guidelines for Biomedical Research Involving Human Subjects.[289] The implications of these instruments for genetic research involving human participants has already been discussed comprehensively in chapter two. The relevant federal regulations, which are discussed hereunder, are the Department of Health and Human Services (HHS) Regulations for Protection of Human Research Subjects,[290] which are referred to as the 'Common Rule'; the Food and Drug Administration Regulations for the protection of Human Subjects,[291] and the HIPAA Regulations[292] which are referred to as the Privacy Rule. The Office for Human Research Protections (OHRP) of the HHS is responsible for monitoring compliance with federal regulations for research which is conducted or supported by the HHS.

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[284] Pauline T. Kim 'Genetic discrimination, genetic privacy: Rethinking employee protections for a brave new workplace' (2002) 96:4 *Northwestern University Law Review* 1497 at 1526.

[285] Supra note 283.

[286] Kim op cit note 284 at 1528.

[287] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report - Ethical Principles and Guidelines for the protection of human subjects of research* (1979) available at http://ohsr.od.nih.gov/guidelines/belmont.html accessed on 3 August 2011.

[288] World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants* Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and last amended by the 55th WMA General Assembly, Tokyo, Japan, October 2004.

[289] Council for International Organisations of Medical Schemes *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) available at http://www.cioms.ch/publications/layout_guide2002.pdf accessed on 29 May 2011.

[290] Supra note 243.

[291] 21 CFR Part 50.

[292] Supra note 254.

(1) Regulations for Protection of Human Research Subjects (Common Rule) [293]

The Common Rule applies to all research involving human subjects which is conducted, supported or otherwise subject to regulation by any federal department or any agency which has adopted the rule.[294] It requires approval and ongoing review by an Institutional Review Board (IRB).[295] A second crucial requirement[296] is that of informed consent, which is founded on the principle of respect for persons as enshrined in the Belmont Report.

The Common Rule sets out the basic elements of informed consent.[297] The informed consent process entails three crucial aspects:

(1) disclosure of all information that is needed to make an informed decision;

(2) ensuring that the disclosed information is properly understood; and

(3) ensuring that the decision to participate is completely voluntary.

Informed consent must be obtained prior to commencement of research in order to be legally valid. The requirement of informed consent may be waived or altered by an IRB if it finds that:

(a) the research involves public benefit or service programs and the research could not practicably be carried out without the waiver or alteration;[298]

(b) other general research involves no more than minimal risk to the participants; the research could not practicably be carried out without the waiver or alteration; the rights and welfare of participants will not be adversely affected by the waiver or alteration; and the participants will be provided with additional information after participation.[299]

An additional waiver of the general requirements for obtaining informed consent may apply to limited classes of research. [300] Such waiver currently applies to research in emergency settings provided that the research meets the requirements of the HHS Secretarial waiver.[301]

The Common Rule provides additional protection for certain vulnerable groups who participate in research.[302] Such groups include pregnant women, human foetuses, neonates, prisoners, and children. The additional protection offered by the Common Rule is clearly aimed

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293 Supra note 243.
294 Ibid s 46.101(a).
295 Ibid s 46.103(b).
296 Ibid ss 46.116 and 46.117.
297 Ibid s 46.116(a).
298 Ibid s 46.116(c).
299 Ibid s 46.116(d).
300 Ibid s 46.101(i).
301 Ibid, Federal Register (October 2, 1996) 61:192 at 51531.
302 45 CFR Part 46 Subparts B, C, D.

at preventing coercion as well as minimising the risks to vulnerable research participants. The emphasis is on free and informed consent. There is no scope within the rule for the extension of additional protection to genetic research participants who do not fall into the established categories.

(2) Food and Drug Administration Regulations[303]

The FDA regulations deal with informed consent[304] and IRB review[305] for research on products regulated by the FDA. This includes articles subject to the Federal Food, Drug, and Cosmetic Act, [306] food and colour additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. The requirements for and elements of informed consent are almost identical to those in the Common Rule. Compliance with the FDA regulations will be necessary in pharmacogenomic research.

(3) Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule)[307]

The HIPAA Privacy Rule establishes a set of national standards for the protection of individually identifiable health information which is referred to as protected heath information (PHI). It addresses the use and disclosure of PHI by healthcare providers, insurers, and others who transmit information electronically ('covered entities'). It does not apply to research using human biological materials or to de-identified data and is only binding on covered entities. Although the rule does not apply to the regulation of human biological materials, it does apply to identifiable associated patient data. The rule requires patient authorisation for the use and release of identifiable information. This requirement is different and distinct from the informed consent requirement which exists in the Common Rule.

(4) Genetic Information Nondiscrimination Act[308]

For the purpose of research protections, the Office for Human Research Protections (OHRP) has noted that 'GINA's prohibitions apply to 'genetic information' which is defined as including receipt of genetic services (genetic tests, genetic counseling, or genetic education) by an

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303 21 CFR 50; 21 CFR 56.
304 Ibid s 50.20.
305 21 CFR 56, s 56.103.
306 21 U.S.C. 355(i), 357(d), and 360j(g).
307 Supra note 238.
308 Supra note 199.

individual or family member participating in clinical research.'[309] The OHRP has issued guidance on the implications of GINA for researchers and IRB's that are involved with human participant research which entails genetic testing or the collection of genetic information. The emphasis of the guidance is on criteria for IRB approval of genetic research and the requirements for obtaining informed consent. Researchers and IRBs are advised to consider -

(i) 'the provisions of GINA when assessing whether genetic research satisfies the criteria required for IRB approval of research, particularly whether the risks are minimized and reasonable in relation to anticipated benefits and whether there are adequate provisions in place to protect the privacy of subjects and maintain the confidentiality of their data;' and
(ii) 'whether and how the protections provided by GINA should be reflected in a consent document's description of risks and provisions for assuring the confidentiality of the data.'[310]

With regard to (i) above, the OHRP draws the attention of IRBs to the potential for discrimination in employment and insurance as a risk typically associated with genetic research.

(5) Certificates of Confidentiality

Any person who is involved in research in which sensitive information is gathered from human participants, may apply for a Certificate of Confidentiality. Sensitive information includes inter alia genetic information and information that could be detrimental to a person's financial standing, employability, reputation within the community, or that might lead to social stigmatisation or discrimination.[311] This certificate is issued by the National Institute of Health in terms of the Public Health Service Act.[312] A researcher who obtains a Certificate of Confidentiality will be entitled to resist compelled disclosure of a participant's indentifying information in any federal, State, or local civil, criminal, administrative, legislative, or other proceedings. The protection afforded by a Certificate of Confidentiality is permanent in the sense that it continues even after the death of research participants. The certificate is a means of protecting the privacy of participants in an attempt to encourage public participation in research.

All of the regulations discussed above reflect a common acceptance of the need for free and informed consent of participants in the research process. The existence of this common thread

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309 Department of Health and Human Services *The Genetic Information Nondiscrimination Act of 2008: Information for Researchers and Health Care Professionals* (April6, 2009) at 3, available at http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf accessed on 5 February 2012.

310 Ibid 3-4.

311 Office of Extramural Research (Department of Health and Human Services) *Frequently Asked Questions: Certificates of Confidentiality* available at http://grants.nih.gov/grants/policy/coc/faqs.htm accessed on 19 January 2012.

312 42 U.S.C. 241(d).

can be traced back to the Belmont Report which is considered to be 'the primary ethical framework for the protection of human research participants in the USA.'[313] The minimisation of potential risks to research participants is also a common factor in all of the regulations. It is important to note that the Common Rule makes provision for additional protection to be afforded to vulnerable research participants although, in its current form, it is unable to extend such additional protection to genetic research participants. The entire concept of vulnerability, as discussed in chapter three, will have to be reconsidered if the Common Rule is to be extended to protect genetic research participants.

(6) Law Reform Initiatives

The position pertaining to research protections in the USA is unduly complex, bureaucratic, fragmented and confusing. The federal regulations discussed above do not automatically apply to research which is funded or conducted by State governments, non-governmental organisations, or industry. The distinction between publicly funded and privately funded research defies understanding. There is no single oversight authority, which serves only to further complicate matters. This results in the lack of uniformity in the definitions, approaches, and rules pertaining to research. The current system makes it difficult to address new and developing areas of research such as genetic research. The following statement by the National Bioethics Advisory Commission is cause for concern as far as the future of genetic research is concerned:

> 'Today's research protection system cannot react quickly to new developments. Efforts to develop rules for special situations, such as research on those who can no longer make decisions for themselves, have languished for decades in the face of bureaucratic hurdles, and there is no reason to believe that efforts to oversee other emerging research areas will be any more efficient. In addition, the current system leaves people vulnerable to new, virtually uncontrolled experimentation in emerging fields, such as some aspects of reproductive medicine and genetic research. Indeed, some areas of research are not only uncontrolled, they are almost invisible. In an information age, poor management of research using medical records, human tissue, or personal interview data could lead to employment and insurance discrimination, social stigmatization, or even criminal prosecution. The privacy and confidentiality concerns raised by this research are real, but the federal response has often been illusory. There is almost no guidance and certainly no coordination on these topics. The time has come to have a single source of guidance for these emerging areas, one that would be better positioned to effect change across

[313] Janet F. Zimmerman 'The Belmont Report: An ethical framework for protecting research subjects' (1997) *The Monitor* available at http://www.impactcg.com/docs/BelmontReport.pdf accessed on 22 March 2012.

> all divisions of the government and private sector, as well as to facilitate development of specialized review bodies, as needed.'[314]

It is, nevertheless, encouraging to note that the abovementioned concerns have not gone unnoticed. On 22 July 2011 the HHS announced its intention to improve the rules protecting human research participants.[315] The HHS, together with the Office of Science and Technology Policy (OSTP), issued notice of the proposed rulemaking on 26 July 2011.[316] The introductory paragraph in the notice explains the reasons behind the proposed changes as follows:

> 'The current regulations governing human subjects research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Although the regulations have been amended over the years, they have not kept pace with the evolving human research enterprise, the proliferation of multi-site clinical trials and observational studies, the expansion of health services research, research in the social and behavioral sciences, and research involving databases, the Internet, and biological specimen repositories, and the use of advanced technologies, such as genomics. Revisions to the current human subjects regulations are being considered because OSTP and HHS believe these changes would strengthen protections for research subjects.'[317]

The changes being contemplated by the HHS are intended inter alia to improve the standards of protection for human participants involved in research and to enhance the effectiveness of oversight.[318] In the notice the HHS takes cognisance of the report by the NBAC as well as the numerous recommendations made.[319] The HHS identified the following issues for further deliberation:

1. 'Lack of alignment between the level of review and the level of risk;
2. the inefficiencies of review by multiple IRBs for multi-site studies, which add bureaucratic complexity to the review process and delay initiation of research projects without evidence that multiple reviews provide additional protections to participants;
3. the extent and quality of the protections afforded by current informed consent requirements and practices;
4. the increasing use of genetic information, existing (stored) biospecimens, medical records, and administrative claims data and the changing nature of associated risks and benefits of research participation;
5. the monitoring and evaluation of the current system for protecting human participants;
6. the inadequacy of the current regulatory system in adequately protecting all research participants; and

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[314] *Ethical and Policy Issues in Research Involving Human Participants* (August 2001) Vol.1 at vi, available at http://bioethics.georgetown.edu/nbac/human/overvol1.html accessed on 6 February 2012.

[315] Press release available at http://www.hhs.gov/news/press/2011pres/07/20110722a.html accessed on 6 February 2012.

[316] Advance Notice of Proposed Rulemaking (ANPRM) Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators *Federal Register* (July 26, 2011) Vol. 76 No. 143. pp 44512-44531.

[317] Ibid 44512.

[318] Ibid.

[319] Ibid 44513.

7. the complexity, inconsistency and lack of clarity in the multiple, differing regulatory requirements that can apply to a single research study, which results in unwarranted variability across institutions and their IRBs in how the requirements are interpreted and implemented.'[320]

In an attempt to address the abovementioned concerns, the HHS proposes the following:

1. 'Refinement of the existing risk-based regulatory framework;
2. utilization of a single IRB review of record for domestic sites of multi-site studies;
3. improvement of consent forms and the consent process;
4. establishment of mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data;
5. establishment of an improved, more systematic approach for the collection and analysis of data on unanticipated problems and adverse events;
6. extension of Federal regulatory protections to all research, regardless of funding source, conducted at institutions in the U.S. that receive some Federal funding from a Common Rule agency for research with human participants; and
7. improvement in the harmonisation of regulations and related agency guidance.'[321]

The proposals put forward by the HHS should be welcomed by researchers, IRBs and research participants. These changes, if approved and implemented, will modernise the current regulatory system and remove many obstacles to research. The current system is clearly outdated, flawed, and disjointed and most of its positive attributes are overshadowed by its numerous negative aspects. The issue of genetic research has not yet been addressed by the current regulatory system but the revision of the system is very likely to close this gap. For these reasons the review being conducted by the HHS must be seen as a positive development and its benefits for genetic research should be assessed at a later date. The promulgation of GINA and the commencement of the review of the current regulatory system relating to research, bode well for the future of genetic privacy in the USA.

(c) Privacy

The right to privacy in the USA is strongly associated with the right to be left alone. This may be attributed to the seminal writing of Warren and Brandeis as far back as 1890[322] where they

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320 Ibid 44513- 44514.
321 Ibid 44514.
322 Samuel D. Warren & Louis D. Brandeis 'The right to privacy' (December 15, 1890) 4:5 *Harvard Law Review* 193.

argued for recognition of a right to privacy and for remedies for invasion of such privacy.[323] Brandeis later defined the right to be let alone as 'the most comprehensive of rights, and the right most valued by civilized men.'[324] Despite these strong sentiments expressed such a long time ago, the US still has no single, overarching privacy law. Privacy legislation is adopted as and when the need arises in the different sectors. There is no independent privacy oversight agency in the USA either.

In addition to the notable absence of a single overarching privacy law, the U.S. Constitution does not contain an explicit right to privacy. However, in the landmark decision of *Griswold v Connecticut*[325] the U.S. Supreme Court recognised a constitutional right of privacy based on the First, Third, Fourth, and Fifth Amendment rights. Justice Douglas held that the 'specific guarantees in the Bill of Rights have 'penumbras, formed by emanations from those guarantees that help give them life and substance.'[326] In support of their views, the majority relied on the Ninth Amendment which provides that 'The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.' This approach to the recognition of a right to privacy is controversial.[327] The right to information privacy was first recognised by the United States Supreme Court in 1977 in *Whalen v Roe.*[328] The court noted that the Constitution protected two kinds of privacy interests; namely, the interest in avoiding disclosure of personal information and the interest in making independent decisions.[329]

The tort[330] of invasion of privacy is well established under the common law of the USA. Prosser classifies privacy torts into four categories:

(i) unreasonable intrusion upon an individual's seclusion or private affairs,

(ii) appropriation of an individual's name or likeness;

(iii) publication of embarrassing private facts, and

(iv) painting an individual in a 'false light' in the public eye.[331]

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323 Ben Bratman 'Brandeis and Warren's right to privacy and the birth of the right to privacy' (2002) 69 *Tennessee Law Review* 623.

324 *Olmstead v United States* 277 U.S. 438 (1928) at 478.

325 381 U.S. 479 (1965).

326 Ibid 484.

327 Ibid 485.

328 429 U.S. 589 (1977).

329 Ibid 599-600.

330 A tort is a private or civil wrong or injury.

331 Restatement (Second) of Torts at §§ 652A-652I.

In addition to the common law, the following statutes may be used to protect medical, and possibly, genetic privacy:

(1) Privacy Act of 1974[332]

The Privacy Act protects records held by government agencies and prohibits disclosure except in specific circumstances. On the other hand, the U.S has no similar privacy protection law for the private sector. A sectoral approach is adopted in the private sector which has resulted in a patchwork of federal laws covering only certain categories of personal information.[333] It follows therefore that the main weakness of the Privacy Act is its limited scope.

(2) HIPAA Privacy Rule[334]

The Privacy Rule was the first federal health privacy law. It provides federal protection for individually identifiable health information and gives individuals specific rights in respect of such information. It also specifies the conditions under which protected health information may be used and disclosed and provides civil and criminal penalties for violations of privacy. The positive aspect of this rule is that it treats genetic information as health information and its protections therefore extend to genetic information. The Privacy Rule does not replace state laws which may be more stringent but rather serves as a baseline level of protection.

(3) Genetic Information Nondiscrimination Act (GINA)[335]

GINA is primarily an anti-discrimination statute but it also protects genetic privacy. It has specific confidentiality and privacy provisions in both Titles.[336] Under section 105 of Title I, GINA requires the amendment of the HIPAA Privacy Rule to prohibit the use or disclosure of genetic information by a covered entity for underwriting purposes. The relevant confidentiality provisions relating to Title II have already been discussed above.[337]

The only case dealing with genetic privacy that has come before the Courts in the USA is *Norman-Bloodsaw v Lawrence Berkeley Laboratory*.[338] This was an appeal before the United States Court of Appeals for the Ninth Circuit. The facts are briefly as follows:

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[332] (1974) 5 U.S.C. § 552a.

[333] Records relating to financial activities, health, credit transactions, video rentals, cable television, children's online activities, education, motor vehicle registrations, and telemarketing.

[334] Supra note 238.

[335] Supra note 199.

[336] Ibid Title I, s 105; Title II, s 206.

[337] At 193-195.

[338] 135 F. 3d 1260 (9th Cir. 1998).

Plaintiffs/Appellants ('employees') were employed by the Defendant/Appellee ('employer'). They had provided the employer with blood and urine samples during their pre-placement examinations. The employees alleged that the employer had, without their knowledge or consent, tested their blood and urine for intimate medical conditions such as syphilis, sickle cell trait, and pregnancy. They claimed that such testing violated inter alia their right to privacy as guaranteed by the constitutions of the USA and California. The District Court dismissed the claim but this was reversed on appeal.

In the Appeal Court, Justice Reinhardt stated that '[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.'[339] The Judge recognised the sensitivity around and the wider implications of carrying the sickle cell trait, which has genetic origins. He accordingly concluded that 'the conditions tested for were aspects of one's health in which one enjoys the highest expectations of privacy.'[340] This judgment may be used to strengthen any argument in support of the recognition of a right to genetic privacy. There is no single overarching law that governs data protection or privacy in the USA. As mentioned above[341] the Privacy Act applies only to federal government agencies. It is to be expected that much will be left to self-regulation.

