PRIVACY, CONFIDENTIALITY AND GENETIC DATABASES:

A MODIFIED RIGHTS APPROACH

By

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ABSTRACT

Privacy, Confidentiality and Genetic Databases:
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The Human Genome Project has the potential to bring about enormous benefits to medicine. Large scale databases of genetic information and material serve an important function in advancing the knowledge brought about by the Human Genome Project. Such databases raise concerns for group and individual privacy. This thesis advocates that a modified rights approach to privacy ought to underlie the legal regulation of genetic databases. A purely individualistic rights approach towards the protection of privacy is not appropriate for the regulation of genetic information. The modified rights approach takes account of the familial and social nature of genetic information whilst recognizing the inherent importance of privacy. The extent to which the current law, including the Human Rights Act 1998 achieves this approach is considered. Account is taken of the Select Committee of the House of Lords Report, "Human Genetic Databases, Challenges and Opportunities".

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Preface

I began thinking about the legal and ethical implication of the Human Genome Project and the genetic revolution for privacy by asking myself all sorts of questions. I wanted first of all to find out what the Human Genome Project and Genetic Revolution were and to gain insight into their potential to reveal genetic information. I thought about individuals and parties who had an interest in accessing such information, and whether they ought to have access to it, and in what circumstances. I tried to predict some of the possible uses of this information and considered what uses society ought to endorse and prohibit. Were there any ways in practice that could permit and prevent such uses? I questioned whether my instinctive responses as to who ought to control genetic information were justified ethically. In essence, I was enquiring into how the law ought to regulate genetic privacy.

However, I was beginning with the wrong questions. I was taking it for granted that such information would be produced in the first place. That it ought to be produced. That science would discover new ways of analysing and producing genetic data. That research would be undertaken that in time might link certain diseases or behaviours or character traits with certain genes.

A prior question that I should have asked when considering the genetic revolution and genetic research is why is it necessary in the first place? Are the enormous amounts of money being invested in genetic research justified in terms of its actual and potential benefits? Are there consequences of genetic research for privacy that simply cannot be undone by any amount of legal regulation? Instead of starting with the question of how to regulate such information once produced, we should determine first of all whether we want to regulate the genetic revolution in itself by stopping certain research from being undertaken. These are the primary questions that ought to be asked. They are of major significance. The way in which they are answered will change the world we live in. They are not the principal focus of this thesis, but in considering some of the implications of the genetic revolution, it is hoped that attention will be drawn towards these issues. They will underlie the discussion about the way in which genetic information and material ought to be regulated.

Introduction

Chapter one will set out the reasons why it is essential to consider the implications of the genetic revolution and genetic databases for privacy. The genetic revolution has already resulted and will increasingly result in the ability to analyse cells of the body to produce vast amounts of highly sensitive personal information. Increasingly, large-scale centralised databases of genetic material and information are being formed and utilised in the course of genetic research. The potential benefits of such databases are enormous. This chapter argues that genetic information is special, for a number of reasons including that it reveals something of the genetic makeup of family members and the community or other groups to which the person belongs. It also argues that genetic databases raise particular issues for privacy, and that there is an urgency for the law to consider the implications of genetic databases for privacy. This fact is important when considering who ought to have access to, and who ought to be able to use genetic information and material.

Chapter two examines the values that ought to underlie the law with regard to privacy of genetic information. In order to do this, it discusses the meaning of privacy, and some of the values underpinning it. It argues that privacy is important in society, not just because of its functional value in encouraging people to participate in research and to have treatment, but also because of its inherent value in protecting human dignity, and individuality. This analysis of the importance of privacy adds force to the argument that it is necessary not only to prevent certain uses of genetic information, but also to enable individuals to keep their information private in certain circumstances. This chapter draws attention to the importance of enabling individuals to assert a right not to know certain information as well as a right to know it. It also highlights the fact that groups can have a collective right to privacy. It is argued that the law ought to adopt a rights approach to protecting privacy.

The approach that the law ought to adopt in the regulation of genetic information is expanded upon in chapter three. It is argued that the fact that genetic information is familial and social, and the fact that community interests also have ethical importance, warrants the adoption of a modified rights approach to genetic information. This takes account of communitarian arguments that criticise a purely individualistic approach to genetic information.

Finally, chapters four and five critically evaluate some of the law relating to the regulation of genetic information and material. These chapters compare the approach that the law ought to take with the approach that is currently taken. It was argued that the approach taken by the courts in the common law action for breach of confidence was primarily concerned with expediency of medicine rather than with protecting a patient's right to privacy. However, the Data Protection Act 1998 and the Human Rights Act 1998, have signalled a change in the approach of the law towards the adoption of a rights approach to privacy. This is to be welcomed.

The thesis will conclude by drawing together the arguments made throughout and by making certain recommendations. It also evaluates the findings of the recent Report of the House of Lords Select Committee on Science and Technology enquiry into Genetic Databases[1].

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[1] These are included in House of Lords, Science and Technology 4th Report, Session 2000-2001, 29th March 2001, Human Genetic Databases, Challenges and Opportunities, HL57 ISBN 0104057017.

Chapter One

Genetic Information and Blue Prints on File

> "Imagine a society where the government had samples of tissue and fluid from the entire community on file and a computerized databank of each individual's DNA profile. Imagine then that not only law enforcement officials, but insurance companies, employers, schools, adoption agencies and many other organizations could gain access to those files on a "need to know" basis or on a showing that access is "in the public interest". Imagine then that an individual could be turned down for jobs, insurance, adoption, health care and other social services and benefits on the basis of information contained in her DNA profile, such as genetic disease, heritage or someone else's subjective idea of a genetic flaw."[1]

> We all "have to be aware of the really terrible past of eugenics...we have to reassure people that their own DNA is private and no one else can get it."
> James Watson, First Director of the Human Genome Project, (1981).[2]

1.1 Introduction

This chapter will begin by explaining the developments brought about by the Human Genome Project and the genetic revolution as a whole. It will go on to consider what

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[1] Janet C Hoeffel, "The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant" (1990) 42 *Stanford Law Review* 465 at 533-34 as cited in the *Privacy Commission of Canada Report on Genetic Testing*, (Privacy Commission of Canada, 1992).