(d) Privilege

The Federal Rules of Evidence do not include rules on privilege. Instead, this area of law is governed by the common law. Rule 501, which deals with privilege in general, provides that a claim of privilege is governed by the common law unless the United States Constitution, a federal statute, or rules prescribed by the Supreme Court provide otherwise. To date the common law has not recognised a medical professional privilege. The closest it has come to this has been the recognition of a psychotherapist-patient privilege in *Jaffee v Redmond.*[342] In this case the appellant sought discovery of notes made by a social worker in the course of counselling sessions held with the respondent. The respondent refused to comply on the basis that the notes were protected from disclosure by a psychotherapist-patient privilege. The Supreme Court had

339 Ibid 1269.
340 Ibid 1270.
341 At 204.
342 *Jaffee, Special Administrator for Allen, Deceased v. Redmond et al* 518 U.S. 1 (1996).

to decide whether such a privilege should be recognised or not. The Supreme Court noted that 'Rule 501 of the Federal Rules of Evidence authorizes federal courts to define new privileges by interpreting 'common law principles…in the light of reason and experience.'[343] Guided by such authority, the court began by reiterating the common law principles[344] that 'the public has a right to every man's evidence'[345] and that exceptions to this rule may be justified by a 'public good transcending the normally predominant principle of utilizing all rational means for ascertaining the truth.'[346] Based on these guiding principles, the question which the court addressed was whether a psychotherapist-patient privilege 'promotes sufficiently important interests to outweigh the need for probative evidence.'[347] The court was persuaded by reason and experience to recognise the privilege.'[348]

It is important to note that the Supreme Court also expressly rejected the balancing test that had been implemented by the Court of Appeals in an earlier decision in *Jaffee v Redmond.*[349] The Court of Appeals had been willing to recognise a psychotherapist-patient privilege based on the facts of this case but it indicated that in future cases the privilege would not apply if the need for disclosure outweighed the privacy interests of the patient. The reason given by the Supreme Court for rejecting this test was that '…it would eviscerate the effectiveness of the privilege by making it impossible for participants to predict whether their confidential conversations will be protected.'[350] Two important issues for consideration may be taken from the decision of the Supreme Court. First, as already argued in chapter five, certainty that sensitive information will be protected is crucial for the enjoyment of certain rights. A statutory privilege provides the certainty or precision which the common law sometimes lacks. This certainty may be described as rigidity but even so it serves an important purpose in this context. In a discussion of the future of privilege law after *Jaffee,*[351] Poulin argues that '[p]rivilege law is peculiarly suited for statutory treatment; it embodies policy choices and details of application that are best addressed

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343 Ibid 8.
344 Ibid 9.
345 Ibid fn 8 explains that the phrase 'every man's evidence' originated in the mid-18th century during the course of a debate in the House of Lords.
346 Quoted by the Supreme Court from the case of *Trammel v. United States* 445 U.S. 40 (1980) at 50, as originally stated in *Elkins v. United States* 364 U.S. 206 (1960) at 234.
347 Supra note 357 at 9-10.
348 Supra note 357 at 10.
349 United States Court of Appeals for the Seventh Circuit No. 94-1151 (April 1995).
350 Supra note 342 at 2.
351 Supra note 342

by the legislature.'[352] As regards genetic information, the future of healthcare depends on the findings of genetic research. Such research requires the participation of individuals who must be given the assurance that their personal information will be protected from disclosure in judicial proceedings. This assurance will not be provided if the reasoning of the Court of Appeals[353] is followed.

Secondly, the public interest that may be served and the public good that may be promoted by the recognition of certain privileges must not be overlooked. With regard to mental health, the Supreme Court noted that '[t]he privilege also serves the public interest, since the mental health of the Nation's citizenry, no less than its physical health, is a public good of transcendent importance.'[354] In chapter five a similar argument has been made in respect of genetic information. There the importance of promoting genetic research has been put forward as one of the arguments for the recognition of a genetic information privilege. Genetic research will benefit the whole of humankind and it should therefore be in the public interest to promote such research. As mentioned above, one of the ways to promote genetic research is to assure research participants that their genetic information will be adequately protected. The Supreme Court's recognition of the need for certainty as well as the recognition of the importance of the public interest are therefore very encouraging.

Even after *Jaffee* there has been no judicial recognition of a general medical professional privilege at the federal level. *United States v. Be*k[355] is a fairly recent case in which the court once again confirmed that a physician-patient privilege is not recognised at federal level. The defendant, Bek, was a medical practitioner who was convicted of illegally distributing controlled substances to his patients and committing health care fraud. On appeal he argued inter alia that the trial court's admission of patients' medical records was irregular since the records were protected by a physician-patient privilege. The Appeal Court rejected this argument, reiterating that 'federal common law has not historically recognised a privilege between patients and physicians.'[356] Bek acknowledged this state of the law but argued further that, based on the

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352 Anne Bowen Poulin 'The psychotherapist-patient privilege after *Jaffee v. Redmond:* Where do we go from here?' (1998) 76:1341 *Washington University Law Quarterly* 1341.
353 Supra note 349.
354 Supra note 342 at 11.
355 493 F.3d 790 (7th Cir. July 6, 2007).
356 Ibid 801.

decision in *Jaffee v. Redmond,*[357] in which the U.S. Supreme Court had recognised a psychotherapist-patient privilege, the Appeal Court should recognise a physician-patient privilege in this case.[358] He also pointed out that Rule 501 of the Federal Rules of Evidence grants the federal courts authority to define new privileges.[359] The Appeal Court declined to do so as it could find no circuit authority in support of a physician-patient privilege. Furthermore, the court noted that even after the decision in *Jaffee v Redmond*[360] they had expressly declined to recognise a physician-patient privilege.[361] The court could accordingly find no reason to create such a privilege in the current case.

The Appeal Court also rejected Bek's argument that HIPAA[362] created a protection mechanism that could be construed as a physician-patient privilege. The court cited *Northwestern Memorial Hospital v Ashcroft*[363] in support of their stance that 'HIPAA did not give rise to a physician-patient or medical records privilege.' As regards HIPAA's requirement that covered entities should obtain patient authorisation before disclosing protected health information, the court pointed out that there are exceptions to the rule. One of the exceptions is the disclosure of protected health information for law enforcement purposes[364] when the information is subject to 'a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer.' The court acknowledged that HIPAA does 'create a procedure for obtaining authority to use medical records in litigation'[365] but found that in this case, none of the requirements regarding disclosure had been violated.[366]

The creation of a physician-patient privilege could provide protection for the genetic privacy of patients. It is, however, quite clear from the cases[367] that the federal courts have no intention of creating such a privilege. In any event, a physician-patient privilege would provide only limited protection for genetic privacy. What is needed to protect genetic privacy is more than a

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357 518 U.S. 1 (1996).
358 Supra note 355 at 802.
359 Ibid.
360 Supra note 357.
361 *Northwestern Memorial Hospital v. Ashcroft* 362 F.3d 923(7th Cir. 2004).
362 Supra note 197.
363 Supra note 361 at 926.
364 Supra note 197, s 164.512(f).
365 Supra note 355 at 16.
366 Ibid.
367 *Whalen v. Roe* 429 U.S. 589(1977); *United States v. Witt* 697 F.2d 301 (2d Cir. 1982); *United States v. Burzynski Cancer Research Institute* 819 F.2d 1301 (5th Cir. 1988); *Hancock v. Dodson* 958 F.2d 1367 (6th Cir. 1992); *United States v. Bercier* 848 F.2d 917 (8th Cir. 1988); *United States v. Lindstrom* 698 F.2d 11549 (11th Cir. 1983).

mere physician-patient privilege because genetic information is not only generated or imparted in clinical settings. A considerable amount of genetic information undoubtedly exists in the research arena. When the time comes, a possible solution would be to persuade a federal court to extend the *Jaffee v Redmond*[368] framework to genetic information. This would require proof that the individual's need for genetic privacy outweighs the court's need to receive evidence of a genetic nature. It may also prove useful to show that a genetic information privilege will serve a greater public interest by promoting genetic research, which in turn will yield great benefits for pharmacogenomics and healthcare. On the contrary, the absence of a privilege will have negative consequences for society at large as well as future generations. If, despite these arguments, the idea of a genetic information privilege is rejected, it appears that only Certificates of Confidentiality may be used to prevent disclosure of the information of research participants in judicial proceedings. All other genetic information will have no protection from compelled disclosure in court. The current position is undoubtedly unsatisfactory but the positive conclusion is that great potential exists for the recognition of a genetic information privilege in the USA.

6.2.3 THE NETHERLANDS

The Netherlands has certain important characteristics which make it suitable for this review. First it is a member state of the European Union, secondly it is a signatory to the Convention on Human Rights and Biomedicine,[369] and thirdly it has data protection legislation which is also intended to apply to genetic privacy protection. The Netherlands does not have genetics-specific legislation. The various legal aspects of genetics are dealt with by existing general laws pertaining to such aspects. A general data protection statute,[370] supplemented by sectoral laws and industry codes, is in existence. It deals with the processing of personal data, including data concerning 'inherited characteristics'. This Act is important because the South African

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[368] Supra note 342.

[369] 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* (1997)

[370] Personal Data Protection Act of 2000 (Wet Bescherming Persoonsgegevens) *Staatsblad* 302 (2000).

Protection of Personal Information Bill[371] is modelled along similar lines. The Netherlands differs from the other jurisdictions under review to the extent that it has general legislation which protects genetic privacy together with a moratorium on the use of genetic information by insurance companies.

(a) Genetic Databases

(i) Forensic DNA Databases

The Netherlands was the first country in the world to introduce specific forensic DNA legislation in 1994.[372] The Dutch Criminal Code and the DNA Investigation in Criminal Proceedings Act 1994[373] provided inter alia that DNA testing could only be approved where it was urgently necessary to reveal the truth; DNA testing of crime scene samples, volunteers and suspects of serious violent and sexual crimes was permitted; DNA testing was only permitted where the crime carried a penalty of eight years' imprisonment or more; DNA profiles could be retained in a database managed by the Netherlands Forensic Institute; the profile of an accused person who was subsequently acquitted or had the case against him/her discontinued had to be removed from the database; the maximum period of retention of profiles in respect of crime scene samples and reference samples was 18 years and 30 years respectively.[374]

The Criminal Code and DNA Investigation in Criminal Proceedings Act 1994 were amended in 2001[375] to provide inter alia that DNA samples collected for forensic purposes may not be used for any other purpose; DNA testing may be approved where necessary for the investigation; all DNA profiles are stored in the database and compared to all other profiles on the database; only convicted persons' profiles are retained in the database; DNA profiles of crime scene stains,

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371 B9-2009.

372 Victor Toom 'DNA fingerprinting and the right to inviolability of the body and bodily integrity in the Netherlands: Convincing evidence and proliferating body parts' (2006) 2:3 *Genomics, Society and Policy* 64 at 68.

373 Wet DNA-ondersoek Strafzaken *Staatsblad* 596 (1993). The Act was signed by the Queen on 8 November 1993 and came into effect on 1 September 1994.

374 Dr. Ir. C.P. van der Beek 'Evolution of the Dutch DNA-law' (2004) 36:7/8 *Der Kriminalist* 293, available at http://www.docstoc.com/docs/28879916/The-Dutch-DNA-law, accessed on 23 March 2012.

375 *Staatsblad* 335 (2001). The amending legislation was signed on 5 July 2001 and came into effect on 1 November 2001.

persons convicted of crimes requiring 4-6 years imprisonment and persons convicted of crimes requiring more than 6 years imprisonment are 18, 20 and 30 years respectively.[376]

In 2003 the law was amended even further to provide for DNA testing to be done on crime scene samples to determine externally visible properties/physical characteristics of unknown persons.[377] This is useful where DNA of an unknown person is found at a crime scene and such DNA can be analysed with the aim of generating a physical profile of such person. This route is followed only if all other attempts at identification fail. The physical characteristics that may be investigated are limited to gender and ethnicity. Testing for indicators of genetic predisposition to disease or behavioral traits is prohibited. The hope is that such unknown person will turn out to be the perpetrator of the crime. It has been observed that this approach is unique as the Netherlands is the only country which has legislation specifically permitting the analysis of physical characteristics on DNA samples.[378] This approach is tempered by the fact that such results are not stored in any database but are simply used to assist the police in finding the suspect based on physical appearance. Once the suspect is found a further DNA test is conducted to confirm that the crime scene sample does belong to the suspect.

The DNA Testing (Convicted Persons) Act came into effect on 1 February 2005.[379] Prior to the passing of this Act, DNA samples could only be taken from suspects. This Act made it possible to take DNA samples of all persons convicted of crimes carrying a statutory period of imprisonment of four years or more. The statutorily prescribed sentence rather than the sentence imposed by a judge is the determining factor here. DNA samples may also be taken in the case of specific offences[380] carrying a lower penalty. The Act is applicable to adults and minors alike. Mouth swab samples are used for DNA testing. Samples are be taken from offenders who are

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376 Ibid.

377 Act To Adapt the Regulation of Forensic DNA Investigation in Relation to Determining Externally Perceptible Personal Characteristics From Cell Material *Staatsblad* 201 (2003)).

378 Christopher H. Asplen, Esquire & Smith Alling Lane *The Non-Forensic Use of Biological Samples Taken for Forensic Purposes: An international Perspective* Report prepared for the American Society of Law, Medicine & Ethics (2006) at 5, available at http://www.aslme.org/dna_04/spec_reports/asplen_non_forensic.pdf , accessed on16 December 2008.

379 Wet DNA-onderzoek bij veroordeelden *Staatsblad* 465 (2004).

380 Supra note 370, Appendix. Crimes include serious offences that threaten national security; serious offences against the Royal dignity; serious offences against Heads of allied nations and other internationally protected persons; serious offences against politicians; serious offences against public authority; acts of violence in public places; arson; serious offences against public decency; making a child drunk or coercing someone to drink by making threats; child abandonment; kidnapping; serious offences against life; physical abuse; criminally negligent homicide; robbery; extortion/blackmail by an act of violence or threat of violence; certain shipping and aviation crimes.

sentenced to imprisonment, suspended sentences, community service, placement in a penal institution, placement in a psychiatric institution, and placement in a juvenile detention facility. Offenders who have only a fine imposed on them will not be subjected to DNA testing. The DNA sample and the profile are retained in a database administered by the Netherlands Forensic Institute. The period of retention depends on the offence and the statutory sentence. In respect of offences carrying a maximum statutory sentence of six years or more, the period of retention for samples and profiles is thirty years. For offences carrying a lower maximum sentence, the period of retention is twenty years.

The Dutch parliament ratified the Prüm Treaty[381] on 15 January 2008. This treaty operates between the Netherlands, Belgium, Germany, Spain, France, Luxembourg, and Austria. The aim of the treaty is to increase cross-border co-operation, particularly the mutual exchange of information amongst contracting states in three areas: terrorism, cross-border crime and illegal migration. This requires each contracting state to permit automated searching of its national DNA database by all other contracting states. The principal purpose of the Treaty is to improve the exchange of information between contracting States by affording reciprocal access to national databases containing DNA profiles,[382] fingerprints[383] and vehicle registration data[384]. Two significant concerns have been raised in relation to the cross-border sharing of information : first, the treaty has privacy implications for all European Union citizens, 'primarily due to the absence of common legally binding data protection standards' and secondly, the absence of a harmonised approach to the collection and retention of samples will result in the sharing of sensitive information of innocent people.[385] Ratification of the Prüm Treaty by the Netherlands means that genetic information contained in databases in the Netherlands must be shared with other contracting States. The provisions of chapter 2 of the Treaty on reciprocal access to information held by another State are based on the principle of availability. This principle means that 'throughout the Union, a law enforcement officer in one Member State who needs information in order to perform his duties can obtain this from another Member State, and that the law enforcement agency in the other Member State which holds this information will make it

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[381] Council of the European Union *Prüm Convention* available at http://register.consilium.europa.eu/pdf/en/05/st10/st10900.en05.pdf accessed on 12 February 2012.

[382] Ibid Article 2.

[383] Ibid Article 8.

[384] Ibid Article 10.

[385] Sylvia Kierkegaard 'The Prüm decision – An uncontrolled fishing expedition in 'Big Brother' Europe' (2008) 24:3 *Computer Law & Security Report* 243.

available for the stated purpose.'[386] The requested information must be provided if it is available. In the light of the concerns mentioned above, this is not an ideal situation.

There are two major concerns relating to the taking of DNA samples for forensic use. The first concern relates to permissible DNA analysis for the purpose of determining ethnicity. This paves the way for human rights abuse, stigmatization, racial tension, targeting of certain ethnic groups and communities in the investigation of crime. This is bound to create problems in racially diverse countries. The second concern is that minors are treated no differently from adults. It is not clear how this fits in with the Riyadh Guidelines[387] issued by the United Nations, of which the Netherlands is a member. The Riyadh Guidelines are soft law and are not binding on international or national legislative bodies. This does not detract from the fact that it is a crucial proposal for the protection of children's interests. A positive aspect of the Dutch position is that it does not permit the permanent or indefinite retention of samples and profiles.

(ii) Genetic Research Databases

There are many public and private biobanks and research databases in the Netherlands.[388] There is, however, no specific legislation governing biobanks or research databases. Guidance may be found in the Personal Data Protection Act (PDPA)[389] but this is not adequate for regulation of biobank or database activities. Biobanking is different from traditional medical research so it cannot be adequately governed by laws pertaining to medical research. Specific policies and/or legislation are required to address issues such as informed consent, data sharing, and data security. Ethics Review Committees require more guidance in order to do justice to the review process and ultimately, to those individuals whose data are included in a biobank or database. Due to the large number of databases in the Netherlands the lack of regulation is cause for concern. Issues of consent, access to databases, ethics approval, sharing of data, returning of results to donors, and database governance need to be adequately addressed. A recent study

386 The Hague Programme, paragraph 2.1, agreed by the European Council on 4–5 November 2004.

387 Articles 5(e) and (f) of the UN Guidelines for the Prevention of Juvenile Delinquency (*The Riyadh Guidelines*) (1990) Adopted and proclaimed by General Assembly resolution 45/112 of 14 December 1990.

388 Eleni Zika, Daniele Paci, Tobias Schulte in den Bäumen, Anette Braun, Sylvie RijKers-Defrasne, Mylène Deschênes, Isabel Fortier, Jens Laage-Hellman, Christian A. Scerri, Dolores Ibarreta 'Biobanks in Europe: Prospects for Harmonisation and Networking' *European Commission* (2010) at 76.

389 Wet Bescherming Persoonsgegevens *Staatsblad* 302 (2000).

commissioned by the European Commission found that consent,[390] data sharing,[391] returning of results to donors,[392] access to database information,[393] and ethics approval[394] are not being approached in any consistent or uniform manner in the Netherlands. This is clearly not a satisfactory situation.

(b) Genetic Discrimination

Discrimination on grounds of genetic heritage is not specifically prohibited in the Netherlands. The Dutch Constitution stipulates in general that 'All persons in the Netherlands shall be treated equally in equal circumstances. Discrimination on the grounds of religion, belief, political opinion, race or sex or on any other grounds whatsoever shall not be permitted.'[395]

(i) Insurance

The Medical Examinations Act 1998[396] prohibits the insurer from requiring medical tests that could indicate that the applicant may be suffering from a severe, incurable disease. It provides that any testing for life insurance must not unreasonably infringe on a person's privacy.[397] A 'medical examination' must not include a test that entails a disproportionate risk for the subject when compared to the usefulness of the test for the requesting party.[398] Based on this, the Act also prohibits the use of presymptomatic or susceptibility genetic testing for serious, untreatable disorders. Article 5 of the Act, which deals with medical examinations for insurance purposes, prohibits insurers from requesting information about previous genetic tests and from questioning relatives regarding family history unless the sum insured exceeds a specified monetary limit ('the enquiry limit'). The said enquiry limit for life insurance was set 300,000 Dutch Guilders in

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390 Eleni Zika, Daniele Paci, Tobias Schulte in den Bäumen, Anette Braun, Sylvie RijKers-Defrasne, Mylène Deschênes, Isabel Fortier, Jens Laage-Hellman, Christian A. Scerri, Dolores Ibarreta *Biobanks in Europe: Prospects for Harmonisation and Networking* Report prepared for the European Commission (2010) at 82, available at http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=3259 accessed on 26 March 2012.

391 Ibid 81.

392 Ibid.

393 Ibid.

394 Ibid.

395 Article 1 of the Netherlands Constitution (17 February 1983).

396 Wet op de Medische Keuringen *Staatsblad* 365 (1997).

397 Ibid Article 3.

398 Ibid Article 3(2)(a).

1998, to be adjusted every three years according to the cost of living index.[399] This approach allows individuals to obtain a basic amount of life insurance.

(ii) Employment

The Medical Examinations Act 1998[400] applies equally to genetic testing in the employment sphere. Presymptomatic and predictive testing for serious, untreatable disorders are prohibited as this entails a disproportionate risk for the individual being tested as compared to the usefulness of the test for the employer. Section 4 prohibits medical testing of employees except where it is necessary to ensure that the employee will not pose a risk to his own safety or that of others while performing his duties. Section 5(2) provides that the necessary medical testing may be done only after all other recruitment procedures have been completed and the decision has been made to appoint the individual. Medical testing of the prospective employee must be the last step in the recruitment process, where appointment is subject to medical fitness.

(iii) Genetic Research

The Medical Research involving Human Subjects Act (WMO)[401] regulates medical research involving human participants in the Netherlands. It regulates two types of medical research in the Netherlands; namely, research in which participants are subjected to interventions and research which requires participants to follow specific behavioural rules.[402] It has been observed that the Netherlands was one of the first European countries to develop and implement research ethics committees.[403] The WMO establishes two types of research ethics committees, which are responsible for reviewing medical research protocols.[404] These committees are Medical Research Ethics Committes (METC) and the Central Committee on Research Involving Human Subjects (CCMO). The WMO requires all research involving human subjects to be assessed in advance by an ethics committee.[405] The type of research will determine which ethics committee

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399 Ibid Article 5(2).
400 Supra note 396.
401 Wet Medisch-Wetenschappelijk Onderzoek met Mensen *Staatsblad* 161 (1998).
402 Ibid s 1. Definition of 'research'.
403 Privireal Project (European Commission funded project examining the implementation of the Data Protection Directive 95/46/EC in relation to medical research and the role of ethics committees), available at http://www.privireal.org/content/rec/netherlands.php, accessed on 12 February 2012.
404 Supra note 401, ss 14 and 16.
405 Ibid s 2(2).

will review the research protocol.[406] The WMO stipulates that a research ethics committee may only approve a research protocol if it is satisfied that -

'(i) the trial could reasonably lead to the advancement of medical science;
(ii) the involvement of human participants is necessary to achieve the research objectives;
(iii) the benefits outweigh the risks to participants;
(iv) the methodology meets the requisite standard;
(v) the trial is to be performed at suitable institutions and by or under the supervision of persons possessing relevant research expertise;
(vi) monetary payments offered to participants would not unduly influence them to participate in the research;
(vii) any payments to be received by the investigator and the institution at which the trial takes place are reasonably commensurate with the nature, scale and purpose of the clinical trial;
(viii) the potential benefits to participants;
(ix) suitable criteria for the recruitment of subjects; and
(x) the trial satisfies all other criteria which may reasonably be set for it.'[407]

In addition to ethics committee approval, the WMO requires consent for participation in research.[408] This requirement is treated very seriously. Failure to obtain the requisite consent results in a penalty of imprisonment up to one year or a fine.[409] The penalty will be imposed regardless as to whether the contravention was intentional or not. The WMO also requires insurance[410] to cover losses due to death or injury. It provides that 'such insurance need not cover injury which is inevitable or almost inevitable, given the nature of the trial.'[411]

The WMO covers all of the ethically challenging issues that arise in the course of research involving human participants. Dute observes that the WMO has achieved its main objective which is to 'protect research participants without unnecessarily hampering the progress of biomedical research.'[412] It is evident that the WMO has achieved this balance. Section 12 places a duty on researchers to ensure that the privacy of research participants is respected 'as far as possible.' This is a positive factor for the protection of genetic privacy of genetic research participants. The WMO also imposes special consent requirements in respect of minors and those participants who are incapable of giving informed consent.[413] Although this is a good development for persons who fall into those categories, it does not accommodate other

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406 Ibid s 2.
407 Ibid s 3.
408 Ibid s 6.
409 Ibid s 33.
410 Ibid s 7.
411 Ibid s 7(1).
412 J.C.J. Dute 'Medical Research Involving Human Subjects Act' (2005) 5 *Health Policy Monitor* at 5-6, available at http://www.hpm.org/survey/nl/b5/1, accessed on 26 March 2012.
413 Supra note 401, ss 4 and 6.

vulnerable participants. The only grounds of vulnerability that are accommodated are age and capacity to consent. As argued in chapter three, this approach leaves a huge gap in protection for genetic research participants who may also be vulnerable albeit not for the traditional reasons. Although the WMO is a balanced piece of legislation, in its current form it is not entirely adequate for the purposes of the protection of genetic privacy.

(c) Privacy

The Constitution of the Netherlands contains an explicit right to privacy. Article 10 of the Constitution provides as follows:

> '(1) Everyone shall have the right to respect for his privacy, without prejudice to restrictions laid down by, or pursuant to, Acts of Parliament.
> (2) Rules to protect privacy shall be laid down by Act of Parliament in connection with the recording and dissemination of personal data.
> (3) Rules concerning the rights of persons to be informed of data recorded concerning them, of the use that is made thereof, and to have such data corrected shall be laid down by Act of Parliament.'

The Personal Data Protection Act of 2000[414] (PDPA) implemented the European Directive (95/46/EC) on the Protection of Individuals with regard to the Processing of Personal Data and the Free Movement of such Data.[415] Article 1 of the European Directive requires member States to protect the individual's right to privacy with respect to the processing of his/her personal data. The PDPA applies to the public and private sectors. It provides a generic framework for the processing of personal data. For this reason it has to be supplemented by sectoral legislation and codes of conduct. The PDPA treats medical data as special personal data and includes genetic data within the category of medical data.[416] It provides that personal data concerning 'inherited characteristics' may only be processed with respect to the data subject from whom such data was obtained.[417] The exceptions to the prohibition are 'where a serious medical interest prevails, or where the processing is necessary for the purpose of scientific research or statistics.[418]

Koops notes that 'the policy focus has been on "the law in the books", with a comprehensive Act containing open norms, supplemented by sectoral legislation with more specific norms and

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414 Supra note 389.
415 Supra note 105.
416 Supra note 389, Article16.
417 Ibid Article 21(4).
418 Ibid .

stimulation of codes of conduct.'[419] Unfortunately he goes on to point out that in 2011 less than ten codes of conduct had been approved, all of which were in the private sector and did not contain much more than the PDPA itself.[420] This clearly defeats the purpose of codes of conduct and doesn't take the implementation of the PDPA any further. Koops acknowledges that great strides have been made since the 1980's to protect personal data but he is also mindful of the 'considerable work (that) remains to be done to translate these open norms into workable, sector-specific and context-specific rules and practices.'[421]

The PDPA establishes a Data Protection Commission to oversee the processing of personal data[422] and to provide advice on draft legislation pertaining to the processing of personal data.[423] The Commission is authorised to impose specific sanctions against responsible parties for contraventions of the PDPA.[424] Koops notes that the Commission's '...enforcement and sanctioning powers are felt to be rather limited.'[425] He also observes that '…its advice is not always influential: the legislator pays token attention to the supervisory authority's judgment and suggestions…'[426]

All of Koop's criticisms are very important to take note of. They will serve as valuable lessons for South Africa since the South African Protection of Personal Information Bill[427] is modelled to some extent on the Dutch PDPA. South Africa has much to gain from the Dutch experience as far as the implementation of the legislation is concerned. Shortcomings in the PDPA have now been identified and more will surface as the different sectors attempt to implement the PDPA through codes of conduct. These developments will require ongoing monitoring if maximum benefit is to be gained from the Dutch experience.

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419 Bert-Jaap Koops 'The evolution of privacy law and policy in the Netherlands' (April 2011) 13:2 *Journal of Comparative Policy Analysis* 165 at 169.
420 Ibid.
421 Ibid.
422 Supra note 389, Article 51(1).
423 Ibid Article 51(2).
424 Ibid Articles 65 and 75.
425 Op cit note 419.
426 Ibid.
427 B9-2009.

(d) Privilege

Medical confidentiality is accorded great importance in the Netherlands. Physicians owe their patients a statutory duty of confidentiality in terms of the Medical Treatment Contracts Act of 1997. Article 457 of this Act requires physicians not to disclose patient information to third parties or to grant access to the patient's records, unless required by law to do so. Professional confidentiality is a two-pronged concept in the Netherlands. It entails an oath of secrecy as well as a privilege of non-disclosure as found in Article 218 of the Dutch Penal Code. It extends to employees of the physician as well, thereby ensuring maximum protection for the patient.

The approach of the Netherlands towards genetic information is not to introduce genetics-specific legislation where the existing general legal framework is able to address genetic-related issues. It is not unreasonable to suggest that since existing legislation already protects medical confidentiality, such protection should simply be extended to genetic information instead of trying to craft something new specifically aimed at genetic information. After all, the PDPA[428] already treats genetic information as a subcategory of health information for the purpose of information processing. Genetic information gained during the course of treatment by a physician can be handled just like other medical information for purposes of statutory confidentiality. If so, this means that genetic information would be protected from disclosure in Dutch courts. Unfortunately, since such a privilege would be based on a professional relationship and not on the nature of the information, it will be limited to genetic information gained in a clinical setting. It will not be possible to extend such a privilege to genetic information gained in the course of medical research by researchers who are not physicians. The recognition of a specific genetic information privilege may, however, still be possible as the Dutch are not completely averse to recognising new privileges. This recognition usually occurs through court cases. The position is therefore promising.

6.2.4 AUSTRALIA

In 2003 the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) undertook

[428] Supra note 389.

a joint inquiry into the protection of human genetic samples and information.[429] The project has been referred to as 'the most comprehensive consideration of the ethical, legal and social implications of the 'New Genetics' ever undertaken.'[430] Since the ALRC project covered all the legal, social, and ethical issues relating to genetic information, it is not necessary to repeat that process here. The ALRC inquiry examined the current position, identified the gaps/flaws, and made recommendations for reform. The focus here will be on the recommendations made by the ALRC. The report contains 144 comprehensive and well-reasoned recommendations for reform (ALRC Report).[431] On 9 December 2005 the Australian Government issued a formal response to the recommendations. Many of the recommendations in the report were accepted by the government.

The ALRC recently completed an in-depth investigation into Australian privacy law and practice.[432] This investigation focused on the effectiveness of the current Australian privacy framework. It entailed a critical analysis of every aspect of the Privacy Act 1988 (Cth) and other related legislation. The investigation culminated in a report containing 295 recommendations for reform.[433] Due to the large number of recommendations, the Australian government decided to respond in two stages. The first stage dealt with 197 recommendations. Some of the recommendations relating to health information privacy are relevant for this discussion. However, since no finality has been reached in respect of a number of the recommendations thus far,[434] they will be briefly discussed where necessary to highlight possible improvements in the Australian privacy framework which may benefit genetic privacy protection.

The Australian position is important to consider because it is a progressive one. A Human Genetics Advisory Committee has been established for the purpose of advising the NHMRC on high-level technical and strategic issues in human genetics, and on the social, ethical and legal implications of human genetics and related technologies.[435] This is a means of ensuring that

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[429] Australian Law Reform Commission (Project 26) *The Protection of Human Genetic Information in Australia* (2003).

[430] Australian Law Reform Commission Report 96 (Project 26) *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003) at 33.

[431] Ibid.

[432] Australian Law Reform Commission *Australian Privacy Law and Practice* (2006).

[433] Australian Law Reform Commission Report 108 *For Your Information: Australian Privacy Law and Practice* (2008).

[434] Progress updates available at http://www.dpmc.gov.au/privacy/reforms.cfm accessed on 20 February 2012.

[435] Available at http://www.nhmrc.gov.au/about/committees-nhmrc/human-genetics-advisory-committee-hgac accessed on 15 February 2012.

Australia keeps abreast of all developments in human genetics as well as the implications of such developments for healthcare, law, ethics, and policy. In a rapidly evolving and highly specialised field like human genetics, this is a useful and necessary mechanism which will enable government to be proactive in its handling of emerging issues.

(a) Genetic Databases

(i) Forensic DNA Databases

The Crimes Act 1914 (Cth) governs the operation of forensic DNA databases in Australia.[436] Australia has a national forensic DNA database called the National Criminal Investigation DNA Database ('NCIDD'). This database is operated by the Crim Trac Agency which is an executive agency of the Commonwealth government. The Australian Federal Police also have a DNA database for law enforcement purposes. The Crimes Act 1914 authorises the inclusion of crime scene, serious offenders, suspects, missing persons, volunteers, and statistical indexes in a national forensic DNA database. [437] Part 1D provides that intimate and non-intimate DNA samples may be taken from suspects, volunteers, and convicted persons.[438] The Crimes Act 1914 prohibits the conducting of a forensic procedure (taking of an intimate or non-intimate sample) on persons under the age of ten. [439] It provides for imprisonment to be imposed for contraventions of its provisions.

Part 1D of the Crimes Act governs the storage, use, disclosure, and removal of data held in a forensic DNA database. The following are offences under the Act, each of which is punishable by a penalty of imprisonment for a period of two years:

(i) Accessing of data stored in a forensic DNA database system except for specified purposes.[440]
(ii) Reckless matching of DNA profiles within the same index or with profiles in another forensic database index, which is not permitted under the Act.[441]
(iii) Reckless disclosure of data held in a forensic DNA database.[442]

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[436] Australia does have state and territory legislation relating to forensic DNA databases but a discussion of all is not possible within the limited parameters of this research.
[437] Crimes Act 1914 (Cth) , s 23YDAC.
[438] Div 6, ss 23XWE and 23XWQ(5).
[439] Ibid, s 23YQA.
[440] Ibid s 23YDAE.
[441] Ibid s 23YDAF.
[442] Ibid s 23YO.

(iv) Reckless retention of identifying information obtained from forensic material in a forensic database after the forensic material is required to be destroyed.[443]

Section 23YD of the Act provides that forensic material taken from a suspect[444] must be destroyed immediately if -

(i) 'an interim order for the carrying out of a forensic procedure is disallowed;
(ii) a period of 12 months has elapsed since the forensic material was taken and proceedings in respect of a relevant offence have not been instituted against the suspect or have been discontinued;
(iii) the suspect has been convicted but no conviction has been recorded; or
(iv) the suspect is acquitted and no appeal has been lodged against the acquittal or the acquittal is confirmed on appeal or the appeal is withdrawn.'

The ALRC considered the possibility of DNA profiles also being protected by the Privacy Act 1988.[445] The report notes that DNA profile information can be combined with information held by a DNA forensic laboratory to identify individuals from whom such profiles were obtained. This information then becomes identifiable information and will fall within the definition of 'personal information' under the Privacy Act 1988. Personal information is subject to the Information Privacy Principles and National Privacy Principles of the Privacy Act as discussed below.[446]

The ALRC report contains a discussion of both negative and positive aspects of database regulation.[447] All of the abovementioned sections are positive aspects of the regulation of forensic DNA databases in Australia. For the purposes of the discussion here, it is encouraging to note that there is formal regulation of forensic DNA databases which reduces the potential for inappropriate use, disclosure, and storage of DNA data in forensic databases.

(ii) Genetic Research Databases

Genetic research databases are regulated by a myriad of legislation, policies, and guidelines at State, territory, and federal level. The instruments that are relevant at federal level are the Privacy Act 1988 and the National Statement on Ethical Conduct in Research Involving Humans 2007 (issued by the NHMRC).

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443 Ibid s 23YDAG.
444 Ibid s 23WA defines a suspect to include 'A person who is suspected of having committed an offence; a person charged with an indictable offence; or a person who has been summoned to appear before court in respect of an indictable offence.'
445 Supra note 430 at 1073.
446 At 232 below.
447 Supra note 430 at 1071 –1089.

(1) Privacy Act 1988 (Cth)

The definition of a record under the Privacy Act includes a database. The Act applies to identifiable information only. Personal information is defined as 'information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.' This implies that de-identified genetic data will not be protected by the Privacy Act. Identifiable data will be protected under the Information Privacy Principles (IPPs) and the National Privacy Principles (NPPs). The basic difference between IPPs and NPPs is that the former apply to government agencies whilst the latter applies to the private sector. Both sets of principles deal with the collection, use, disclosure, and storage of personal information. With regard to storage of personal information, both provide that reasonable security safeguards must be implemented to prevent unauthorised access, use, modification, disclosure, and misuse. Both sets of principles also impose limits on use and disclosure of personal information contained in records. One of the glaring loopholes in the Privacy Act is the provision that the NPPs apply only to collections created after the date of commencement of the section, which is 21 December 2001.[448]

(2) National Statement on Ethical Conduct in Research Involving Humans (2007)

The ALRC recommended that the NHMRC should amend the National Statement on Ethical Conduct in Research Involving Humans 1999 to provide ethical guidance on the establishment, governance and operation of human genetic research databases.[449] The 2007 National Statement accordingly deals with 'databanks,' which is deemed to include databases. It includes an entire chapter dealing with databanks[450] in general whilst acknowledging that genetics is one of the areas that most commonly uses databanks.[451] The National Statement provides that the privacy of participants must be safeguarded.[452] It also recognises that the uses of certain data may be harmful to participants and therefore requires those who exercise control over data to limit or prohibit access to data.[453] This is a very important issue in respect of genetic databases which

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448 Privacy Act 1988 (Cth), s 16(C).
449 Supra note 431, recommendation 18-1.
450 National Health and Medical Research Council *National Statement on Ethical Conduct in Research Involving Humans* (2007) ch 3.2 at 29, available at http://www.nhmrc.gov.au, accessed on 15 February 2012.
451 Ibid.
452 Ibid clause 3.2.5 at 30.
453 Ibid clause 3.2.2 at 31.

contain information which may be used to discriminate against individuals in various areas such as insurance and employment. Such discrimination may extend beyond individuals to families, communities, ethnic groups, and even race groups.

The ALRC also recommended that the NHMRC should establish and administer a public register of human genetic research databases. It was further recommended that conditions of registration should be established and that no genetic research using information from a database should be allowed under the National Statement unless such database is registered. This recommendation was accepted in principle by the NHMRC. The National Statement does require researchers who are planning a databank to clearly indicate how the collection, storage, use, and disclosure of data will comply with its provisions.[454]

In addition to the abovementioned instruments, the different states and territories have their own pieces of legislation which will apply in circumstances where the application of the Privacy Act is excluded. There is often confusion about which legislation covers certain research.[455] Databases that are maintained by institutions which are considered by the Privacy Act to be 'state or territory authorities',[456] are governed by state or territory legislation. Unfortunately not all states have the relevant legislation so some research databases are not subject to any privacy legislation.[457] The ALRC cited the Menzies Centre for Population Research database within the University of Tasmania, as an example of a database that is not subject to any privacy legislation simply because Tasmania does not have such legislation.[458] This is a major gap in protection as it creates potential for misuse of research data.

The three major gaps in protection relate to de-identified genetic data, databases that were created prior to 21 December 2001, and databases that exist in states or territories which do not have the necessary legislation for privacy protection. The inadequacy of the regulatory framework led the ALRC to recommend that new regulation is necessary.[459]

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454 Ibid, clause 3.2.1 at 30.
455 Supra note 430 at 476.
456 Supra note 448, s 6(c).
457 Ibid.
458 Supra note 430 at 476.
459 Ibid 470.