[2] James Watson, quoted in J Davis, *Mapping the Code*, (Wiley, 1991) at 262.

genetic information consists of, that is, what sort of information it is possible to produce from genetic analysis of a human cell, and why such information may cause concern for privacy of individuals, groups and society.

It will argue that because genetic information by its very nature does not relate exclusively to one person, but reveals information about families and societies, therefore it is distinct from other health information. Certain other features of genetic information, which make it sensitive, and which ought to influence the law and policy regarding the regulation of genetic privacy and genetic databases will be highlighted.

This chapter will then describe the importance of considering the legal and ethical implications of genetic databases in particular. Genetic databases are collections of genetic information, or more commonly collections of human tissue samples from which it is possible to derive genetic information by molecular analysis.

This section will act as a foundation for the following chapters of this thesis that will argue that the law regulating genetic databases ought to adopt a "modified rights" approach to genetic privacy that takes account of the social nature of genetic information. This argument is premised on the inherent importance of privacy and the fact that the value of privacy is under threat from large-scale genetic databases unless the law adopts a proactive regulatory approach in meeting the challenges posed by the genetic revolution.

1.2 The Human Genome Project and the Genetic Revolution

Before examining the nature of genetic information, it is necessary to consider the developments in genetics, often described as the 'genetic revolution', which have resulted in the ability to produce genetic information, as well as some of the forces behind the genetic revolution. Caulfield regards this stage of the discussion as essential since, "In order to develop sustainable and effective genetic policies we must be sensitive to the scientific, economic and cultural forces currently behind genetics."[3] The genetic revolution is a series of scientific developments in the field of genetics that has created the potential for human cells to be analysed to produce genetic information. One major driving force behind the genetic revolution has been the Human Genome Project. The Human Genome Project was established in 1990, as an international collaboration of scientists who set out to map and sequence the human genome. Enormous investment has supported these efforts. It has been estimated that $3 billion has been invested in the project in the United States of America alone over a period of 15 years.[4] It has been noted that this investment has significantly shaped the direction that this research has

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[3] Timothy Caulfield, "Underwhelmed: Hyperbole, Regulatory Policy and the Genetic Revolution" (2000) 45 *McGill L. J.* 437-460 at 440.

[4] Thomas H Murray, "Ethical Issues in Human Genome Research" (1991) 5 FASEB 54 at 54.

taken.[5] Indeed, the potential benefits to be made from commercial activities arising out of genetic research are enormous.[6]

The Human Genome Project aims to unravel the mystery of the human genome, sometimes referred to as the "human blueprint."[7] It is made up of 23 pairs of chromosomes that reside in the nucleus of almost every cell in the body. The chromosomes are made up of DNA molecules, which in turn are composed of sequences, called genes. Half of an individual's genes comes from each biological parent. Shapiro uses a useful analogy to explain the components of the genome.[8] He describes the genome as two sets of encyclopaedias, and the chromosomes are represented by the 23 pairs of volumes. The letters within each volume represent the genetic information of the genes and although everyone carries the same set of genes, the gene sequence within each gene varies from person to person.[9] The variations in the gene sequence cause the human body to make different proteins, which result in different characteristics and

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[5] Hilary Rose 'The Politics of Reproductive Science' in Michelle Stanworth, ed., *Reproductive Technologies, Gender, Motherhood and Medicine* (University of Minnesota Press, 1987) at 169:

> Unquestionably we are in the middle of a massive investment in research and development into the process of human reproduction. The economic and social forces which shape that development are those which have shaped the history of modern science and technology; what is new is the areas of research activity and the level of investment and, therefore the speed of technological change.

[6] See generally the discussion in N H Carey and PE Crawley, "Commercial Exploitation of the Human Genome: What are the Problems?" in Ciba Foundation Symposium, *Human Genetic Information, Science, Law and Ethics* (Chichester: Wiley, 1990) at 155. See also Melissa L Sturges, "Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind" (1997) 13 *Am. U. Int'l. L. Rev* 219 at 221. Sturges notes that since the international community's agreement in 1988 to collaborate in the Human Genome Project and to share its findings, "as private corporations have increased their involvement in the project, they have begun to attempt to patent their discoveries of partial gene sequences."

[7] Robert Shapiro refers to the Human Genome as the human blueprint in the title of *The Human Blueprint, The Race to Unlock The Secrets of Our Genetic Script*, (New York; St Martin's Press, 1991).

[8] *Ibid.*

[9] Sturges, *supra* note 6 at 225, notes that it has been estimated that, "only two to five per cent of the genome contains genes and that the remaining 95-98 percent are "junk genes" which are of little use to the Human Genome Project."

certain genetic mutations result in genetic disease.[10] Everyone except for identical twins has a unique sequence of DNA nucleotides and consequently, analysis of a person's genetic profile can be used for extremely accurate identification. [11]

The main purpose of the Human Genome Project is to localise all of the estimated 80,000 genes on the human chromosomes and then determine the sequence of all three billion units of DNA that constitute one set of those chromosomes. The completion of a working draft of the Human Genome was announced on 26th June 2000 revealing the locality and order of 3.12 billion base pairs of the Human Genome.[12]

Much work remains to be done in terms of sequencing and discovering what the genes on each of the chromosomes actually do[13] and by investigating how disease can result from errors in their function.[14] This research will determine what further work is necessary to better understand disease and develop therapies.