(b) Genetic Discrimination

Australian law recognises direct[460] and indirect discrimination.[461] In both cases there is no need to prove intention to discriminate on the part of the person who is accused of discrimination. The ALRC noted that indirect discrimination is sometimes referred to as 'adverse impact discrimination because it focuses on the effect of the discriminator's action rather than on the attributes of the person towards whom the action is directed…'[462] Based on the conclusion of the ALRC that there is no need for specific legislation to deal with genetic discrimination, the government agreed that potential misuses of genetic information should be dealt with by the existing Disability Discrimination Act 1992.[463] This approach has merit insofar as the prevention of discrimination is concerned because the Disability Discrimination Act does prohibit discrimination based on genetic predisposition to disability[464] but it does not address the need for protection of genetic privacy. The protection of genetic privacy requires the restriction of access to genetic information rather than restrictions on the use of genetic information. Genetic privacy protection may therefore be considered to be proactive as opposed to the anti-discrimination approach which is reactive. The approach of the ALRC and the Australian government is therefore not satisfactory in the context of genetic privacy.

(i) Insurance

There is no specific legislation aimed at genetic testing in the insurance sphere. The potential impact of genetic testing on health insurance is of no relevance in Australia due to the system of universal health insurance. The National Health Act 1953 prohibits the discriminatory use of genetic information in private health insurance.[465] This discussion accordingly focuses on life insurance. The terms of reference of the ALRC investigation included the use of human genetic information in insurance as one of the areas requiring investigation. The report notes that concern about the use of genetic information by insurers was one of the factors giving rise to the inquiry.[466] In respect of insurance and genetic privacy the ALRC recommended that 'Insurers

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460 Disability Discrimination Act 1992 (Cth), s 5.
461 Ibid, s 6.
462 Supra note 431 at 295.
463 Supra note 430 at 301.
464 Supra note 460, s 4.
465 Section 73(2A) of the National Health Act 1953 (Cth).
466 Australian Law Reform Commission Report 96 (Project 26) *Essentially Yours: The Protection of Human Genetic Information in Australia*) at 652.

should review their consent forms, including medical authority forms, to ensure that they contain sufficient information about the collection, use and disclosure of genetic information to allow applicants to make an informed decision about whether to proceed with their application and consent to the collection of the information.'[467]

The Investment and Financial Services Association (IFSA)[468] has issued a genetic testing policy which applies to its members. This code, which was previously a voluntary industry code, has now become a mandatory standard for IFSA members. The Code provides inter alia as follows:

'(i) Insurers will not require applicants to undergo any genetic test.
(ii) Insurers may request disclosure of all existing genetic test results for the purposes of assessing risk.
(iii) Insurers will not offer insurance at lower rates based on the results of genetic tests.
(iv) When assessing the overall risk associated with a particular genotype, insurers will consider the existence of possible medical intervention and/or treatment.
(v) Insurers will ensure that results of existing genetic tests are only obtained with the written consent of the applicant.
(vi) The results of genetic tests will not be used in the assessment of insurance applications of relatives of the tested individual.
(vii) Insurers will ensure that strict standards of confidentiality apply to the handling and storage of the results of genetic tests.
(viii) Insurers will limit access to genetic test results to those who are involved in the underwriting assessment and other experts.
(ix) All underwriting decisions involving a genetic test should be thoroughly documented so that adequate information can be provided to the applicant on request.
(x) Insurers will provide reasons for their decisions relating to an application for insurance.'[469]

The Privacy Amendment (Private Sector) Act 2000, which came into effect on 21 December 2001, extended the application of the Privacy Act 1998 to private sector organisations. Since then private sector insurers are bound by the National Privacy Principles (NPPs) contained in the Privacy Act 1998. These NPPs regulate the use, storage, and disclosure of an insured individual's personal information. Insurers have the option to develop their own privacy codes which must be approved by the Privacy Commissioner.[470] Such approved privacy codes must

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[467] Supra note 430, recommendation 28-1.
[468] IFSA is the national not-for-profit organisation representing the life insurance industry to Government, regulatory agencies, consumers and the community.
[469] IFSA Standard No. 11.00(2005) available at http://www.ifsa.com.au/documents/IFSA%20Standard%20No%2011.pdf, accessed on 25 March 2009.
[470] Privacy Act 1998 (Cth), s16A.

provide the same level of protection that is afforded by the NPPs. In the absence of an approved privacy code, the NPPs will automatically apply.[471]

(ii) Employment

Australia does not have legislation specifically prohibiting employers from requiring employees to undergo genetic testing or to disclose results of previous genetic tests. In the course of its inquiry,[472] the ALRC did not find substantial evidence of 'broad-based and systematic collection' of genetic information by employers.[473] The ALRC nevertheless noted that 'federal anti-discrimination laws generally target the unlawful use of information, but it is also important to ensure that the information itself is protected by ensuring that genetic information is collected, used, stored and disclosed by employers only in appropriate ways.'[474] The Disability Discrimination Act 1992 (Cth) prohibits discrimination based inter alia on genetic predisposition to disability[475] but does not prohibit access to employees' genetic information. There is, however, nothing to suggest that such a right of access does exist. This point is made with the aim of supporting the observations of the ALRC.

The Privacy Act 1988 regulates the collection, use, storage, and disclosure of employees' personal information. The Information Privacy Principles (IPPs) apply to public sector employers. Since 21 December 2001 the National Privacy Principles (NPPs) apply to private sector employers unless they exercise the option of developing their own privacy code which has to be approved by the Privacy Commissioner.[476]

(iii) Genetic Research

Research involving human participants is well regulated in Australia by practice codes and legislation. The adequacy of these instruments in relation to genetic research is, however, questionable. There are major gaps in respect of enforceability and scope of application of practice codes. It is encouraging to note the acknowledgement of different types of harm in one

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471 Ibid s 16A(2).
472 Supra note 429.
473 Supra note 430 at 846.
474 Ibid 845.
475 Supra note 464.
476 Supra note 470.

of the Codes, as discussed below.[477] This express acknowledgement bodes well for the extension of the concept of vulnerability as discussed in chapter three. The codes and legislation, together with their respective flaws, positive attributes, and implications for genetic research, are discussed below.

(1) The Australian Code for the Responsible Conduct of Research (2007)

The Australian Code for the Responsible Conduct of Research was developed by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.[478] It replaced the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997). The Code is divided into two parts: Part A covers principles and practices which are intended to encourage responsible research conduct and part B provides a framework for resolving allegations of research misconduct as well as breaches of the Code. The Code requires researchers to comply with ethical principles of integrity, respect for persons, justice, and beneficence. Researchers are also required to obtain written approval from appropriate ethics committees, safety, and other regulatory bodies.[479] The emphasis of the Code is on responsible research. There are two obvious gaps in the protection offered by the Code. First, it does not deal specifically with human genetic research and secondly, compliance with the Code is required for receipt of National Health and Medical Research Council and Australian Research Council funding.[480] All other researchers and research institutions are merely encouraged to comply with the guidelines in the Code.

(2) *National Statement on Ethical Conduct in Research Involving Humans (2007)*

The aim of the National Statement is to promote ethics in research. The introduction to the Code states that 'The conduct of research in Australia is characterised by high ethical and scientific standards, and the dangers to participants have been few. The continued promotion of ethically good human research – the purpose of this National Statement – will help to maintain these standards.'[481] An entire chapter of the National Statement is devoted to human genetic

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[477] National Statement on Ethical Conduct in Research Involving Humans (2007).

[478] National Health and Medical Research Council, Australian Research Council and Universities Australia *Australian Code for the Responsible Conduct of Research* (2007) available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf accessed on 8 February 2012.

[479] Clause 1.8.

[480] Ibid 1.

[481] Chapter 2.1 at 15.

research.[482] The National Statement covers two aspects which are important for the purposes of this discussion. First, it requires researchers to protect the privacy of research participants and the confidentiality of genetic data because of the potential for genetic information to be used to stigmatise people or to unfairly discriminate against them. Specific reference is made to the areas of insurance and employment.[483] Researchers are required to inform research participants of such potential risks. Secondly, researchers are required not to transfer genetic data to any other researcher who is not involved in the particular research project except in specified circumstances.[484] This is meant to ensure that the privacy of participants remains protected.

The National Statement acknowledges the importance of a proper risk-benefit analysis in any research involving human participants.[485] In so doing it takes cognisance of the following types of harm:

> (i) 'Psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
> (ii) devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
> (iii) social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
> (iv) economic harms: including the imposition of direct or indirect costs on participants.'[486]

The recognition of these types of harm is very important for genetic research even though the Code does not specifically mention this.

The National Statement provides that genetic research involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC). In the course of conducting ethical assessments of research proposals, HRECs will consider the safeguards that researchers intend to put in place to protect the privacy of research participants. Unfortunately the guidelines are only enforceable against researchers who are funded by the NHMRC. Compliance by other organisations is purely voluntary, thus leaving a gap in protection.

(3) Privacy Act 1988 (Cth)

The Privacy Act contains Information Privacy Principles (IPPs)[487] and National Privacy principles (NPPs)[488] which regulate the collection, use, storage, and disclosure of personal

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[482] Supra note 450, ch 3.5.
[483] Ibid clause 3.5.6.
[484] Ibid clause 3.5.7.
[485] Supra note 481.
[486] Chapter 2.1 at 16.

information by public sector bodies and private sector organisations respectively. In an attempt not to unduly hamper medical research by insistence on compliance with the IPPs, the Privacy Act provides for deviation from the IPPs in the research context.[489] To meet this objective, s 95 of the Privacy Act authorises the NHMRC, subject to approval by the Privacy Commissioner, to issue guidelines for the conduct of health research which would otherwise be in breach of the IPPs. Compliance with the guidelines is sufficient to prove that particular research is not being conducted in breach of the IPPs. The approval of guidelines is not an automatic or 'rubber-stamping' function performed by the Privacy Commissioner. It requires the Commissioner to conduct a balancing exercise. To this end the Privacy Act provides that 'the Commissioner shall not approve the issue of guidelines unless he or she is satisfied that the public interest in the promotion of research of the kind to which the guidelines relate outweighs to a substantial degree the public interest in maintaining adherence to the Information Privacy Principles.'[490] In what may be considered a gesture of fairness in the whole process, the Act provides that 'where the Commissioner refuses to approve the issue of guidelines an application may be made to the Administrative Appeals Tribunal for review of the Commissioner's decision.'

The NHMRC, with the approval of the Federal Privacy Commissioner, issued guidelines under s95 of the Privacy Act in March 2000.[491] These guidelines are meant to be read in conjunction with the National Statement on Ethical Conduct in Research Involving Humans. It includes guidelines on the protection of privacy in the conduct of medical research; procedures to be followed by researchers; a prerequisite of approval by a Health Research Ethics Committee (HREC); guidance for HREC's in assessing research proposals which are in breach of IPPs; reporting requirements; and complaints mechanisms.

In a similar manner the Privacy Act also authorises deviations from the NPPs.[492] Section 95A allows the Privacy Commissioner to approve guidelines regulating the use and disclosure of health information for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety without obtaining consent of the individuals to whom

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487 Section 14.
488 Schedule 3.
489 Section 95.
490 Section 95(2).
491 National Health and Medical Research Council *Guidelines Under Section 95 of the Privacy Act 1998* (March 2000) available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e26.pdf accessed on 19 February 2012.
492 Section 95A.

such information relates.[493] The Commissioner may give such approval only if satisfied that the public interest in the use and disclosure of health information outweighs the public interest in maintaining the level of privacy protection afforded by the NPPs.

The Act also allows the commissioner to revoke approval if circumstances change such that he or she is no longer satisfied that guidelines are continuing to satisfy the necessary requirements for approval.[494] The power of the Commissioner to refuse approval or to revoke approval is subject to review. The Act clearly provides that 'application may be made to the Administrative Appeals Tribunal for review of a decision of the Commissioner to refuse to approve guidelines or to revoke an approval of guidelines.'[495] The NHMRC issued guidelines under s 95A of the Privacy Act in December 2001. The content of the guidelines is similar to that issued under s95 of the Privacy Act.

Section 95AA of the Privacy Act 1988 allows the Privacy Commissioner to approve, for the purpose of the NPPs, 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. As is the case in respect of sections 95 and 95A, the decision of the Commissioner to refuse approval may be reviewed by the Administrative Appeals Tribunal. Pursuant to s95AA, in October 2009 the NHMRC issued guidelines entitled 'Use and Disclosure of Genetic Information to a Patient's Genetic Relatives under Section 95AA of the Privacy Act 1988 (Cth).' These guidelines came into effect on 15 December 2009 and their purpose is to specify the requirements that must be met by health practitioners in the private sector when disclosing patients' genetic information without their consent. These Guidelines do not apply to clinical genetics services or other medical practices in the public health sector since the NPPs do not apply to the public sector. Furthermore, the guidelines only apply to genetic information collected on or after 21 December 2001; they only apply to genetic information about living persons; and they do not apply to the use of genetic information in human research. All of these exclusions are loopholes in the guidelines which, in the context of genetic privacy, may be considered to be serious flaws.

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493 Section 95A(2).
494 Section 95(A)6.
495 Section 95(A)7.

(c) Privacy

The Australian Federal Constitution does not contain specific provisions relating to privacy. Until recently there was no recognition of a general tort of invasion of privacy either. Privacy rights were pursued through actions for breach of confidence. It has been observed that 'as a result of the severe limits in Australia's constitution, common law rights, and international obligations in relation to protection of privacy, Australian law's protection of privacy has principally involved legislation, or attempts to legislate.'[496] Certain sectors and activities are accordingly governed by specific privacy statutes.

The Privacy Act 1988 is the main piece of federal legislation governing privacy in Australia. It regulates the handling of personal information in the public and private sectors. The Information Privacy Principles (IPPs) apply to the federal public sector whilst the National Privacy Principles (NPPs) apply to the private sector. Due to the constitutional framework that applies in Australia, the Privacy Act does not regulate the handling of personal information by state governments. The Privacy Act defines health information to include '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. [497] The definition of sensitive information includes 'genetic information about an individual that is not otherwise health information.' All of this means that genetic information is protected under the Privacy Act. The NPPs offer additional protection to genetic information which falls within the definition of 'sensitive information'.[498]

Two points are important to note in respect of the application of the Privacy Act to genetic information. First, genetic information is not defined in the Privacy Act. This is likely to pose interpretation and application problems due to the fact that various definitions of 'genetic information' are possible. Secondly, genetic information is dealt with just like other personal information. There are no separate provisions addressing privacy concerns which may be unique to genetic information. The inclusion of genetic information within the Privacy Act is a positive step but whether it is enough has yet to be decided.

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[496] European Commission 'Comparative Study on Different Approaches to New Privacy Challenges, in Particular in the Light of Technological Developments' *Country Study B.2 – Australia* (May 2010) at 2, available at http://ec.europa.eu/justice/policies/privacy/docs/studies/new_privacy_challenges/final_report_country_report_B2_australia.pdf accessed on 19 February 2012.

[497] Privacy Act 1988 (Cth), s 6.

[498] Ibid schedule 3, s 10.

One of the recommendations made by the ALRC in its report on privacy[499] is that the Privacy Act should be redrafted and restructured to achieve significantly greater consistency, clarity and simplicity.[500] The ALRC also recommended a rationalisation of the current NPPs and IPPs that would result in these principles being replaced by one set of principles regulating the handling of personal information.[501] The proposed new principles are referred to as Uniform Privacy Principles (UPPs). The Government agreed that the Privacy Act should be redrafted as recommended and that the current principles should be replaced by one set which should be referred to as Australian Privacy Principles (APPs) instead of UPPs. In June 2010 the Government released an exposure draft of the new APPs for comment. The APPs have not yet been finalised.

The ALRC recommended that those elements of the privacy principles that deal specifically with the handling of health information should be set out in new health-specific privacy regulations.[502] The Government rejected this proposal on the basis that it would create a 'multi-layered regulation of privacy' which could cause confusion. The proposal was not rejected in its entirety, though, as the Government agreed to address it in the Privacy Act itself.[503]

A very important recommendation is that relating to the protection of a right to personal privacy. The ALRC recommends that federal legislation should provide –

(a) for a statutory cause of action for a serious invasion of privacy including, but not limited to, the disclosure of sensitive facts relating to an individual's private life;[504]

(b) that, for the purpose of establishing liability, a claimant must show that he or she had a reasonable expectation of privacy and that the act complained of is highly offensive to a reasonable person of ordinary sensibilities;[505]

(c) that a claimant will not be required to furnish proof of damage and that only intentional or reckless acts will be actionable;[506] and

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499 Supra note 433.
500 Ibid recommendation 5-2.
501 Ibid recommendation 18-2.
502 Ibid recommendation 5-1.
503 Australian Government *First Stage Response to the Australian Law Reform Commission Report 108 For Your Information: Australian Privacy Law and Practice* (October 2009) at 22, available at http://www.dpmc.gov.au/privacy/alrc_docs/stage1_aus_govt_response.pdf accessed on 26 March 2012.
504 Ibid recommendation 74-1.
505 Ibid recommendation 74-2.
506 Ibid recommendation 74-3.

(d) an exhaustive list of defences.[507]

The ALRC also recommends that a court dealing with a statutory claim for serious invasion of privacy should be empowered by the federal legislation to choose the most appropriate remedy regardless of existing constraints[508] and that federal legislation should abolish any common law action for invasion of privacy upon enactment of a statutory cause of action. The majority of the recommendations are progressive. However, the restricted application of the proposed statutory cause of action to 'serious invasions of privacy' is cause for concern as it constitutes a serious limitation on the protection of a right to personal privacy. This concern cannot be alleviated by the proposed provision of a non-exhaustive list of the types of invasion that may fall within the statutory cause of action. It is difficult to fathom on what basis the ALRC draws a distinction between serious invasions of privacy and other invasions of privacy, all of which affect the right to personal privacy. Such a recommendation by the ALRC is not in keeping with the progressive tone that has been set by the rest of the report. These recommendations will be dealt with by the government in the second stage of its response.

(d) Privilege

The Australian common law does not recognise medical privilege. Statutory medical privilege does exist in three Australian jurisdictions; namely, Victoria, Tasmania, and the Northern Territory. Such privileges are limited in scope and only apply in civil litigation. It must also be noted that the privilege only applies in respect of information gained by medical professionals with a view to diagnosis and treatment of a patient.[509] It may be argued that if clinical genetic research by a medical professional is coupled with treatment of a patient, the information gained during such research should be privileged. Other genetic research will, however, not be subject to a privilege. In such a case a party to legal proceedings will have to rely on the court's general discretion to exclude certain evidence. The fact that three Australian jurisdictions recognise a medical professional privilege bodes well for the potential recognition of other privileges. There

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507 Ibid recommendation 74-4.
508 Ibid recommendation 74-5.
509 *Johnston v Commonwealth of Australia* [1974] V.R. 638 (SC of Victoria).

is a lack of rigidity in the Australian approach, which is a positive sign for the future protection of genetic privacy.

6.2.5 CANADA

Canadian developments are based largely on the work of the Canadian Biotechnology Advisory Committee (CBAC)[510] and the application of the Personal Information Protection and Electronic Documents Act (PIPEDA)[511] to genetic information. An analysis of the Canadian position is intended to demonstrate how general legislation may be used to protect genetic privacy. The CBAC noted the following in respect of genetic information protection in Canada:

> '…apart from legislation dealing with DNA in criminal investigations, most provisions relevant to genetic privacy and discrimination are not found in laws dealing specifically with genetic issues. Instead, they appear in more general legislation – constitutional laws, laws governing professional confidentiality, data protection (privacy) and human rights laws among them. Many of these general laws were drafted without genetics in mind. Nonetheless, they provide a substantial, if incomplete, legal framework for handling personal genetic information.'[512]

(a) Genetic Databases

Canada has a national DNA databank which is used for law enforcement purposes. The operation of this databank is governed by legislation.[513] Canada also has a large number of research biobanks.[514] A considerable amount of biobank activity is taking place in Canada for the purpose of genetic research but the exact number is unknown due to the fact that there is no formal process of registration for such biobanks.[515] The regulation of research databases is complex. As discussed further below,[516] the rigid distinction between public and private sector entities results in loopholes which can allow hybrid research databases to remain unregulated. For the purpose of the protection of genetic privacy, this is an issue that must be addressed.

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510 The mandate of the committee concluded in May 2007.
511 S.C 2000, C.5.
512 Eugene Oscapella (Canadian Biotechnology Advisory Committee) 'Protecting Privacy in the Age of Discrimination – Genetics, Privacy and Discrimination' *Project Report* (2004) at 6.
513 DNA Identification Act S.C. 1998.
514 Supra note 388 at 102.
515 Ibid.
516 At 94.

(i) Forensic DNA Databases

DNA evidence has been used in criminal prosecutions in Canada since 1988. The admissibility of such evidence was, however, called into question by the courts in cases where DNA samples had been obtained without the consent of the accused.[517] The unauthorised collection of biological samples was seen as an interference with an accused's right to bodily integrity. In order to alleviate the difficulties being experienced, the Criminal Code[518] was amended in 1995 and the DNA Identification Act[519] was passed in 1998. These created a legislative framework for the collection and use of DNA evidence. The DNA Identification Act came into force in 2000.

The DNA Identification Act[520] authorised the establishment of the National DNA Data bank to be maintained by the Commissioner of the Royal Canadian Mounted Police. The purpose of the databank is to assist law enforcement agencies in solving crimes. The databank consists of a Crime Scene Index (CSI) and a Convicted Offenders Index (COI). The CSI contains DNA profiles derived from bodily substances that are found:

(a) at any place where a designated offence was committed;
(b) on or within the body of the victim of a designated offence;
(c) on anything worn or carried by the victim at the time when a designated offence was committed; or
(d) on or within the body of any person or thing or at any place associated with the commission of a designated offence.[521]

DNA samples may only be taken if authorised under a warrant issued by a court. In deciding whether to issue a warrant, the judge must consider the nature of the designated offence, the circumstances of its commission, and whether a properly trained person is available to take the DNA sample.[522] The judge must also be satisfied that issuing the warrant would be in the best interests of the administration of justice.[523]

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[517] In *R.* v. *Borden*, [1994] 3 S.C.R. 145 and *R.* v. *Stillman*, [1997] 1 S.C.R. 607, the Supreme Court ruled DNA evidence inadmissible because bodily substances had been seized by police who had neither the consent of the accused nor any prior judicial authorization. The taking of bodily substances could not be justified as a search incidental to an arrest and violated the accused's rights under sections 7 and 8 of the Charter.
[518] Criminal Code R.S.C. 1985.
[519] DNA Identification Act S.C 1998.
[520] Ibid.
[521] Ibid s 5(3).
[522] Section 487.05(2) of the Criminal Code R.S.C. 1985.
[523] Ibid s 487.05(1)(d).

The COI consists of DNA profiles derived from bodily substances. DNA samples may be taken from offenders who were convicted before the DNA Identification Act came into effect.[524] A warrant is also required for the taking of a DNA sample from a suspect.[525] These samples must, however, be destroyed if the results of the DNA analysis establish that the bodily substance did not come from the suspect. Any profile derived from DNA analysis must be permanently deleted and may not be stored in any database.[526] The DNA sample must also be destroyed.[527]

Section 9 of the DNA Identification Act provides that information in the Convicted Offenders Index will be retained indefinitely. This section does, however, provide for permanent removal of access to this information in specified cases. It provides that where the conviction is quashed, access is removed immediately. In the case of an unconditional discharge, access is removed one year after the discharge, unless the person is convicted of another offence during that year. With a conditional discharge the rule is similar except that the time period is three years. Section 10(7) provides for the destruction of bodily samples in cases where the conviction is quashed or there has been a discharge. Where the conviction is quashed the sample is destroyed immediately. In the case of an unconditional discharge, the sample is destroyed one year after the person is discharged, unless the person is convicted of another offence during that year. With a conditional discharge the time period is three years.

The DNA Identification Act makes a concerted effort to protect the privacy of individuals from whom DNA samples are taken. The Act recognises that -

> '(a) the protection of society and the administration of justice are well served by the early detection, arrest and conviction of offenders, which can be facilitated by the use of DNA profiles; and
> (b) to protect the privacy of individuals with respect to personal information about themselves, safeguards must be placed on:
> (i) the use and communication of, and access to, DNA profiles and other information contained in the national DNA data bank, and
> (ii) the use of, and access to, bodily substances that are transmitted to the Commissioner for the purposes of this Act.'[528]

As regards the sharing of information with foreign law enforcement agencies, the DNA Identification Act provides that such sharing is only authorised if the Government of Canada or

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524 Ibid s 487.055.
525 Ibid s 487.05.
526 Section 8.1(b) of the DNA Identification Act 1998.
527 Section 487.09 of the Criminal Code R.S.C.1985.
528 Section 4 of the DNA Identification Act 1998.

one of its institutions has entered into an agreement or arrangement, in accordance with paragraph 8(2)(*f*) of the Privacy Act,[529] with that government, international organisation or institution, as the case may be. The sharing of information is only permitted for the purposes of the investigation or prosecution of a criminal offence.[530]

Section 11 of the Act imposes penalties for the use of biological samples or the communication of DNA analysis results, other than in accordance with the requirements of the Act. Pursuant to the passage of the DNA Identification Act and the accompanying DNA Identification Regulations, a DNA Data Bank Advisory Committee was established to monitor the operation of the data bank. This committee has an oversight role. It includes the Privacy Commissioner of Canada and representatives of the police, legal, scientific, and academic communities among its members. It is mandated to report and advise the Commissioner on all matters related to the effective and efficient operation of the databank and to assist in preventing potential misuse of DNA information. The setting up of such a Committee was recommended by the Standing Senate Committee on Legal Constitutional Affairs in its Sixteenth Report dated December 1998, wherein the need for an independent advisory committee was deemed necessary to review and advise on the implementation and ongoing administration of the National DNA Data Bank.'[531]

It is evident from the above discussion that the DNA Identification Act has many safeguards which ensure that the Canadian National DNA Data Bank is appropriately regulated with privacy interests in mind. In order to protect privacy the Act ensures inter alia that judicial authorisation is obtained for the taking of DNA samples, samples are only used for forensic DNA analysis, samples are used for identification purposes only, the retention of samples is only for the purpose of renewed profiling using new technologies, an oversight committee is formed, and only profiles as opposed to samples are shared with other governments. The court in *R v Rodgers*[532] found that 'the data bank provisions strike an appropriate balance between the public interest in the effective identification of persons convicted of serious offences and the rights of individuals to physical integrity and privacy.'

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529 R.S., 1985, c.P-21.
530 Ibid ss 6(3) – (5).
531 Available at http://www.rcmp-grc.gc.ca/dna_ac/index_e.htm , accessed on 21 December 2008.
532 [2006] 1 S.C.R. 554.

(ii) Genetic Research Databases

In August 2010 Canada's three federal research agencies, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), issued the second edition of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS).[533] This is a joint policy of the three agencies. In order to receive funding from these agencies, researchers must agree to comply with the TCPS. Chapter 13 of the TCPS deals exclusively with human genetic research. Article 13.7 of the TCPS provides as follows:

> '(a) Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings, and withdrawal by participants, as well as future contact of participants, families, communities and groups.
> (b) Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.'

The TCPS defines a biobank as 'a collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected.' This clearly covers research databases and is not limited to collections of biological material. Article 12.5 provides that:

> '[i]nstitutions and researchers that maintain biobanks -
>
> (a) shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards; and
> (b) shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorised handling.'

The abovementioned guidelines are only applicable to research that is funded by the three federal agencies. Private biobanks which fall within the scope of PIPEDA[534] will be bound by the PIPEDA requirements for storage and disclosure of personal health information, which may include genetic information. The challenge lies in respect of those biobanks which cannot be classified as purely public or private, more particularly those which are public-private partnerships. It has been observed that 'the frequent, watertight dichotomy between public

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[533] Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2ed (August 2010) available at http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf accessed on 23 February 2012.

[534] Supra note 511.

sector or private sector privacy legislation fails to recognise current hybrid biobank structures, which often serve as resources for future, unspecified research which may or may not include commercial support or use. Constitutional divisions between trade and commerce (federal jurisdiction) and healthcare and civil rights (provincial jurisdiction) also complicate the modern, mixed picture.'[535] Sheremeta concludes that 'the existing legislative framework is complex and may compel consideration of biobank-specific legislation that could address the complex privacy issues.'[536] This may be the only solution and even though Canada has not adopted genetic-specific legislation it has clearly recognised that genetic information needs to be dealt with differently in certain circumstances. The TCPS, which includes a separate chapter on genetic research, is an example of this approach. There is clearly a major gap in the regulatory framework which has to be closed and it appears that the only way to achieve this in such a complex system is through specific legislation.

(b) Genetic Discrimination

Canada does not have specific legislation dealing with genetic discrimination by insurers or employers. It has been noted that the Canadian position 'contrast(s) starkly with leading norms in Europe, the U.S. and the international community, where a growing number of jurisdictions provide explicit and often stringent statutory protection of genetic and health privacy. Canadians would seem to enjoy less clear, less rigorous and likely, fewer protections of genetic privacy than do many citizens of Europe and the U.S.'[537]

(i) Insurance

The Personal Information Protection and Electronic Documents Act (PIPEDA)[538] is a federal statute which regulates how private-sector organisations collect, use and disclose personal

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[535] Edward S. Dove, Lee Black, denise Avard & Bartha M. Knoppers 'Privacy in Canadian Paediatric Biobanks: A Changing Landscape' *Report Delivered to the Office of the Privacy Commissioner of Canada'* (August 1, 2011) available at http://www.humgen.org/int/GI/Privacy_in_Canadian_paediatric_Biobanks.pdf, accessed on 23 February 2012.

[536] Lorraine Sheremata 'Population Biobanking in Canada: Ethical, Legal and Social Issues' *Document Prepared for the Canadian Biotechnology Advisory Committee* (2004) available at http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/enah00482e.html, accessed on 14 June 2007.

[537] Health Canada 'Selected Legal Issues in Genetic Testing: Guidance from Human Rights' at 1, available at http://www.hc-sc.gc.ca, accessed on 6 September 2006.

[538] Supra note 511.

information in the course of commercial business. As of 1 January 2004, PIPEDA applies to commercial activities of life and health insurers in those provinces which have not adopted 'substantially similar' legislation. PIPEDA accordingly applies throughout Canada with the exception of Québec, Alberta, and British Columbia. It has been observed by the insurance industry that 'the requirements in the legislation are similar to the industry guidelines that life and health insurers had been following since 1980, and complement long-standing industry practices.'[539]

PIPEDA draws a distinction between personal information and personal health information. Personal information is defined as 'information about an identifiable person but does not include the name, title or business address or telephone number of an employee of an organization.' Personal health information is defined as:

> '(a) information concerning the physical or mental health of the individual;
> (b) information concerning any health service provided to an individual;
> (c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;
> (d) information that is collected in the course of providing health services to the individual; or
> (e) information that is collected incidentally to the provision of health services to the individual.'[540]

PIPEDA does not specifically refer to genetic information. It is nevertheless possible to interpret the definition of 'personal health information' to include genetic information. In this way it would be possible to extend the protection offered by PIPEDA to cover genetic information.

The policy in the insurance industry is that insurers will not request genetic testing as a prerequisite for insurance. Insurers believe that they are, however, entitled to results of genetic tests that were conducted prior to an application for insurance. In 2000 the Canadian Life and Health Insurance Association (CLHIA) issued a position statement on genetic testing, which was last updated in April 2010.[541] The pertinent points made in the policy are as follows:

> '(i) Information derived from genetic tests is medical information that is potentially relevant to risk classification.[542]

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[539] Canadian Life and Health Insurance Association Inc. *CLHIA Position Statement on Genetic Testing* (April 2010) at 3, available at http://www.clhia.ca/domino/html/clhia/CLHIA_LP4W_LND_Webstation.nsf/resources/Guidelines/$file/Genetic_Testing_CLHIA_Industry_Position_2010.pdf accessed on 21 February 2012.

[540] Supra note 511, s 2(1).

[541] Supra note 539.

[542] Ibid 1.

(ii) No genetic information will be used in risk assessment unless its actuarial relevance has been scientifically proven.[543]
(iii) Genetic information will be treated with utmost confidence and will not be disclosed to any other party except with the consent of the applicant or as required by law.[544]
(iv) Genetic information will be used only for risk assessment purposes.[545]
(v) Genetic information will only be collected with the consent of the applicant for insurance.'[546]

The CLHIA has also issued a Consumer Code of Ethics in terms of which all CLHIA members agree 'to respect the privacy of individuals by using personal information only for the purposes authorised and not revealing it to any unauthorised person.'[547] The Genetic Testing Position Statement indicates that 'personal information' includes genetic information. The CLHIA is, however, merely a voluntary trade association even though its membership accounts for 99 percent of the life and health insurance in force in Canada. It can accordingly not guarantee genetic privacy protection. The current position is flexible but not ideal.

(ii) Employment

There is no legislation which specifically protects genetic information privacy in the employment sphere. The Privacy Act[548] regulates the collection, disclosure, storage, and protection of information by federal government agencies. The definition of 'personal information' under the Act includes the medical history of identifiable individuals.[549] This could possibly be interpreted to include the results of genetic tests that have been undergone by employees of federal government agencies. PIPEDA plays the same role in the private sector. It protects 'personal information about employees of an organisation that collects, uses, or discloses the information in connection with the operation of a federal work, undertaking, or business. It is unlikely that PIPEDA will protect genetic information of employees because it applies to 'personal information' and not to 'personal health information' of employees. As discussed above,[550] it is only the definition of 'personal health information' that may be interpreted to include genetic information. Such interpretation is not possible with the definition of 'personal information'.

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543 Ibid.
544 Ibid.
545 Supra note 539 at 2.
546 Ibid.
547 Principle 8.
548 Supra note 529.
549 Ibid s 3.
550 At 241.

This means that genetic information of private sector employees will not be protected by PIPEDA.

(iii) Genetic Research

The TCPS[551] provides that research involving living human participants requires ethics review and approval by a Research Ethics Board (REB) before the research commences. It also requires such approval for research involving human biological materials, derived from living and deceased individuals. Human biological materials include tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids. This clearly encompasses genetic research.

Chapter 13 of the TCPS[552] deals exclusively with genetic research. The introductory section explains why genetic research demands a slightly different approach. It states as follows:

> 'Research may help us better understand the human genome, and genetic contributions to health and disease. It may lead to new approaches to preventing and treating disease. Individuals may benefit from learning about their genetic predispositions, if intervention strategies are available to prevent or minimize disease onset and mitigate symptoms, or to otherwise promote health. Genetic research also has the potential, however, to stigmatize individuals, communities or groups, who may experience discrimination or other harms because of their genetic status, or may be treated unfairly or inequitably.'[553]

It is also emphasized that chapter 13 'does not reiterate guidance set out in earlier chapters. Rather it focuses on issues that arise specifically in the context of human genetic research and provides guidance for managing information revealed through genetic research, provision of genetic counselling, participation of families, communities and groups in genetic research, banking of human biological materials, and research involving gene transfer.'[554] Researchers are expected to include in the research proposal a plan for managing information that may be revealed in the course of genetic research; submit the plan to the Research Ethics Board; and advise prospective participants of the plan.[555] The aim of this chapter is clearly to prevent the potentially harmful consequences of the disclosure of genetic information.

In addition to the genetic-specific requirements contained in chapter 13, researchers are expected to abide by all the other relevant provisions in the TCPS. Article 13.1 states that

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551 Supra note 533, Article 2.1
552 Ibid.
553 Ibid para 3.
554 Ibid Article13.1.
555 Ibid Article 13.2.

'[g]uidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials and other ethical guidance described in earlier chapters of this Policy apply equally to human genetic research.' Researchers are also expected to comply with applicable legal and regulatory requirements. What is applicable will depend on the jurisdiction within which the research is being conducted and on the source of funding. This is due to the Canadian constitutional dispensation as well as the distinction that is drawn between the private and public sectors. In the event of a conflict between the TCPS and the law, researchers should comply with the law. Privacy rights must, however, be respected at all times in accordance with the Canadian Charter of Rights and Freedoms. As far as private sector research is concerned, researchers may have to comply with PIPEDA or similar provincial legislation in order to ensure that the rights of research participants are protected.

(c) Privacy

The Canadian Charter of Rights and Freedoms[556] does not include a specific right to privacy. Section 7 of the Charter provides a right to liberty and security of the person whilst section 8 provides a right to be free from unreasonable search and seizures. The courts have interpreted the rights under sections 7[557] and 8[558] of the Charter as protecting citizens against unreasonable invasions of privacy by government agencies. The court in *R. v O' Connor* made it clear, however, that the right to privacy is not absolute and 'must be balanced against legitimate societal needs.'[559] It is not certain whether the courts will extend the interpretation to protect genetic privacy. The approach of the Canadian Supreme Court in the following cases has been positive. In *R v Big M Drug Mart Ltd.* the Supreme Court stated that the rights guaranteed in the Charter 'must be interpreted generously and not in a narrow or legalistic fashion.'[560] In *Hunter v Southam Inc.* Dickson J stated that the function of the Charter is 'to provide…for the unremitting protection of individual rights and liberties.'[561] These sentiments were reiterated by the Supreme Court in *R v Dyment*.[562]

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556 Constitution Act 1982, Part I.
557 *R. v O'Connor* [1995] 4 S.C.R. 411.
558 *R v Dyment* [1988] 2 S.C.R. 417.
559 Supra note 557 at 485.
560 [1985] 1 S.C.R. 295 at 344.
561 [1984] 2 S.C.R. 145 at 155.
562 Supra note 558.

The Supreme Court of Canada has clearly acknowledged a right to privacy stemming from other rights in the Charter. In *Hunter v Southam Inc.* Dickson J stated that the purpose of s 8 'is…to protect individuals from unjustified intrusions upon their privacy.'[563] The rights in the Charter are only enforceable against the government and have no horizontal application. This will prove to be a limiting factor in the protection of genetic privacy since a considerable amount of genetic information is handled in the private sector. What is important to note here, though, is that it may be possible to protect genetic privacy on the basis of the existing rights in the Charter. This lies in the hands of the Canadian courts.

Canada has two federal privacy statutes; namely, the Privacy Act[564] and PIPEDA.[565] The Privacy Act regulates the collection, disclosure, storage, and protection of personal information in the federal public sector whilst PIPEDA addresses the same issues in the private sector. Neither of these statutes refers specifically to genetic information. In order to enjoy the protection afforded by these statutes in their current form, it will be necessary to show that genetic information is encompassed within the definitions of the information which is subject to their protection. The definition of 'personal information' under the Privacy Act includes the medical history of identifiable individuals.[566] This could possibly be interpreted to include genetic information. PIPEDA deals with personal and personal health information. The definition of 'personal health information' includes 'information derived from the testing or examination of a body part or bodily substance of the individual.' This can undoubtedly cover genetic information since DNA is derived from bodily substances.

Both statutes are overseen by the Privacy Commissioner of Canada who receives complaints, conducts investigations and issues findings. The Commissioner can make recommendations, which are non-binding, but is not authorised to issue orders or impose penalties. The Commissioner is expected to conduct periodic audits of both federal institutions and private organisations for the purpose of determining their compliance with the respective statutes.