Great claims have been made about the developments that have been and will be brought about as a result of the Human Genome Project. For example, in a joint statement on the 14th March 2000, the then President of the United States of America, Bill Clinton and the

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[10] A full explanation of the role that genetic information plays in the onset of genetic disease can be found in Monique K Mansoura and Francis S Collins, "Medical Implications of the Genetic Revolution" (1998) 1 *Journal of Health Care Law & Policy* 329.

[11] Human Genetics Commission, "Whose Hands on Your Genes? A discussion document on the storage, protection and use of personal genetic information" (UK: Human Genetics Commission, 2000) at 3. Online at <www.hgc.gov.uk>.

[12] See Richard S. Fedder, "To Know or Not to Know, Legal Perspectives on Genetic Privacy and Disclosure of an Individual's Genetic Profile" (2000) 21 *J of Legal Medicine* 557 at 558.

[13] See R. L. Zimmern, "The Human Genome Project: A False Dawn?" (1999) 319 *BMJ* 1282 at 1284: "At a scientific level, there is now ready acknowledgement that the ascertainment of the genomic sequence is but the first of many complex steps in the understanding of disease processes."

Prime Minister of the UK, Tony Blair declared that unencumbered access to the human genetic code as it is deciphered, "[w]ill reduce the burden of disease, improve health around the world and enhance the quality of life for all mankind."[15]

Some argue that these sorts of claims are something of an exaggeration.[16] However, all of the indications from medical science suggest that genetic technology will make enormous improvements to medicine's knowledge base by increasing understanding of genetic disease, enabling the early diagnosis of disease by genetic testing and by the eventual development of therapies or treatments for genetic disease.[17] Even if genetic technology is not yet able to benefit health through therapy[18], many are confident that this is an inevitable consequence of increasing genetic knowledge. As Maddox says, although "understanding does not always presage more effective treatment...the promise is high."[19] Indeed, it is hoped that it will be possible to determine more effective and safer drug treatments tailored to an individual's genetic makeup by developments in the

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[14] See Ari Patrinos and Daniel W Drell, "Introducing the Human Genome Project: Its Relevance, Triumphs, and Challenges" [1997] *The Judges Journal* 5.

[15] Blair and Clinton are quoted in Tim Radford, "Blair and Clinton in plea over gene code" Guardian, (15th March 2000). Online at <www.guardianunlimited.co.uk>.

[16] See British Medical Association, *Our Genetic Future; The Science and Ethics of Genetic Technology* (OUP, 1992) at 1820:

> At this relatively early stage in the development of applied genetics it is too early to be certain precisely how extensive its benefits may become. While great prospective benefits for medical science have been claimed by some protagonists, others have argued that genetic modification may have a great deal to offer to medical science but may be of less practical value to patient care...

[17] Cf. Michael M Burgess, Claude M Laberge, Bartha Maria Knoppers, "Ethics and Genetics in Medicine" (1998) 158 *CMAJ* 1309-13 at 1310 (arguing that "the development of useful clinical responses to the results of testing has not kept pace with the development of genetic tests...").

[18] See LeRoy Walters, "Genetics and Reproductive Technologies" in Robert M. Veatch, ed., *Medical Ethics* 2nd ed. (Sudbury, Mass.: Jones and Bartlett, 1997) 202 at 212: "For a minority of genetic diseases some helpful therapy can currently be offered to patients. For the most part however, the medical treatment of genetic disease is a future goal."

[19] J. Maddox, "The Case for the Human Genome" (1991) 352 *Nature* 11 at 12, cited in Sheila McLean, *Old Law, New Medicine, Medical Ethics and Human Rights* (Pandora, 1999).

science of pharmacogenics based on genetic knowledge.[20] It has been estimated that 4000 simply inherited genetic disorders are known and affect an estimated 1-2 per cent of the population.[21] The prevalence of genetic disease in the populous is therefore significant and developments in genetics will impact on almost all areas of medicine. Developments in human genetics are therefore likely to benefit the health of at least some of the world's population.[22]

Genetic knowledge not only has the potential to make improvements to health, but may also enhance self-determination by providing individuals with the knowledge to make informed choices about health, reproduction and other aspects of life. For example, pre conception or prenatal diagnosis of genetic conditions may enhance informed decision making for couples deciding whether to conceive or to proceed with a pregnancy as they may be able to determine, through testing the risk of their progeny having a genetic condition. However, as Stanworth argues, this only enhances autonomy if the choice remains in the hands of future parents and in particular mothers, rather than with doctors or society.[23] Similarly, the knowledge that one may develop a genetic condition in the future, may allow individuals to structure their life choices around that fact thereby

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[20] See Zimmern, *supra* note 13 at 1283.

[21] British Medical Association, *Human Genetics, Choice and Responsibility* (Oxford University Press, 1998) at 1.

[22] See John Bell, "The New Genetics in Clinical Practice" (1998) 316 *BMJ* 618 at 618 (claiming that "[t]he rapid advances in human molecular genetics seen over the past five years indicate that within the next decade genetic testing will be used widely for predictive testing in healthy people and for diagnosis and management of patients...").

[23] See Rose, *supra* note 5 at 33:

> In circumstances where parents and particularly mothers assume the overwhelming burden of maternal and emotional responsibility for the children they bear, it must be parents and particularly mothers who decide under what circumstances they are prepared to parent.

enhancing autonomy, provided that individuals retain control over what information they do and do not know.