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563 Supra note 561 at 160.
564 Supra note 548.
565 Supra note 538.
566 Supra note 548, s 3.

(d) Privilege

Two of the foundational rules of litigation are that parties must disclose all relevant documents and witnesses must answer all questions put to them. There are, however, exceptions to these rules in the form of legal privilege. Canadian law recognises three legal privileges; namely, solicitor-client privilege; litigation privilege; and settlement privilege. In addition to these privileges the courts are willing to recognise other claims of privilege which satisfy Wigmore's four-part test as discussed in chapter five. The test requires that:

(i) the communications must originate in a confidence that they will not be disclosed;

(ii) this element of confidentiality must be essential to the full and satisfactory maintenance of the relationship between the parties;

(iii) the relationship must be one which in the opinion of the community ought to be 'sedulously fostered'; and

(iv) the injury that would inure to the relation by the disclosure of the communications must be greater than the benefit thereby gained for the correct disposal of litigation.

The decision of the Supreme Court in *M. (A.) v. Ryan*[567] is important for any discussion on the recognition of new claims of privilege in Canada. This case dealt with a psychiatrist's claim that the contents of a patient's file were protected from disclosure by a privilege. Since there is no blanket privilege for communications between patient and physician, the court applied the Wigmore test to the facts of the case. It found that the first three requirements were satisfied. In respect of the fourth requirement, the court pointed out that the common law must develop in a way that reflects Charter values, including the interest in privacy. The court found that there was a compelling interest in protecting the communications at issue from disclosure but indicated that such compelling interest had to be balanced against the interest in the correct disposal of litigation. This, according to the court, would not have to result in any one of the interests at stake being subordinated to the other if the idea of a 'partial privilege' is accepted. The court noted that 'disclosure of a limited number of documents, editing by the court to remove non-essential material, and the imposition of conditions on who may see and copy the documents are techniques which may be used to ensure the highest degree of confidentiality and the least damage to the protected relationship, while guarding against the injustice of cloaking the truth.'

[567] [1997] 1 SCR 157.

McLachlin J, on behalf of the majority, concluded that a judge may afford a privilege to psychiatrist-patient records in appropriate circumstances.

The reasoning by the majority in this case is important for the protection of genetic information. The concept of a partial privilege indicates progressive thinking based on constitutional values. The following comments by the majority are important for the purpose of assessing the Supreme Court's attitude towards the recognition of new heads of privilege:

(i) 'While the circumstances giving rise to a privilege were once thought to be fixed by categories defined in previous centuries…it is now accepted that the common law permits privilege in new situations where reason, experience and application of the principles that underlie the traditional privileges so dictate.'[568]

(ii) '…the law of privilege may evolve to reflect the social and legal realities of our time, including the Canadian Charter of Rights and Freedoms.'[569]

(iii) '…the common law must develop in a way that reflects emerging Charter values. It follows that the factors balanced under the fourth part of the test for privilege should be updated to reflect relevant Charter values. One such value is the interest affirmed by s.8 of the Charter of each person in privacy.'[570]

The attitude of the Supreme Court is positive even though Canada does not recognise a general physician-patient privilege. The courts have not yet dealt with a claim of privilege based on confidential genetic information. Recognition of a genetic information privilege will depend on the nature of the relationship within which genetic information is imparted as well as whether the court will find the interest in preserving confidentiality to be compelling. If the court finds that the first three requirements of the Wigmore test are satisfied and that there is a compelling interest in protecting the confidentiality of genetic information, it may extend at least a partial privilege to genetic information. This will be a great step towards the protection of genetic privacy in Canada.

6.3 CONCLUSIONS

The cross-jurisdictional review has focused on legal, ethical, and policy developments in the UK, USA, Australia, Canada, and the Netherlands. It is established that although the approaches in the jurisdictions under review vary in form and scope, there is a common underlying attempt to allay fears of genetic discrimination in the interest of a greater good, which is that of promoting

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568 Ibid para 20.
569 Supra note 567 para 21.
570 Ibid para 30.

the science of genetics for the benefit of future generations. The importance of genetic research is acknowledged in all jurisdictions although none require additional protection for those human participants who do not fall into the traditional categories of vulnerable groups. This is a common gap that has been identified.

In addition, the following conclusions have been reached:

(1) There are two basic approaches to the protection of genetic information; namely, the privacy approach and the anti-discrimination approach. The anti-discrimination approach, which protects individuals against potentially harmful uses of genetic information, tends to be frequently used. This must be attributed to attempts to allay fears of genetic discrimination.

(2) The privacy model, which represents a paradigm shift from a reactive to a proactive model of genetic information protection, has not yet been fully explored in other jurisdictions.

(3) Even though the anti-discrimination approach has merit, it is inadequate as it does not curb the indiscriminate flow of highly sensitive information. In order to provide maximum protection, anti-discrimination legislation must therefore be complemented by privacy protection mechanisms.

(4) Genetic research databases are not adequately regulated. Self-regulation is often the norm.

(5) There is no common approach to the use of genetic information by insurers.

(6) Human genetic research participants are not adequately protected against potential discrimination and stigmatisation. This inadequacy is most noticeable in private sector research.

(7) The concept of a genetic information privilege has not yet been investigated. There appears to be little scope for the recognition of such a privilege.

The cross-jurisdictional review has revealed merits, flaws, and gaps in the approaches adopted by the various jurisdictions. No jurisdiction has yet developed optimal protection for genetic information. The current approaches focus mainly on the prevention of discrimination and may therefore be described as one-dimensional and inadequate. Nevertheless, every jurisdiction does offer potential solutions and lessons based on experience. These are valuable lessons for South Africa.

CHAPTER VII

LEGAL, ETHICAL, POLICY AND INDUSTRY DEVELOPMENTS IN SOUTH AFRICA

7.1 INTRODUCTION

Genetic information privacy is a relatively new concept which arose in response to concerns created by the completion of the Human Genome Project in 2003. The South African approach to genetic information is still very much in a state of infancy, hence the notable absence of a unified effort to address this issue. As a result, a discussion of the South African approach requires a consideration of relevant legislation, policies, ethical guidelines and industry codes. This chapter identifies those instruments which are or could be relevant to genetic information and aims to determine whether, and in what respects, they may protect genetic privacy.

No similar comprehensive study has been undertaken in South Africa. The closest attempt has been a brief study of the legal regulation of genomics research in South Africa by Slabbert.[1] This study assessed relevant constitutional provisions, legislation, common law principles, ethical guidelines, and the role of ethics committees/IRBs[2] in regulating genomics research. Slabbert concluded that there is currently a legal vacuum in this area and that a legal framework is required for the regulation of genomics research.

The National Health Research Ethics Council (NHREC) undertook an even more focused audit of the laws and guidelines which provide protection for vulnerable research participants in South Africa. In July 2011 a draft report was released for public comment.[3] The audit reviewed primary legislation, subordinate legislation, ethical

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1 Melodie Slabbert *Legal Regulation of Genomics Research in South Africa*, available at http://www.nstf.org.za/ShowProperty?nodePath=/NSTF%20Repository/NSTF/files/Workshops/2011/HGLegalregulation.pdf, accessed on 22 April 2012.

2 Institutional Review Boards.

3 NHREC Draft Report *Ethical-Legal Protection for Vulnerable Research Participants in South Africa: An Audit of Relevant Laws and Ethical Guidelines* (July 2011) available at www.nhrec.org.za/wp-content/uploads/2011/ethicalguidelines.pdf , accessed on 22 April 2012.

guidelines, and policies relating to vulnerable research participants.[4] The audit did identify gaps in the legal[5] and ethical[6] frameworks. It did conclude that the ethical framework offers more comprehensive protection than the legal framework does.[7] Of interest is its other finding that the law does not contain a definition of vulnerability.[8] Unfortunately the audit concentrated solely on vulnerable research participants and in this sense, the audit and its findings are limited.

The following instruments are accordingly discussed in this chapter with the aim of providing a more complete assessment of the state of genetic privacy protection in South Africa:

1. National Health Act;[9]
2. Regulations relating to stem cell banks;[10]
3. Regulations relating to the use of human biological material;[11]
4. Employment Equity Act;[12]
5. Protection of Personal Information Bill;[13]
6. Criminal law (Forensic Procedure) Amendment Bill.[14]
7. Human Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth Defects and Disabilities;[15]
8. National Guidelines for the Care and Prevention of the Most Common Genetic Disorders, Birth Defects and Disabilities;[16]
9. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa;[17]

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4 Ibid Appendices A – D.
5 Ibid 13.
6 Ibid 22.
7 Ibid 22-23.
8 Ibid 13.
9 Act 61 of 2003.
10 GN R.183 *GG* 35099 of 2 March 2012.
11 GN R.177 *GG* 35099 of 2 March 2012.
12 Act 55 of 1998.
13 B9-2009.
14 B2-2009.
15 Department of Health , Pretoria, South Africa (2001).
16 Department of Health, Pretoria, South Africa (2005).
17 Department of Health , Pretoria, South Africa (2006).

10. Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research;[18]

11. Code of Ethical Practice for Medical Biotechnology Research in South Africa;[19]

12. Guidelines for Good Practice in the Health Care Professions – Confidentiality: Protecting and Providing Information;[20]

13. Code of Genetic Testing;[21] and

14. National Patients' Rights Charter.[22]

Based on discussions of the abovementioned instruments, conclusions regarding the current state of genetic information protection in South Africa are reached at the end of this chapter.

7.2 LEGISLATION

(1) National Health Act 61 of 2003

In terms of s 27(2) of the South African Constitution[23] the State must take reasonable legislative and other measures within its available resources to achieve the progressive realisation of the right of the people of South Africa to have access to health care services. The National Health Act[24] may be regarded as the most important piece of legislation in the health sector since it gives effect to this section of the Constitution. It establishes a framework for a structured uniform health system. The framework is intended to be supplemented by regulations issued by the Minister of Health as and when required.

The objective of the National Health Act is to regulate national health and to provide uniformity in the provision of health services.[25] One of the means of achieving this objective is by protecting, respecting, promoting and fulfilling the rights of vulnerable

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18 South African Medical Research Council (2002).
19 A Dhai, N Msomi & DJ McQuoid-Mason (2005).
20 Health Professions Council of South Africa, Booklet 10, Pretoria, South Africa (2008).
21 Association of Savings and Investment SA *Standard on Genetic Testing* (2009) available at http://www.asisa.org.za/index.php/members/codes.html accessed on 7 February 2011.
22 Department of Health *The Patients' Rights Charter* (1999).
23 Constitution of the Republic of South Africa Act 108 of 1996.
24 Supra note 9.
25 Supra note 9 s 2.

groups. The Act specifically seeks to protect the rights of vulnerable groups such as women, children, older persons, and persons with disabilities.[26] I would argue that the express reference to vulnerable groups can facilitate the protection of genetic information in two ways. First, based on the wording of the Act, the list of vulnerable groups is not exhaustive. This means that those research participants who qualify as 'vulnerable' can derive protection from the Act. The challenge, however, lies in the fact that the law does not define vulnerability.[27] It simply refers to certain groups as being vulnerable. This makes it difficult to argue for the inclusion of new groups in the category of vulnerable research participants. Despite the envisaged difficulty, extensive arguments for such inclusion have already been made in chapter three and are therefore not repeated here.

The National Health Act[28] grants specific protection to research participants by providing that research or experimentation on a living person may only be conducted in the prescribed manner and with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences for his or her health.[29] As discussed in chapter three, the issue of vulnerability in research is a complex one. It is often assumed, as is evident from the reading of section 21(1), that informed consent can eliminate vulnerability. This is not entirely correct, especially in the case of genetic research. Participants in genetic research are vulnerable due to the risk of genetic discrimination based on their participation in as well as the findings of genetic research. Viewed from this perspective, it appears that section 21(1) would not address the concerns of genetic research participants.

Secondly, it is possible to include persons who have genetic disorders within the category of 'persons with disabilities'. This is particularly relevant for individuals who are diagnosed with genetic disorders but are presymptomatic. Those who do display symptoms can be classified as disabled based on the nature or severity of visible symptoms. A finding of disability can be made by observation or physical examination of the individual by a medical practitioner. When symptoms are present, there would be no problem in determining disability. The matter becomes complicated when faced with

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26 Ibid s 2(c)(iv).
27 Supra note 3 at 13.
28 Supra note 9.
29 Ibid s 21(1).

an individual who has been diagnosed with a genetic disease but has not yet started to display external symptoms. The time of onset of the disease may not be predictable. As a precautionary measure such individuals may be excluded from particular types of employment because of the potential threat they pose to others. The typical scenario is that of airline pilots and machine operators as discussed in chapter three. Such individuals may be considered to have a disability even though there is no external manifestation of disease. Not every genetic disorder may qualify as a disability but there is scope for the inclusion of certain genetic disorders. Examples would be those that render the individual ineligible for certain types of work even though he or she does not display symptoms of disease. I would argue that individuals with such genetic disorders should be entitled to protection under the Act on the basis of disability.

Section 13 of the National Health Act[30] requires persons in charge of health establishments to ensure that a health record for every user of health services is created and maintained at the health establishment. The person in charge must also implement measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, records are kept.[31] Failure to do so amounts to an offence for which the penalty is a fine, imprisonment for a period up to one year or both a fine and imprisonment. Section 14 of the National Health Act[32] protects the right to confidentiality. It provides that no information about a health services user may be disclosed unless the user consents to that disclosure in writing; a court order or any law requires that disclosure; or non-disclosure of the information represents a serious threat to public health.

All of the abovementioned sections of the Act are designed to protect users of health services. Vulnerable groups are expressly mentioned. The right to privacy is given due consideration by virtue of the protection of confidentiality[33] and by prohibition of the unauthorised disclosure of health records.[34] The regulations which are discussed below have been issued in terms of the National Health Act 61 of 2003.

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30 Supra note 9.
31 Ibid s 17.
32 Supra note 12.
33 Ibid s 14.
34 Ibid s 16.

(2) Regulations Relating to Stem Cell Banks[35]

These regulations were issued in terms of s 68 of the National Health Act.[36] Section 68 only came into operation on 17 May 2010.[37] The regulations deal inter alia with the use, processing, storage, and distribution of stem cells. Regulation 9(d) requires a stem cell establishment to store data for a period of thirty years after donation or clinical use so as to ensure traceability. Regulation 10 provides that all data, including genetic information, collated within the scope of the regulations, shall remain confidential. The penalty for a contravention or failure to comply is a fine, imprisonment for a period not exceeding ten years, or both such fine and imprisonment.[38] It is unfortunate that neither the National Health Act[39] nor these regulations define the term 'genetic information'.

(3) Regulations Relating to the Use of Human Biological Material[40]

These regulations were issued in terms of s 68 of the National Health Act.[41] Section 68 came into operation on 17 May 2010.[42] The regulations are intended inter alia to control the flow of genetic information. The following regulation is relevant for this purpose:

> '13. An authorised institution that keeps or discloses genetic material records and other individually identifiable or related health information in any form, whether electronically, orally or on paper must ensure that-
> (a) the information is treated confidentially;
> (b) ensure that health care providers or planners give users a clear explanation of how the user can use, keep and disclose their information;
> (c) users have access to their records;
> (d) user's written informed consent is obtained before information is released to health insurers, other health care providers or any other relevant person;
> (e) the information is used for the purpose for which it was originally intended;
> (f) the written informed consent of the user or donor is obtained for long term storage of genetic material, stem cells or research findings;
> (g) the records are destroyed after the purpose for which they were created has been served; and
> (h) the information is treated as anonymous if used for research purposes.'

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35 Supra note 10.
36 Supra note 12.
37 Proc. 20 *GG* 33187 of 14 May 2010.
38 Supra note 10 reg 21.
39 Supra note 1.
40 Supra note 11.
41 Supra note 9.
42 Supra note 37.

Regulation 14 provides that the penalty for contravention of or failure to comply with these regulations, is a fine or imprisonment not exceeding ten years, or both such fine and imprisonment. These regulations do not define genetic information.

(4) Employment Equity Act[43]

This Act aims to achieve equity in the workplace by promoting equal opportunity and fair treatment in employment through the elimination of unfair discrimination.[44] It does not apply to members of the National Defence Force, National Intelligence Agency, South African Secret Service, South African National Academy of Intelligence or Comsec.[45]

The Act prohibits medical testing of employees unless the testing is required or permitted by law or there are justifiable reasons for doing so.[46] Medical testing according to the Act 'includes any test, question, inquiry or other means designed to ascertain, or which has the effect of enabling the employer to ascertain, whether an employee has any medical condition.'[47] The protection is extended to job applicants who are also considered to be employees for the purposes of this Act.[48] It is not clear whether 'medical testing' would be interpreted to include genetic testing and screening.

The Act prohibits unfair discrimination against employees on the basis of race, gender, sex, pregnancy, marital status, family responsibility, ethnic or social origin, colour, sexual orientation, age, disability, religion, HIV status, conscience, belief, political opinion, culture, language and birth.[49] It does not expressly deal with unfair discrimination based on results of genetic testing or genetic screening in the employment sphere. The term 'disability' is not defined in the Act thus making it difficult to determine whether a genetic disorder could be regarded as a disability or not. The Oxford Dictionary defines disability as 'a physical or mental condition that limits a

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43 Supra note 12.
44 Ibid s 2.
45 Ibid s 4(3). The National Defence Force is governed by the Defence Act 42 of 2002 whilst the National Intelligence Agency, the South African Secret Service, and the South African National Academy of Intelligence are governed by the Intelligence Services Act 65 of 2002. Comsec refers to the Electronic Communications Security (Pty) Ltd established and governed by the Electronic Communications Security (Pty) Ltd Act 68 of 2002.
46 Supra note 12, s 7(1).
47 Ibid s 7(2).
48 Ibid s 9.
49 Supra note 12 s 6.

person's movements, senses, or activities.' For legislative purposes, 'disability' could possibly be widely interpreted to include predisposition to certain genetic disorders since a genetic disorder is a physical condition which may render the affected individual ineligible for particular types of employment related activities. On the other hand, the Act provides that it is not unfair discrimination to distinguish, exclude or prefer any person on the basis of an inherent requirement of a job.[50] It is thus possible that persons who test or screen positive for certain genetic disorders may legitimately be excluded from particular types of employment due to the nature of the work involved. Their exclusion would not amount to the prohibited 'unfair discrimination' envisaged by the Act.

The Act does not expressly address the issue of genetic discrimination. Whether or not the Act can be utilised to prevent genetic discrimination would depend on how its provisions are interpreted.

(5) Protection of Personal Information Bill[51]

The South African Law Reform Commission (SALRC) commenced its investigation into privacy and data protection in 2003 and released its report in August 2009.[52] The report includes the Protection of Personal Information Bill.[53] The bill is intended to give effect to the constitutional right to privacy by regulating the processing of personal information. It also gives effect to internationally recognised core information protection principles. The bill takes the form of a general information protection statute which may be supplemented by sector-specific statutes and codes of conduct. The report acknowledges the negative consequences of inadequate information protection in the area of genomic research.[54] The list of consequences includes stigmatisation, insurance discrimination, and employment discrimination.

Section 25(b) of the bill provides special protection to health information by prohibiting unauthorised processing of such information. Processing refers to 'any

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50 Ibid.
51 Supra note 13.
52 South African Law Reform Commission Report (Project 124) *Report on Privacy and Data Protection* (2009).
53 Supra note 13.
54 Supra note 52 at 110.

operation or activity or any set of operations, whether or not by automatic means, concerning personal information, including the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation, use, dissemination by means of transmission, distribution or making available in any other form, merging, linking, as well as blocking, degradation, erasure or destruction of information.'[55] The protection is not absolute as section 30 provides exemptions to the prohibition on the processing of personal information concerning health. Such exemptions apply in specified circumstances to the processing by medical professionals, healthcare institutions or facilities, social services, insurance companies, medical aid schemes, medical scheme administrators, managed healthcare organisations, schools, institutions for probation, child protection or guardianship, the Ministers of Justice and Constitutional Development and of Correctional Services, administrative bodies, pension funds, employers or institutions working for them. The relevant subsections of s 30 provide as follows:

> '30.(1) The prohibition on processing personal information concerning a data subject's health or sexual life, as referred to in section 25, does not apply to the processing by –
>
> …
>
> (b) insurance companies, medical aid schemes, medical scheme administrators and managed healthcare organisations, provided that this is necessary for -
>
> (i) assessing the risk to be insured by the insurance company or covered by the medical aid scheme and the data subject has not objected to the processing;
>
> (ii) the performance of an insurance or medical aid agreement; or
>
> (iii) the enforcement of any contractual rights and obligations.
>
> …
>
> (f) administrative bodies, pension funds, employers or institutions working for them, if this is necessary for –
>
> (i) the implementation of the provisions of laws, pension regulations or collective agreements which create rights dependent on the health or sexual life of the data subject; or
>
> (ii) the reintegration of or support for workers or persons entitled to benefit in connection with sickness or work incapacity.
>
> …
>
> (5) Personal information concerning inherited characteristics may not be processed in respect of a data subject from whom the information concerned has been obtained, unless -
>
> (a) a serious medical interest prevails; or
>
> (b) the processing is necessary for the purpose of scientific research or statistics.
>
> (6) More detailed rules may be prescribed concerning the application of subsection (1)(b) and (f).'

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[55] Supra note 13, s 1.

Upon reading s 30(5) it can be said that the Bill attempts to address the processing of genetic information, thereby offering some recognition to genetic privacy. Special reference to 'personal information concerning inherited characteristics' may indicate that a distinction is being drawn between genetic information and other health information. Such a distinction may prove useful for regulating the processing of genetic information in the future since genetic information is different from other health information and may require different rules. Section 30(6) which provides that more detailed rules may be prescribed in respect of the processing of health information by insurers and employers is particularly relevant for the purpose of protecting genetic privacy.

The difficulty lies in reconciling ss 30(1) and 30(5). It is not clear whether section 30(5) is intended to provide additional exemptions to the prohibition on the processing of genetic information or to be treated as the only exemptions applicable to genetic information. If intended to be the only exemptions, it would mean that the exemptions provided for in s 30(1) would not apply in respect of genetic information. The result would be that no person or entity, including those referred to in s 30(1), may process genetic information in any circumstance except those specified in s 30(5). The consequences of such a restrictive approach, especially in respect of the insurance industry, have been discussed comprehensively in chapter 3.

(6) Criminal Law (Forensic Procedure) Amendment Bill[56]

The Bill was drafted as part of the Department of Justice and Constitutional Development's review of the criminal justice system. It seeks to amend the Criminal Procedure Act,[57] South African Police Service Act,[58] Firearms Control Act,[59] and Explosives Act[60] in an attempt to address certain shortcomings in the South African criminal justice system. The shortcomings identified related to the absence of legislation to provide for the establishment and administration of a DNA database as a criminal intelligence tool and the lack of legislative provision for the collection of DNA evidence. The Bill therefore provides inter alia for the creation of a DNA database to assist in

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56 Supra note 14.
57 Act 51 of 1977.
58 Act 68 of 1995.
59 Act 60 of 2000.
60 Act 15 of 2003.

addressing crime in South Africa. It also facilitates the linking of governmental fingerprint databases; namely the Department of Transport's e-NATIS system[61] and the Department of Home Affairs' HANIS system.[62] This is intended to be achieved by the insertion of Chapters 5A and 5B into the South African Police Service Act.[63] The DNA database, referred to as the National DNA Database of South Africa (NDDSA), will be established by the insertion of chapter 5B into the South African Police Service Act. Chapter 5B clearly states that its purpose is to establish and maintain a national DNA database. The NDDSA will contain biological samples as well as DNA profiles derived from such samples.

Clause 9 of the Bill seeks to insert chapter 5B into the South African Police Service Act.[64] Section 15E of the proposed chapter 5B states as follows:

> 'The purpose of this chapter is to establish and maintain a national DNA database which may only be used for purposes related to the identification of missing persons, the identification of unidentified human remains, the prevention or detection of crime, the investigation of an offence or the conduct of a prosecution and not for any unauthorised purpose in order to, among others –
> (a) serve as a criminal intelligence tool in the fight against crime;
> (b) identify persons alleged to have committed offences, including those committed before the entry into force of this chapter;
> (c) where applicable, prove the innocence or guilt of accused persons; or
> (d) where applicable, the identification of missing persons or unidentified human remains.'

The Bill[65] provides that the NDDSA shall contain five indexes; namely a crime scene index, reference index, convicted offenders index, volunteer index, and personnel, contract and supplier elimination index.

The aims of the Bill are laudable and necessary but also a source of concern. These concerns are addressed in the light of international experience, relevant literature and cases. The concerns mentioned briefly below and have been addressed in more detail in chapter two:

(i) The Bill is applicable to adults and children.

(ii) Non-intimate samples may be taken from arrested and convicted persons as well as from suspects.

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61 National Traffic Information System.
62 Home Affairs National Identification System.
63 Act 68 of 1995.
64 Ibid.
65 Clause 9.

(iii) The Bill permits speculative searching of databases.[66]

(iv) The proposed permanent retention of samples and profiles as envisaged in the Bill is problematic.[67]

(v) The provision relating to sharing of NDDSA information with foreign law enforcement agencies poses a great threat to privacy of individuals.

(vi) Consent given by volunteers cannot be withdrawn.

The position envisaged in the Bill is untenable. Many of the provisions violate the right to privacy and will not pass constitutional muster. The *Marper* case is a good example of how competing rights should be balanced. It is hoped that the provisions in the Bill will be tempered as the Bill proceeds through the legislative process. If not, it risks being successfully challenged in court.

7.3 POLICY DEVELOPMENTS

(1) Human Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth Defects and Disabilities[68]

In August 2001 the Department of Health issued policy guidelines for the management and prevention of genetic disorders, birth defects, and disabilities. The foreword to these policy guidelines acknowledges that genetic disorders have not received adequate attention in South Africa. The purpose of the policy guidelines is to facilitate the integration of genetic services into primary health care in an attempt to prevent the recurrence of genetic disorders and to reduce genetic related morbidity. A comprehensive genetic service is envisaged for South Africa.

The guidelines envisage the creation of a Medical Genetic Advisory Board which will be responsible for addressing inter alia issues such as the release of genetic information to third parties. Insurers and employers are given as examples of such third parties. The guidelines include general ethical guidelines which provide for confidentiality of genetic

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[66] Clause 3 (Proposed s 36B(5) of the Criminal Procedure Act 51 of 1977); clause 9 (Proposed Ch 5B, s 15M of the South African Police Service Act 68 of 1995).

[67] Clause 3 (Proposed s 36B(6)*(a)* of the Criminal Procedure Act 51 of 1977); clause 9 (Proposed ch 5B, s15P(1)*(a)*).

[68] Supra note 15.

information.[69] The ethical guidelines also provide for the protection of individual privacy from institutional third parties such as employers, insurers, schools, commercial entities, and government agencies.[70]

(2) National Guidelines for the Care and Prevention of the Most Common Genetic Disorders, Birth Defects and Disabilities[71]

In 2006 the Department of Health launched the National Guidelines for the Care and Prevention of the Most Common Genetic Disorders, Birth Defects and Disabilities. The purpose of these guidelines to facilitate the management of the common genetic disorders. Like the policy guidelines discussed above, these guidelines also mention ethical considerations such as confidentiality. It notes that genetic information should be protected from third parties except where lack of information may affect the safety of the individual. Informed consent is required before the release of genetic information even to family members. This document is a further reflection of the commitment of the Department of Health to improving genetic services in South Africa and an acknowledgement of the importance of protecting genetic privacy.

7.4 ETHICAL GUIDELINES

(1) Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa[72]

These guidelines were issued by the Department of Health. They are intended to promote good practice in the conduct of clinical trials involving human participants in South Africa. They provide a basis for the scientific and ethical integrity of research involving human participants. This includes protecting the rights and safety of research participants. It is noted that ethical guidelines for clinical trials are crucial because of the 'potential to violate the rights of trial participants particularly vulnerable communities'.[73] The main ethical principles addressed are respect for the dignity of persons, beneficence

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69 Ibid 49.
70 Ibid.
71 Supra note 16.
72 Supra note 17.
73 Ibid 8 para 1.2.

and non-maleficence, and justice.[74] Patient privacy is also accorded due consideration in the guidelines. It is clearly stated that 'participants' right to privacy must be protected at all costs.'[75]

The drafting of these guidelines was guided by the contents of the following documents and South African researchers are expected to observe the principles contained in these documents:[76]

(i) ICH Guideline for Good Clinical Practice, ICH Harmonised Tripartite Guideline;

(ii) Declaration of Helsinki;

(iii) International Guidelines for Ethical Review of Epidemiological Studies, Council for International Organisations of Medical Sciences (CIOMS) 1991;

(iv) World Health Organisation, WHO Technical Report Series, No. 850, Guidelines for good clinical practice (GCP) for trials on pharmaceutical products (1995);

(v) World Health Organisation (2000) Operational Guidelines for Ethics Committees That Review Biomedical Research. Geneva. TDR/PRD/Ethics/2000.1;

(vi) MEDSAFE, New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guideline (August 1998);

(vii) Association of the British Pharmaceutical Industry Clinical Trial Compensation Guidelines, Issued January 1991, Reprinted March 1994; and

(viii) Institutional Review Board (IRB) Guidebook. Office for the Protection from Research Risks – National Institutes of Health, USA (1993).[77]

The guidelines dealing with the protection of study participants identify participants whose involvement need special attention. These include minors, women; people with mental disabilities or substance abuse related disorders, persons in dependent relationships or comparable situations, prisoners, and persons who are highly dependent on medical care.[78] This list appears to be an extension of the list of vulnerable groups as contained in the National Health Act which is discussed above.[79] There is no reason why persons with genetic disorders cannot be included in this list since their involvement in

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74 Ibid.
75 Ibid 10 para 1.2.6.
76 Ibid 15 para 2.1.
77 Ibid 12 para 1.3.
78 Supra note 72 at 16 para 2.3.
79 Supra note 26.

research also requires special attention. Drug trials are crucial for the advancement of pharmacogenomics and such trials require the participation of individuals with genetic disorders. Such individuals may understandably be unwilling to participate in clinical trials for fear of discrimination in other spheres of their lives. They are vulnerable in this sense.[80] For this reason it becomes necessary to impose additional safeguards in research involving human genetics. Such safeguards may be imposed by research ethics committees. The guidelines do provide that the list of special groups is not exhaustive.[81] This provision can also facilitate the inclusion of genetic research participants as deserving of heightened protection.

The guidelines also specify the types of research that need additional attention. These are:

(i) Research involving collectivities;
(ii) research involving indigenous medical systems;
(iii) emergency care research;
(iv) research involving innovative therapy or interventions;
(v) research involving vulnerable communities; and
(vi) HIV and AIDS clinical and epidemiological research.[82]

This list can be interpreted to accommodate ethnic groups or communities within which certain genetic disorders may be prevalent. These groups could qualify as 'vulnerable communities' deserving of additional protection. It is interesting to note the special provision in respect of HIV and AIDS. A similar provision for individuals with genetic disorders would prove useful in attracting research participants as well as protecting them.

[4]

According to the guidelines a community may be regarded as vulnerable on any one of the following grounds:

(i) Limited economic development;
(ii) inadequate protection of human rights;
(iii) discrimination on the basis of health status;

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80 Supra note 3 at 13. No definition of vulnerability is provided by the law.
81 Supra note 72 at 29 para 2.3.13.
82 Ibid 16 para 2.3.

(iv) limited ability of individuals in the community to provide informed consent;

(v) limited availability of health care and treatment options; and

(vi) inadequate understanding of scientific research.[83]

Grounds (ii), (iii) and (vi) are pertinent to genetic research. With regard to ground (ii), privacy is a human right and if genetic privacy is not protected it cannot be said that there is adequate protection of human rights. The absence of genetic privacy protection would thus render any community involved in genetic research vulnerable. With regard to ground (iii), it can be argued that discrimination on the basis of genetic disorders is a foreseeable harm which necessitates the protection of genetic information from unauthorised disclosure. The discussion in chapter three is relevant is this regard. With regard to ground (vi), it is possible to assume that due to the technical and complex nature of genetic research, few communities are likely to understand it.[84] Their lack of understanding is what would make them vulnerable.

It is intended that the above guidelines will be enforced via regulations issued in terms of section 90 of the National Health Act.[85] Compliance with these guidelines is compulsory under the direction of the Director-General of Health.[86]

(2) Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research[87]

These guidelines were revised inter alia because of fairly recent developments such as the Human Genome Project. The law and policy relating to genetic screening and genetic testing are discussed. The guidelines try to minimise the negative impacts of genetic screening and testing on access to life insurance and employment prospects.[88] Confidentiality and the right to privacy are considered in some detail.[89] Reference is made to the constitutional right to privacy as well as the common law principles. It is pointed out that the right to privacy is not absolute.

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83 Ibid 24 para 2.3.11.

84 Zulfiqar A. Bhutta 'Beyond informed consent' (2004) 82 *Bulletin of the World Health Organization* 771 at 775.

85 Supra note 9.

86 Supra note 72 at 12 para 1.4.

87 South African Medical Research Council 4 ed (2002).

88 Ibid para 3.3.4.

89 Ibid para 3.3.4.1 – 3.3.4.1.2.

As far as employment is concerned, the guidelines attribute the interest of employers in genetic information to health-related costs of employment.[90] The following paragraph is noteworthy:

> 'The dangers of permitting employers to embark on their own screening programmes are self-evident. The result would be restrictions on the employment of individuals who are at risk of genetic disease, and the creation of class orders based on genetic disposition. In other words, genetic discrimination would ensue…..the cost implications for the State are critical. Whereas the business community currently bears some of the cost of genetic disease in the population, by excluding this cost through genetic screening, business would effectively shift their share of the cost to the State, with repercussions for social welfare and health policy in particular.'[91]

In response to the above concerns, the guidelines recommend that genetic screening programmes in the employment context should be permitted only where –

(i) the programme is approved by the appropriate regulatory body;

(ii) steps have been taken to ensure that individuals are not unfairly treated;

(iii) procedures are in place to assist the individual to find other employment;

(iv) there is strong evidence of a clear connection between the working environment and the development of the condition for which the screening is conducted;

(v) the condition is one which seriously endangers the health of the employee, or is one in which an affected employee is likely to present a serious danger to third parties; and

(vi) the condition is one that cannot be eliminated or made less hazardous by reasonable measures taken by the employer to modify or respond to the environmental risks.[92]

With regard to insurance, the guidelines note the arguments put forward by insurers that using genetic information to predict risk is a mere extension of their current practice of requiring family medical history. The counter-argument is that the results of genetic tests do not always predict outcomes and they lack actuarial import.[93] Based on the differences in approach to the significance of genetic test results, the guidelines recommend a moratorium on disclosure of genetic information until the issue can be settled between the State and the insurance industry. The recommendation is made subject to the following two exceptions:

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90 Ibid para 3.3.4.2.
91 Ibid.
92 Ibid para 3.7.2.3.
93 Ibid para 3.3.4.3.

(i) individuals with a known family history of genetic disease that can be established by the conventional questions about proposers' families may be asked to disclose the results of relevant genetic tests; and

(ii) the moratorium should apply only to policies of moderate value.[94]

(3) Code of Ethical Practice for Medical Biotechnology Research in South Africa

This code was adopted by the Health Professions Council of South Africa (HPCSA) in 2005.[95] The following observation in the code is very encouraging as it succinctly identifies the concerns relating to genetic information and attempts to address such concerns:

> 'In addition to the usual ethical concerns that govern research involving humans, supplementary ethical issues exist which are unique to genetic research. These issues arise from the nature of genes and genetic information which, although personal to the actual participant, are shared with family members and unrelated members of the population. The potential for harm to participants, through the use of genetic information discovered during research, includes stigmatization and the potential for discrimination by, for example, insurance companies and current or potential employers. Subsequently it is important that care be taken to ensure that participants in genetic research are not at risk, due to their participation in genetic research, of being denied the benefits available to other members of the community.'[96]

The code also indicates that in genetic research there are additional requirements for informed consent.[97] Twenty one requirements are thus listed. The code deals inter alia with issues of confidentiality in genetic research. It recognises that' the nature of genetic research raises additional ethical issues in relation to privacy and confidentiality.'[98] The code recommends that genetic research participants be informed of the implications for insurance if they are found to have a predisposition to a genetic disorder. Participants must be made aware, during the consent process, that if a predisposition to a genetic disorder is discovered in the course of the research, such information must be disclosed to the participant's insurer.[99] It is recommended in the code that insurers continue with their

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94 Ibid para 3.7.2.4.

95 Health Professions Council of South Africa *Guidelines for Good Practice in the Health Care Professions – General Ethical Guidelines for Biotechnology Research* Pretoria, South Africa (2008).

96 Ibid 35 para 13.2.

97 Ibid 36 para 13.2.1

98 Ibid 38 para 13.2.2.

99 Ibid 40 para 13.2.4.

current policy of not requiring genetic testing for insurance applications.[100] The reason for such recommendation is the recognition of the following 'dangers':

> '(a) The difficulty of assessing what may be slender evidence on the genetic susceptibility of individuals to develop polygenic and multifactorial diseases (e.g. some cancers and some heart diseases);
> (b) an awareness that ordinary commercial practice will lead companies to be overcautious in their assessment of the risks derived from medical data; and
> (c) The potential for abuse i.e. discrimination.'[101]

In respect of genetic screening of employees for occupational risks during genetic research, the code provides that participants must be informed that if they are found to have genetic disorders which may be potentially harmful to colleagues, such information will have to be disclosed to the employer.[102] The code provides that such genetic screening may only be conducted in the following circumstances:

> '(a) Where there is strong evidence of a clear connection between the working environment and the development of the condition for which genetic screening can be conducted;
> (b) Where the condition in question is one which seriously endangers the health of the employee or is one in which an affected employee is likely to present a serious danger to third parties;
> (c) Where the condition is one for which the dangers cannot be eliminated or significantly reduced by reasonable measures taken by the employer to modify or respond to the environmental risks.'[103]

The code places great emphasis on informed consent as a tool for dealing with the unique issues posed by genetic research. Informed consent may become part of the solution to the lack of genetic privacy protection in the research context.