These potential benefits of genetic research together with powerful commercial interests behind genetic research means that research in this area is likely to increase. Provided that the benefits outweigh the disadvantages brought about by the genetic revolution, then such research may be worthwhile.[24] One consequence of the genetic revolution is the ability of science to reveal extraordinary amounts of genetic information with relative ease from a small sample of genetic material. This information is extremely sensitive, and at the same time, may be of interest to a wide number of parties who may want access to it or to use it for certain purposes. Determining and balancing these parties' interests and rights in knowing and not knowing such information is a complex challenge for the law and society. The approach which the law ought to take in this exercise will be considered in detail in later chapters. First of all, it is necessary to explain why genetic information warrants a distinct approach to its regulation[25].

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[24] The evaluation of what research ought to take place should be determined in light of a full understanding of the genetic revolution. However, this may not yet be the case. See Sturges, *supra* note _ 6 at 228:

> The largest problem with the project is that most people do not even know it exists even though the results of the project will certainly affect them. As a result of this lack of public knowledge, the project was conceived and implemented without any input from the public, and this, without much thought about regulations, whether the benefits outweigh the costs or even whether the project should occur at all…

[25] It will be argued here that certain properties of genetic information warrant a distinct approach to its regulation, and not that it is necessarily unique in all regards. The combination of features discussed means that these ought to be taken into account in regulating genetic databases. Murray describes this argument as the 'weaker" form of the claim of genetic exceptionalism which merely "claims that genetic information is sufficiently distinctive from other information that it ought to receive greater privacy protection" as opposed to the strong claim that 'genetic information is unique." See this important discussion in Thomas H Murray, "Genetic Exceptionalism and 'Future Diaries': Is Genetic Information Different from Other Medical Information?" in M. A. Rothstein, ed,, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven; Yale UP, 1997) at 64.

1.3 What is Genetic Information?

Genetic information includes any information about heredity or disease derived from human genetic material by the application of developments in molecular technology in genetics.[26] Some understanding of the science of genetics is helpful in appreciating the sort of information that may be derived from genetic analysis, and why it may cause concern for privacy. The science of genetics is not new, although some of the technologies now employed in its advancement are recent. Since the discovery of the structure of DNA by Watson and Crick in 1953, which can be thought of as the birth of new genetic technologies there has been an exponential growth in developments in human genetics.[27] Until recently, knowledge of genes and how they are passed down from one generation to the next "came largely from experimental genetics, which depends on breeding for identifying, characterizing and mapping genes."[28] Developments in new techniques of molecular genetics have revolutionised genetic analysis, which enables the identification of genetic defects in the DNA molecule itself and makes it possible to derive extraordinary amounts of information from a small sample of DNA. As Clarke states, "The ability to identify genetic defects in the DNA molecule itself has led to a higher degree of specification of genetic disorders than has ever before been possible."[29] These developments have enhanced research techniques in genetics, whilst at the same time leaving fewer natural physical barriers to the protection

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[26] For the purposes of this thesis, it will not include information which is public knowledge, *i.e.*, information that can be derived from someone's appearance.

[27] For a history of the discoveries in genetic science see generally Walter Bodmer and Robin McKie, *The Book of Man, The Quest to Discover Our Genetic Heritage*, (Little, Brown and Company, 1994).

[28] Sydney Brenner, "The Human Genome: the Nature of the Enterprise" in *Human Genetic Information: Science Law and Ethics, Ciba Foundation Symposium* (John Wiley & Sons, 1990) at 7.

of privacy. As McLean says, "The acquisition of this knowledge will tell us more about ourselves than we have ever known."[30]

1.4 Why does Genetic Information Require A Distinct Approach to its Regulation?

There has been considerable debate over the issue of whether genetic information is special and substantially different from other health information.[31] Holm for example, argues that, "there is nothing special about genetic information which distinguishes this kind of information from other health related information in any morally or politically relevant way."[32] These arguments stress that it is not necessary to consider or treat genetic information in a different fashion than other health information since those features of genetic information which are said to make it special, apply to other sorts of health information. On the other hand, Annas et al. argue that, "To the extent that we accord special status to our genes and what they reveal, genetic information is uniquely powerful and uniquely personal and thus merits unique privacy protection."[33]

Genetic information is undoubtedly highly intimate, personal and sensitive. This alone does not really explain its distinctiveness from other sorts of information. It will be

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[29] J. T. R. Clarke, "Professional Norms in the Practice of Medical Genetics' (1995) 3 *Health Law Journal* 131 at 138.

[30] See Maddox, *supra* note 19 at 165.

[31] For example, see Murray, *supra* note 25 at 60; Annas Glantz and Roche, "Introduction" in *The Genetic Privacy Act and Commentary* (1995) at <www.ornl.gov/techtresources/human_genome/resource/p.../privacy.htm>.

[32] Sorn Holm, "There is Nothing Special About Genetic Information" in Ruth Chadwick and Alison Thomson, eds., *Genetic Information, Acquisition, Access and Control* (New York; Kluwer Academic, Plenum Publishing, 1999) 97 at 97.

[33] George J. Annas, Leonard H. Glantz, and Patricia A. Roche, "Drafting the Genetic Privacy Acts: Science, Policy and Practical Consequences" (1995) 23 *J of Law, Med. and Ethics* 360 at 365.

argued here that there are a number of features of genetic information, which when combined, make it important for the law to adopt a distinct approach to its regulation. However, it will not be claimed that genetic information is necessarily unique since some of the features that will be outlined will apply to other sorts of information. Further, the fact that genetic information is familial and social and does not relate exclusively to one person carries significant weight in determining the ethically appropriate way to regulate it.

(a) Information can be obtained with ease and without the proband's knowledge

Practically any cell in the body can be used for DNA analysis including blood, tissue samples, hair and saliva. Genetic information can reveal significant amounts of information about some of the most intimate and personal aspects of an individual's makeup with relative ease and speed, and can be analysed without the person's knowledge. For example, a discarded, used tissue or cigarette butt may be analysed to produce substantial amounts of information without the person ever knowing.[34] This provides one reason why the creation of such information raises distinct issues for privacy.

(b) Accuracy in predicting health well into the future

Current genetic tests can reveal a significant amount of information about present and future physical and mental health by identifying a person's predisposition to, or carrier

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[34] See Murray, supra note 25 at 60: "The cells mixed in with our saliva and the bulbs at the base of the hair that we continually shed are two widely distributed sources of raw material for creating genetic information about each of us."

status for certain conditions.[35] It can predict a number of medical conditions well into the future, with considerable accuracy in some cases, whereas other health information normally focuses on the short or medium term future. Thus Annas et al. have described genetic information as similar to a "future diary", since it describes an important part of someone's future life.[36] Genetic diagnosis is unlike many other forms of diagnosis in that it is possible to test for disease before the onset of the disease process. It is therefore possible to test an asymptomatic child for late onset disorders, such as Huntington's disease, which will not strike until later in life. In addition, genetic testing may reveal a likelihood that a person may develop a particular condition that they may never suffer from which may lead to unnecessary worry and stigmatisation.[37]

(c) Genetic Testing can Reveal Information about Identity

Genetic analysis of human cells also has the potential to reveal information about identity. This must also be borne in mind in determining whether and how databases of genetic information ought to be regulated since identity is an intimate and important aspect of human life. Genetic analysis has been used for identification purposes since

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[35] Currently it is possible to test for adult polycystic kidney disease, fragile X syndrome, sickle cell anemia, duchenne muscular dystrophy, cystic fibrosis, Huntington's disease, hemophilia, phenylketonuria, retinoblastoma, thalassemia, Tay-Sachs disease, familial polyposis. In the future, it is expected that tests will be developed for hypertension, dyslexia, atherosclerosis, cancer, manic depressive illness, schizophrenia, insulin dependent diabetes, familial Alzheimer's, multiple sclerosis and mytonic muscular dystrophy. See *Privacy and Genetic Testing* (Privacy Commissioner of Canada, Ottawa, Ont, 1992).

[36] See Glantz and Roche, *supra* note 31 (observing that "[t]he information in one's genetic code can be thought of as a coded probabilistic future diary because it describes an important part of a unique and personal future.").

[37] In most cases, genetic testing will indicate a likelihood or predisposition to disease rather than a certainty of developing a particular condition. See Burgess et al., *supra* note 17 at 1309 (explaining that "[a]lthough many common diseases are suspected of having a genetic component, few are purely genetic in the sense that the genetic anomaly is adequate to give rise to the disease. In most cases, genetic risk factors must be augmented by other genetic or environmental factors for the disease to be expressed.").

approximately 1984 when a scientific discovery was made[38] which enabled analysis of an individual's DNA to uniquely identify each person (except for genetically identical twins).[39] This process is commonly referred to as DNA fingerprinting since the DNA pattern only provides information about identity and does not provide information about characteristics of sex, age, height or colour. These identification tests have been used in paternity cases, for the establishment of family relationships for immigration purposes (when the documentation of relationships is insufficient), and in the criminal forensic context where a biological sample left at the scene of a crime can be analysed and compared with DNA profiles from suspects or from samples held on a database to convict or exonerate a suspect. Identification testing may also inadvertently reveal information that was not intended by the test, such as evidence that an assumed biological relationship does not exist.[40] This information is extremely personal and sensitive, particularly as estimates of the occurrence of unsuspected non-paternity in the UK is said to range from 1-30%. The fact that genetic material can be used for identification means that genetic samples are never truly anonymous and this also distinguishes them from other sorts of information.

(d) Sensitive and Accurate Information about Behaviour and Characteristics

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[38] For further discussion, see Paul Debenham, "The use of genetic markers for personal identification and the analysis of family relationships" in Ciba Foundation Symposium 149, *Human Genetic Information: Science, Law and Ethics*, (Chichester; Wiley, 1990) at 37-47.

[39] See Human Genetics Commission, *supra* note 11 at 3:

> About 95% of the DNA in the chromosomes lies outside the genes. This DNA is much more variable between individuals than the genes themselves, so it provides a very effective way of identifying individuals or tracing family relationships.

[40] "Individual Identification by DNA Analysis: Points to Consider, Ad Hoc Committee on Individual Identification by DNA Analysis, The American Society of Human Genetics" (1990) 46 *Am. J. Hum. Genet.* 631-634.

Genetic analysis may also be able to reveal sensitive information about links between certain personality traits or behaviours and the presence of certain genes in an individual's genetic makeup.[41] The science of behavioural genetics is in its infancy. However, some research already purports to demonstrate a correlation between certain genes and characteristics such as susceptibility to certain forms of behaviour, intelligence, shyness, risk seeking behaviour, aggression and sexuality amongst other things.[42] Nelkin and Andrews have summarised the power of genetics in the following terms:

> Human tissue has always provided clues to health status. But the body in the biotechnology age is speaking in new ways. Scientists daily report their discoveries of genes for traits and disorders ranging from homosexuality to manic depression, from colon cancer to shyness, from Alzheimer's disease to a tendency to take risks. Tissue such as hair, blood or saliva, when subject to DNA analysis, can reveal intimate and detailed information about a person.[43]

Although these characteristics are manifestly not wholly genetically predetermined, the fact that they may be partially explained by genetics means that any sample of human genetic material holds the key to extremely sensitive information.