(4) Guidelines for Good Practice in the Health Care Professions – Confidentiality: Protecting and Providing Information[104]

These guidelines are issued by the HPCSA and are intended to provide a framework for the protection of patients' rights as well as to assist health care practitioners to comply with their ethical and legal obligations. They are based on international ethical codes, the constitution, and the National Health Act.[105] Clause 3 deals with patients' right to

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100 Ibid 41.
101 Ibid.
102 Ibid 41 para 13.2.5.
103 Ibid 41 para 13.2.5.
104 Supra note 20.
105 Ibid 1 clause 1.6.

confidentiality. It refers to rule 13 of the Ethical Rules of the HPCSA which states that information about a patient may only be divulged if done in terms of law, upon instruction of a court, in the public interest; with the express consent of the patient; with the written consent of the parent or guardian of a minor under the age of 12; or with the written consent of the next of kin or executor of a deceased patient's estate.[106]

7.5 INDUSTRY DEVELOPMENTS

(1) Code on Genetic Testing[107]

In 2001 the Life Offices' Association (LOA) developed a Code of Genetic Testing as part of its Code of Conduct.[108] The introduction to the Code noted that various consumer groups had indicated concern about genetic testing and its impact on the availability of insurance. This concern extended to the potential misuse of genetic information by the insurance industry. The Code provided inter alia that existing genetic test results could be used in underwriting policies; it was inappropriate to request applicants to undergo genetic testing; the LOA would maintain a register of persons whose applications had been adversely treated due to genetic abnormalities; and that all medical information should be handled with respect for privacy and confidentiality. Viewed from the perspective of the LOA, the most important issue raised by the new genetic technology is the ability of insurers to access results of genetic tests that were conducted prior to an application for insurance.[109] The response of the LOA to this issue was that access to information relevant to the risk is a cornerstone of insurance and all relevant information that is known to the applicant must therefore be disclosed to the insurer at the time of application for insurance. In keeping with the fact that insurance is a contract of utmost good faith, this would include disclosure of results of genetic tests that were performed prior to the application.[110] As discussed in chapter three, such a stance by insurers is also aimed at avoiding adverse selection. The Code acknowledged that changes to the policy

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106 Ibid 2 clause 3.2.
107 Supra note 21.
108 Life Offices' Association *Code of Conduc*t (2001) ch 20.
109 Ibid clause 4.
110 Ibid clause 4.1.

may become necessary in time depending on changes in technology and consumer attitudes and the code was accordingly subject to periodic review.

The LOA was disbanded in 2008 and its functions were subsumed by the Association for Savings and Investment SA (ASISA), which is a representative body for many savings, investment, and insurance organisations, including the LOA. ASISA is mandated by its members to engage with policymakers and regulators on issues of common concern. Part of this includes its development of a code on Genetic Testing.[111] The introduction to the code acknowledges the concerns that have arisen due to the mapping of the human genome and advances in genetic technology. Implications for the insurance industry are also noted. The code sets out the rights and obligations of the various parties involved in the insurance industry, namely, the insurance applicant, insurer, underwriter, intermediaries, and ASISA itself. It also gives an assurance of confidentiality in the handling of genetic information.

Although ASISA recommends the code to all of its members, compliance with the code is merely voluntary. It is envisaged that in due course the code will become an entrenched agreement and will be binding on all ASISA members.[112] Like the previous code issued by the LOA, this code is also subject to periodic review due to anticipated changes in technology and consumer attitudes. It is apparent that the insurance industry is monitoring developments in the area of genetics and that their policies will be developed accordingly.

(*2*) *National Patients' Rights Charter*[113]

The charter sets out patients' rights and responsibilities. It also offers guidance to health care workers as to how to deliver health care services to patients in a way that promotes the realisation of their constitutional right of access to health care. It briefly mentions patients' rights to confidentiality and privacy. It notes that information concerning health and treatment may only be disclosed with informed consent except when required in terms of any law or any order of court. Even though the charter is not legally binding, the

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111 Supra note 21.
112 Ibid clause 10.
113 Supra note 22.

Health Professions Council of South Africa requires health care practitioners to adhere to the guidelines provided therein.[114]

It may be argued that persons who are affected by genetic disorders should be able to enjoy equal privacy protection on the basis of the charter. Such individuals have a constitutional right of access to health care which cannot be fully realised due to privacy concerns. They should be able to seek medical care and be involved in clinical research. Their right to privacy should be adequately and expressly protected so as to enable them to realise their right of access to health care. This can only be achieved if genetic information is accorded due recognition as sensitive medical information requiring additional safeguards. The charter would be a good starting point for such an endeavour.

7.6 CONCLUSIONS

The South African approach to the protection of genetic information is not found solely in any particular statute, policy, industry code, or ethical guideline. A study of the current position reflects a reactionary, piecemeal approach to the protection of genetic information. Protective mechanisms are scattered throughout various instruments. In most cases the application of a particular instrument to genetic information requires liberal interpretation of the relevant provisions. A common thread running through all the instruments, however, is that of respect for patient confidentiality and privacy. This is implemented by requiring patients' informed consent for participation in research and for disclosure of medical information. There are, however, two problems which cannot be solved by informed consent: inherent vulnerability amongst genetic research participants, as discussed in chapter three, and compulsory disclosure of confidential medical information in court proceedings, as discussed in chapter five.

Based on the discussion of the various instruments in this chapter it is concluded that only the ASISA Code of Genetic Testing;[115] MRC Guidelines on Ethics for Medical

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[114] Health Professions Council of South Africa: Guidelines for Good Practice in the Health Care Professions – National Patients' Rights Charter, Pretoria, South Africa (2008).

[115] Supra note 21.

Research;[116] and Code of Ethical Practice for Medical Biotechnology Research in South Africa[117] directly address the issue of genetic information and genetic privacy. All other instruments require liberal interpretation in order to be made applicable to genetic privacy. Even the Protection of Personal Information Bill[118] does not expressly deal with genetic privacy. The Bill is too restrictive in its approach to information relating to 'hereditary characteristics'. It accordingly hampers, rather than facilitates the development of sector-specific genetic privacy protection. The Criminal Law (Forensic Procedure) Amendment Bill provides for the establishment of a forensic DNA database but the approach that it adopts is unlikely to pass constitutional muster. The Bill contains controversial provisions which have already been found to be unconstitutional by the European Court of Human Rights.[119]

There is scope for the protection of genetic research participants within the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa.[120] It will be difficult, though, to classify genetic research participants as a vulnerable group worthy of additional protection. On the face of it, the Employment Equity Act[121] does not offer protection to employees who may be affected by genetic disorders.

Confidential medical information is not protected from disclosure in judicial proceedings. This poses a problem in respect of genetic information which is sensitive due to the risk of genetic discrimination posed by disclosure to third parties. The introduction of a genetic information privilege would be consistent with the constitutional right to privacy.

The South African position in respect of genetic information is clearly unsatisfactory. This is not due solely to flaws in the regulatory framework but more to gaps since the legal, ethical, and policy positions are not yet fully developed. What is required is a unified position, which can clearly be attained through a single statute. A statute would

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116 Supra note 18.
117 Supra note 95.
118 Supra note 13.
119 *S and Marper v The United Kingdom* 30562/04 [2008] ECHR 1581 (4 December 2008).
120 Supra note 72.
121 Supra note 12.

eliminate confusion and be enforceable, thus creating an enabling environment in which genetic science can flourish for the benefit of all South Africans.

CHAPTER VIII

CONCLUSIONS AND RECOMMENDATIONS

8.1 INTRODUCTION

> 'Once a civilization has made a distinction between the 'outer' and 'inner' man, between the life of the soul and the life of the body, between the spiritual and the material, between the sacred and the profane, between the realms of God and the realms of Caesar, between church and state, between rights inherent and inalienable and rights that are the power of government to give and take away, between public and private, between society and solitude, it becomes impossible to avoid the idea of privacy by whatever name it may be called.'[1]

The realisation of the potential for diagnosis and prediction of genetic conditions began with the initiation of the Human Genome Project in 1990. The completion of the human DNA sequence in 2003 coincided with the 50th anniversary of Watson and Crick's discovery of the fundamental structure of DNA (the double helix). This has been hailed as a giant step in genetic science. The deciphering of the human genome ushered in a new era of genetics which poses its own challenges to traditional legal concepts and regulatory frameworks. It renewed the debates surrounding the issue of personal privacy and fears of discrimination as a consequential harm resulting from inadequate privacy protection. This is therefore a topic which has to be addressed, especially in a country like South Africa which has a constitutionally entrenched right to privacy.

This thesis anticipates the challenges that South Africa is going to face. It accordingly set out to identify issues and concerns relating to genetic privacy, together with the relevant developments in selected jurisdictions, with the aim of demonstrating that South Africa requires comprehensive genetic privacy legislation. This necessitated a literature review of the legal and ethical debates; a cross-jurisdictional review of legal, ethical, and policy developments; and an assessment of the South African regulatory framework. This undertaking resulted in the overall conclusions which are discussed below.

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[1] Herbert Marcuse *One-Dimensional Man* (1964) 10 quoted in MR Konvitz, 'Privacy and the law: A philosophical prelude' (1966) 31 *Law & Contemporary Problems* 272 at 273.

8.2 OVERALL CONCLUSIONS

(a) Genetic Databases

The benefits of forensic and non-forensic DNA databases are substantial and undeniable. Notwithstanding the benefits of DNA databases, they do pose enormous legal and ethical challenges.

(i) Forensic DNA databases

Forensic DNA databases have far-reaching constitutional implications. It is imperative that a balance be attained between the individual's right to privacy and society's need for crime reduction.[2] The legislative framework must not, however, have an inhibitory effect on crime detection and prosecution. Legal parameters need to be set for the operation of forensic DNA databases. This can be adequately achieved through a genetic privacy statute.

(ii) *Genetic research databases*

There is a general lack of regulation of genetic research databases. This could hamper efforts to recruit participants for genetic research. Due to the importance of genetic research, it is crucial that genetic research databases be adequately regulated. Legal regulation is preferable due to enforceability of the law. It is also important to ensure that research databases are not utilised for forensic purposes. Cross-border sharing of data should be encouraged only where the receiving country has a similar level of privacy protection. All of these issues have serious consequences and can only be adequately addressed through legislation.

(b) Insurance

Insurers have an interest in genetic information for underwriting purposes. Genetic discrimination in insurance has not yet become a major problem anywhere in the world but many governments have foreseen the potential for discrimination and are proactively taking steps to prevent genetic discrimination. Concern about the disclosure of genetic information could result in reluctance to participate in genetic research as well as

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2 *S and Marper v The United Kingdom* 30562/04 [2008] ECHR 1581 (4 December 2008).

reluctance to utilise genetic health services. Preventing harm in the context of insurance is most suitably addressed by the implementation of genetic information privacy protection as opposed to the creation of anti-discriminatory measures. This is simply because the flow of information is easier to monitor and enforce as opposed to the use of information once it is in the hands of an insurer or employer.[3]

Three approaches to the problem have been identified: legislative prohibition, moratoria and the status quo. Concerns have been raised about the enforceability of moratoria.[4] The status quo approach cannot be encouraged because it ignores the gravity of public concern about genetic discrimination.[5] In an area as sensitive and as far-reaching as human genetics, it is safer to rely on legislation as a protective mechanism due to its status and enforceability. The legislative approach offers the most certainty and greatest level of protection.

(c) Employment

There are documented cases of genetic discrimination by employers in the United States of America [6] and in Germany.[7] The economic impact of permitting access to employees' genetic information is an important consideration in the decision to restrict such access. Employers should not have an automatic right of access to genetic information of employees.[8] There are situations in which it may be necessary for employers to gain access to such information but this should only be done in clearly specified circumstances, with the consent of the employee, and with alternative job functions rather than dismissal in mind. Genetic testing at the request of employers may be reasonable and necessary if it is based on the inherent requirements of a job but there is no need for the disclosure of actual test results to the employer. There must also be penalties for

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3 Pauline T. Kim 'Genetic discrimination, genetic privacy: Rethinking employee protections for a brave new workplace' (2002) 96:4 *Northwestern University Law Review* 1497.

4 Yann Joly, Bartha M Knoppers & Béatrice Godard 'Genetic information and life insurance: a 'real' risk' (2003) 11:8 *European Journal of Human Genetics* 561 at 562.

5 Ibid.

6 *Norman-Bloodsaw v. Lawrence Berkeley Laboratoy* 135 F.3d 1260 (9th Cir. 1998); *Echazabal v Chevron USA 213* F.3d 1098 (9th Cir.2000); *Bentivegna v United States Dept of Labour* 694 F.2d 619 (9th Cir. 1982).

7 Jane Burgermeister 'Teacher was refused job because relatives have Huntington's Disease' (2003) 327 *British Medical Journal* 827.

8 Kim op cit note 3 at 1543.

unauthorised access to employees' genetic information. The required level of protection can only truly be achieved through privacy legislation and not through anti-discrimination legislation.[9]

(d) Genetic Research

In order for genetic research to continue and for its potential to be fully realised, it is necessary to alleviate the fear of genetic discrimination. Ethical guidelines provide for the protection of human research participants but these lack enforceability. Research Ethics Committees are not functioning optimally and are therefore unable to provide the required degree of protection. The requirement of informed consent and the conventional concept of vulnerability, which is consent-based, do not provide protection to genetic research participants. None of the relevant national and international instruments regard genetic research participants as vulnerable even though they are exposed to an increased risk of stigmatisation (social harm) as well as potential discrimination by insurers and employers (economic harm). This non-inclusion of genetic research participants as a vulnerable group can be attributed to the foundational basis of the concept of vulnerability, which is the capacity to provide full and informed consent. Since genetic research participants cannot be accommodated within the existing consent-based concept of vulnerability, the foundational basis of the concept must be extended to include increased susceptibility to additional harm due to or resulting from participation in research.

Potential stigmatisation and genetic discrimination arising from genetic research involving human participants warrants the introduction of genetic privacy legislation.

(e) Genetic Privacy

Computer technology and genetic technology demand fresh scrutiny of existing privacy regimes. A combination of both technologies poses a major challenge to privacy in the traditional sense. Even though the right to privacy enjoys constitutional protection, the challenges posed by a combination of genetic technology and information technology require legislative intervention for three reasons. First, judicial development of the

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9 Kim op cit note 3 at 1537.

common law is unlikely to keep pace with the rapidly advancing science of human genetics. Secondly, the courts have not displayed an eagerness to develop the common law.[10] Thirdly, the current regulatory framework (legal and ethical) is limited insofar as the protection of genetic privacy is concerned. There are four major models of privacy protection; namely, comprehensive laws, sectoral laws, self-regulation, and technologies of privacy.[11] All of these models may prove suitable for the protection of genetic privacy. Due to the number of issues that must be addressed, and in order to avoid a piecemeal approach to the protection of genetic privacy, a comprehensive statute will be most effective.

(f) Genetic information privilege

Professional privilege is limited to the legal profession in most jurisdictions. The common law recognition of other privileges has been hampered by a conventional test which is clearly outdated. Genetic information privilege can therefore not be protected by a medical professional privilege because such a privilege does not exist.

The ad hoc development of the law relating to privilege is neither appropriate nor advisable for the protection of genetic information due to the sensitivity of genetic information and its wide-ranging implications. Judicial discretion as a tool for the protection of genetic information requires progressive thinking by judicial officers. This cannot be guaranteed. It is therefore necessary to create a statutory genetic information privilege. This call for the introduction of a new privilege is very likely to meet with resistance.

(g) Cross-jurisdictional review

All of the selected jurisdictions recognise the need for protection of genetic information but have adopted different approaches towards it. The form and extent of protection varies in each country. Countries tend to favour an anti-discrimination approach instead of a privacy approach for this purpose. This is clearly a flawed choice as it cannot

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[10] *NM & others v Smith & others (Freedom of Expression Institute as Amicus Curiae)* 2007 (5) SA 250 (CC) at 281A; *Masiya v Director of Public Prosecutions, Pretoria & another* (*Centre for Applied Legal Studies & another, Amici Curiae)* 2007 (5) SA 30 (CC).

[11] Electronic Privacy and Information Centre (EPIC) and Privacy International *Privacy and Human Rights 2002: An International Survey of Privacy Law and Developments* (2002) 3

adequately protect genetic information. Complete protection can only be attained through a privacy model.

There is a general lack of regulation of genetic research databases worldwide, especially in the private sector. No common approach to the protection of genetic information in the context of insurance has been found and there appears to be little scope for the recognition of a genetic information privilege. No jurisdiction has yet developed optimal protection for genetic information.

(h) South African regulatory framework

A study of the current position reflects an inadequate, reactionary, piecemeal approach to the protection of genetic information. Protective mechanisms are scattered amongst various legal, ethical, and policy instruments. There is little scope for the common law recognition of a genetic information privilege. Except for the National Health Act,[12] no other legislation seeks to enforce the constitutional rights of research participants. There is no research-specific legislation in South Africa. This lacuna threatens the future of genetic research in South Africa. This in turn will have negative consequences for the health system, the insurance industry, employment relationships, and the utilisation of genetic health services. The problem can be addressed by the introduction of a genetic privacy statute.

8.3 RECOMMENDATIONS

Based on the findings of this research, South Africa should develop and implement a comprehensive genetic privacy statute. Such a statute should include provisions aimed at controlling the flow of genetic information to third parties, the regulation of genetic research, the regulation of DNA databases, and the creation of a genetic information privilege. It should be applicable to the public and private sectors.

The preamble to the statute should acknowledge that genetic information is medical information which has unique characteristics. The purpose of the statute should be to protect the constitutional right to privacy by regulating the flow of genetic information.

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[12] Act 61 of 2003.

The statute should contain a clear definition of genetic information. The following definition is accordingly recommended:

> Genetic information is information derived from genetic testing, information about an individual's request for, or receipt of genetic services; information about participation in or results of genetic research; and information contained in forensic and genetic research databases.

Based on the arguments made in chapter three for the extension of the concept of vulnerability, the proposed statute should contain a definition of vulnerability. The following definition is recommended:

> 'Vulnerability includes increased susceptibility to social and economic harm due to or resulting from participation in genetic research.'

Specific restrictions on access to genetic information by employers and insurers should be included in the Act. In respect of employers, the Act should clearly specify the circumstances in which access to genetic information of employees will be permitted, the extent of such access, as well as penalties for contravention of the relevant provisions. In respect of insurers there should be a prohibition on the ability to request applicants to undergo genetic testing as part of the process of application for insurance. The current position is untenable for two reasons; namely, insurers have the right to request results of prior genetic tests regardless of the amount of insurance cover being applied for, and there is no legally enforceable undertaking by insurers not to request genetic testing. It is recommended that government should immediately commence negotiations with the insurance industry to attain certainty in this area instead of waiting for a test case.

The Act should strictly regulate the creation, operation, and governance of genetic research databases. This should include detailed provisions on access to information contained in such databases and a prohibition on the use of data from these databases for forensic purposes. Since the envisaged DNA Bill[13] will regulate forensic DNA databases, the genetic privacy statute should contain provisions which complement those in the Bill with added emphasis on privacy protection.

It has been shown that, due to the unique characteristics of genetic information, a privilege is required and that its creation can be justified. Despite the general resistance

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[13] Criminal law (Forensic Procedure) Amendment Bill B2-2009 (phase 2).

to the creation of new privileges, it is recommended that a genetic information privilege should be created in the Bill.

The statute should provide for a Genetic Information Privacy Commissioner (Commissioner) whose duties should include monitoring compliance with the law, providing guidance on interpretation and implementation of the proposed Genetic Privacy Act, raising public awareness of genetic privacy issues, providing advice to the government and to the public, making recommendations on the Act, and performing other ad hoc functions that may be necessary for the protection of the right to genetic privacy. This is important because this is a dynamic and rapidly advancing field. The Commissioner should be suitably qualified to appear as an expert in judicial proceedings which involve the protection of genetic privacy. The Commissioner should also keep abreast of international developments and disseminate updates on such developments. The statute should be complemented by industry codes of practice which should be approved by the Commissioner.

If the abovementioned recommendations are to achieve their aim, they need to be implemented as a matter of urgency in order to ensure that South Africans do not remain exposed to the identified threat of violation of their right to genetic privacy.

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