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[41] For a discussion of behavioural genetic research that is being undertaken see P Florencio, 'Genetics, Parenting and Children's Rights', (2000) 45 *McGill L. J.* 528.

[42] See Jon Beckwith and Joseph S Alpher, "Human Behavioral Genetics" (1996) 10 *The Genetics Resource* 5-9; Sherman, DeFries, Gottesman, Loehlin, Meyer, Pelias, Rice and Waldman, "Behavioral Genetics '97: ASHG (American Society of Human Genetics) Statement: Recent Developments in Human Behavioral Genetics: Past Accomplishments and Future Directions" (1997) 60 *Am. J. Hum. Genet.* 1265-1275; *Genetics and Mental Disorders* (Report of the National Institute of Mental Health's Genetics Workgroup, 19 September 1997).

[43] Dorothy Nelkin and Lori B Andrews, "Symposium on Legal Disputes Over Body Tissue: Introduction: The Body, Economic Power and Social Control" (1999) 75 *Chi-Kent L Rev* 3 at 4.

(e) Genetic information has historically been used for eugenic purposes[44]

One further feature of genetic information which necessitates a distinct approach to its regulation, and which must be taken into account is the fact that elementary genetic knowledge was used in the early part of this century in the United States, Canada and elsewhere to compulsorily sterilise those suffering from genetically transmittable diseases and in some cases, criminal recidivists.[45] Hitler also used his deterministic view of genetics to justify acts of genocide against particular ethnic groups.[46] Although the term, the "new genetics" was coined as an attempt to distinguish it from the eugenics[47] of the past, the fact that genetic knowledge and heredity have historically been misused must be taken into account in any responsible discussion of genetic information. Kevles makes this point, "Given that changes in individual attitudes inevitably affect the scope of institutional action both public and private, history surely teaches that serious attention is owed to the warnings, however shrill they may sometimes be, of the dissenters of the eugenic revival."[48]

That is not to say that we should stifle scientific enquiry into genetics or even that it is always morally abhorrent to use genetic information in a way which reduces the

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[44] See Annas et al., *supra* note 33 at 365.

[45] See Mason and McColl Smith, *Law and Medical Ethics*, 4th Ed., (Butterworths, 1994) at 83 (noting that non-consensual sterilization "has been carried out in some countries as an official part of programmes of eugenic improvement or birth control.").

[46] R. J. Lifton, *The Nazi Doctors, Medical Killing and the Psychology of Genocide* (New York; Random House, 1986).

[47] Eugenics has been defined as "any effort to interfere with individuals procreative choices in order to attain a societal role." See N Holzman, "Proceed with Caution" (1989), as quoted in D. C. Wertz and J. C. Fletcher, "Feminist Criticism of Prenatal Diagnosis: A Response" (1993) 36 *Clinical Obstetrics and Gynaecology* 541-67.

[48] See D. Kevles, *In the Name of Eugenics: Genetics and the Uses of Human Heredity* (Hammondsworth; Penguin, 1985) 299, cited in Sheila A. M. McLean, "Interventions in the Human Genome" (1998) 61 *Modern Law Review* 681at 682.

prevalence of genetic disorders in society[49], but it should serve as a warning as to the possible consequences of the uses to which genetic information may be put, and which may at first sight appear neutral under the guise of science. Wikler supports this view, "Eugenics is a valuable case study which demonstrates how the prestige of science can be used to disguise the moral premises and motives for a social movement, and how class, racial, and other biases can exert powerful and damaging influence over such a movement while remaining virtually invisible to its advocates." [50]

The use of science for political, social and economic purposes has demonstrated that it is not always a neutral enquiry into the attainment of knowledge. Access to and uses of genetic information ought therefore to be treated with some degree of scepticism in order to ensure that the abuses of the past are not repeated. It cannot be assumed that the scientific advances in genetics and the creation of knowledge will be uncontaminated by a particular social, political and economic context and it is important to be aware that any information "is not a neutral tool but will have been prepared and presented by individuals with their own interests and values."[51] If anything, the fact that genetic technologies now enable more information than ever to be known about individuals heightens the need to be aware of these concerns.[52]

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[49] See George P Smith, II, 'Genetic Enhancement Technologies and the New Society' (2000) 4 *Medical Law International* 85 at 94 (arguing that modern eugenics, in the form of genetic enhancement and engineering, can be used as a positive way of advancing health of the future members of society.).
[50] See Dan Wikler, "Can we learn From Eugenics?" (1999) 25 *J of Med Ethics* 183 at 183.
[51] See Dr. Mairi Levitt, "A Sociological Perspective on Genetic Screening" (1997) 13 *Eur. J. Gen. Soc.* 19.
[52] See Ruth Macklin, "Mapping the Human Genome, Problems of Privacy and Free Choice" in Milunsky and Annas, *Genetics and the Law* (New York, London; Plenum Press, 1984) 107at 113:

(f) Genetic Information has the Potential to Infringe Reproductive Freedom

One potential danger which might arise out of developments in genetics and which must be taken into account when considering the regulation of genetic information is the fact that it may be used in ways that infringe upon an individual's reproductive freedom and in particular the reproductive freedom of women. The creation of information about genetic disorders that may be passed down from one generation to the next, introduces an element of potential control into reproductive decision-making, which was previously not present. Reproduction which was once a private matter is made vulnerable to interference from society, the medical profession and others. As Parker argues, "In some ways genetics, particularly when combined with new reproductive technology, seems to bring the private into the public arena." [53] The way in which this interference is exercised poses extremely important challenges for society.

Commentators have argued that society, sexual partners, or others have an interest in the decision as to whether a child should be created where there is a chance (significant or otherwise) that it may have a particular genetic condition or disease. Indeed, it has also been argued that there may be a duty not only to disclose genetic information one is already aware of, but also to access genetic information one may not wish to know because of a duty to others.[54] For example, Sommerville and English ask:

> Without doubt, the ability to map the human genome, yields information about susceptibility that is more precise, more certain, and potentially more threatening to individual freedom and privacy than earlier methods of presymtomatic diagnosis and vague hypotheses about 'familial' traits.

[53] See Michael Parker, "Public Deliberation and Private Choice in Genetics and Reproduction" (2000) 26 *J of Med Ethics* 160 at 160.

[54] See Walters, *supra* note 18 at 217:

> Thus a complementary and balancing thesis is that individuals and couples have a moral duty to learn what they can about the likelihood that they will transmit genetic conditions to their

> If a couple are planning to have children, for example, the man has a legitimate interest in knowing whether the mother of his potential child is a carrier of a serious x-linked condition. If genetic abnormalities have been detected in either family, it would be important to know if either partner were likely to develop a disabling genetic disorder. Each partner may prefer to remain ignorant of his or her own genetic status but if the technology exists to give an accurate picture, might there not be an obligation to access knowledge for the sake of others - not least for the well-being of the potential child? [55]

It is understandable why sexual partners and others may wish to know information of this sort, but this raises the issue of how this impacts on the interests, and rights of the individual from whom the information derives. Some argue that genetic knowledge may result in the development of an obligation not to reproduce or to terminate a pregnancy where this may result in a child carrying a genetic disorder. Clarke for example discuses the "social pressures that may be exerted on couples, and especially on women, to terminate a pregnancy thought to be affected by a genetic disorder."[56] In addition, although genetic counsellors generally argue that the counselling which they provide is non-directive[57] it has been said that some counsellors make certain assumptions about

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offspring and to take reasonable steps –steps that are compatible with their other ethical convictions to avoid causing preventable harm to their descendants.

[55] Ann Sommerville and Veronica English, "Genetic Privacy: Orthodoxy or Oxymoron?" (1999) 25 *J of Med. Ethics* 144.

[56] See A. Clarke, "Is Non Directive Genetic Counselling Possible?" (1990) 338 *Lancet* 998 at 1000, cited in Rothenberg and Thomson, eds. "Reproductive Genetics and Gender Justice" *in Women and Prenatal Testing: Facing the Challenges of Genetic Technology* (Columbus: Ohio State University Press, 1994) at 67-87.

[57] See, for example, Barbara Bowles Biesecker, "Privacy in Genetic Counselling" in M. A. Rothstein, ed., *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era*, (Yale University Press, 1997) at 108-125.

health and disability, and that these inevitably influence decision-making.[58] It may also be argued that the state has a legitimate interest in accessing genetic information and in influencing reproductive choice because of the financial consequences for society of bringing a child into the world who has a predisposition to or who is suffering from a genetic disorder.[59] It has even been argued that parents may have an obligation to their unborn and potential children to use genetic information in a certain way and that they may have an obligation to request germ line therapy.[60] The consequences of such arguments are far reaching and have the potential to seriously undermine individual liberty. The fact that genetic information can impact upon reproductive freedom in this way is reason for the law to adopt a distinct approach to its regulation.

(g) Discrimination

Access to genetic information provides an opportunity for discrimination in insurance,[61] employment,[62] adoption and by other parties who may have an interest in utilising it.

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[58] Dena S Davis, "Genetic Dilemmas and the Child's Right to an Open Future" (1997) *Hastings Center Report*, 7-15 at 7.

[59] Such arguments have been taken seriously in some parts of the world. For example, in 1993, a draft law on eugenics and health protection was proposed to the Chinese National People's Congress. This proposed to prohibit marriages in which the offspring was likely to become a burden on the state. This proposed law was heavily attacked by western countries and was redrafted. See Bobrow, "Redrafted Chinese Law Remains Eugenic" (1995) 32 *J Med. Genet.* 409, cited in Gunter Bruns and Moshe Wolman, "Morality of the Privacy of Genetic Information: Possible Improvements of Procedures" (2000) 19 *Medicine and Law* 127-139:

> The new draft in which the term eugenics was omitted, still contains mandatory examination prior to marriage but at the same time allows marriage of carriers of diseases deemed "medically inappropriate for child bearing" only if the couple undertakes to take adequate measures to prevent conception.

[60] For example, Harris argues that a parent's obligation to avoid harm can include both not causing harm and taking steps to avoid harm. J. Harris, *Wonder Woman and Superman*, (Oxford University Press, 1992) at 178.

[61] *The Implications of Genetic Testing For Insurance*, (Human Genetics Advisory Commission, 9th July 1997); Alexandra Glazier, "Genetic Predispositions, Prophylactic Treatment and Private Health Insurance: Nothing is Better than a Good Pair of Genes" (1997) 23 *American J of Law and Medicine* 45-68; E. David Cook, "Genetics and The British Insurance Industry" (1999) 25 *J of Med Ethics* 157-162; Ruth Chadwick

There is a wealth of literature on the potential discriminatory uses to which genetic information may be put. In employment, there is little evidence of genetic information being used in this way at present in the UK. However, there is also evidence that such uses are likely to increase in the future as genetic testing produces increasing accurate results for a wider range of conditions at a cheaper cost.[63] Similarly, the widespread use of genetic information in setting life, health and other insurance premiums, is likely to be an inevitable consequence of developments in genetic technologies.[64] The concerns that genetic information may be used for discriminatory purposes is predicated on certain parties having access to it or on a requirement for individuals to disclose such information where known. This potential for discrimination also necessitates a distinct approach to the regulation of genetic information.

(h) Perceptions of Disability in Society and Stigmatisation

An additional argument for a distinct approach to the regulation of genetic information is that genetic technologies will impact upon societies' perceptions of disability. Prenatal testing and screening which reveal the existence of a genetic condition may impact negatively upon how society views disability. If society starts to view certain genetic conditions as being avoidable, a level of blame may attach to those who continue with

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and Charles Ngwena, "The Human Genome Project, Predictive Testing and Insurance Contracts: Ethical and Legal Responses" (1995) 1 *Res Publica* 115-129.

[62] See Trudo Lemmens, "'What about your genes?' Ethical, Legal and Policy Dimensions of Genetics in the Workplace" [1997] *Politics and the Life Sciences* 57-75; Jon D Bible, "When Employers Look for Things Other Than Drugs: The Legality of AIDS, Genetic, Intelligence and Honesty Testing in the Workplace" [1990] *Labor Law Journal* 195-213; Mary Bassett Stanford, "Genetic Testing In Employment: Employee Protection or Threat?" (1993) 15 *Suffolk University Law Review* 1187–1216.

[63] *The Implications of Genetic Testing for Employment* (Human Genetics Advisory Commission, July 1999). Online at <www. hgc.gov.uk>.

pregnancies known to lead to the birth of a child with a genetic condition. In addition, although minimising the level of disability in society may prevent much suffering, if this creates a position whereby disability is more rare and thought to be preventable or a result of choice, this may contribute to less toleration of disability in society. Knoppers has made a similar point, "It is also arguable that if one sees genetic consequences as inevitable and certain, one may be inclined to look to the elimination of the genetically disabled rather than to the finding of ways to accommodate such persons within society."[65] Similarly, the detection of a marker for certain conditions may carry a substantial risk of social stigmatisation regardless of whether the person will ever in fact suffer from it. The fact that these consequences may result means that they ought to be taken into account in the approach that is adopted for the regulation of genetic information.

(i) Changes in Self-Understanding

Another reason that makes genetic information particularly sensitive is that it will lead to changes in our self-understanding.[66] These changes in self-understanding may have profound ramifications for society or certain sectors of it.[67] For example, genetic research may reveal information about a community that challenges the basis of its

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[64] *Report on Insurance and Genetic Testing*, (Human Genetics Advisory Commission, December 1997); *Report on Genetics and Insurance* (House of Lords Select Committee on Science and Technology, March 2001).

[65] Bartha Maria Knoppers, *Human Dignity and Genetic Heritage: A Study Paper* (Ottawa, Law Reform Commission of Canada, 1991) at 2.

[66] See Murray, *supra* note 4 at 59:

> It may be that the most important challenges posed by the Human Genome Project will not be the pragmatic concerns discussed thus far, but will have to do with the way we understand ourselves, our nature and significance, and our connections with our ancestors and descendants.

religion, traditions or history.[68] In addition, genetic developments are frequently the subject of exaggerated reporting in the press, which leads to misinformation in society.[69] These exaggerations add force to the notion that our behaviour and health is determined by our genetic makeup. This concept is known as genetic determinism. Whereas all disorders, diseases, behaviour and characteristics are a combination of the interplay between genes and environment, this fact is often overlooked in for example reports that claim that the gene for intelligence or homosexuality has been located. Taken to an extreme, this may lead to a position in society whereby people are not seen as free willed human beings, but instead may be viewed as purely a product of their genes and as having little control over their choices and actions. Such consequences, whether or not based on scientific fact, would permeate all areas of life, and they demonstrate the potential power of genetic information.

(j) The Limitations of Genetics Are Not Yet Known

The limits of information, which a sample of DNA has the potential to reveal, are not yet known. More precise tests for additional genetic conditions are in the process of development. As Shapiro and Weinberg put it, "It is important that the law realize it is simply not a matter of what we can currently read from the DNA profile analysis, but

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[67] For example, the purpose of the Human Genome Diversity Project, which was proposed by the Human Genome Organisation in 1991, was to find out "who we are as a species and how we came to be." See British Medical Association, *supra* note 21at 195.

[68] Weijer, Goldsand and Emmanuel, "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation" (Nov 1999) 23 *Nature Genetics* 275-280 at 277 (pointing out that Aboriginal peoples are increasingly concerned that genetic research may adversely affect them and their values).

[69] See, on this point, Ruth Hubbard, Elijah Wald, *Exploding the Gene Myth, How Genetic Information is Produced and Manipulated by Scientists, Physicians, Employers, Insurance Companies, Educators* (Boston; Beacon Press, 1993).

what we will be able to read from this genetic information in the very near future."[70] Therefore, genetic material must be considered in the light of what it may be possible to reveal in the future as well as what there is already the potential to know.

(k) Genetic Information is Familial and Social

Genetic information not only reveals information about an individual.[71] It also reveals information about the health, identity and behaviour of all of those who share the genetic heritage of the individual being tested including his or her family and community.[72] Hellsten expands on this point by saying:

> [D]espite the fact that genetic information is extremely personal, it simultaneously concerns more that one person, and thus clearly includes social aspects. Deciphering an individual's genetic code provides the reader of that code with information related not only to a particular, unique individual but about those who are genetically related to him or her. The collection and use of genetic information does not concern only those individuals from whom the samples are collected. In addition it can also affect the future of a great number of other

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[70] E. Donald Shapiro & Michelle L. Weinberg, "DNA Databanking: The Dangerous Erosion of Privacy" (1990) 38 *Clev. St. L. Rev.* 455-486 at 472.

[71] See Lawrence O. Gostin, "Genetic Privacy" [1995] *J of Law, Med And Ethics* 320-330 at 321; Lerman, Peshkin, Hughes, Isaacs, "Family Disclosure in Genetic Testing For Cancer Susceptibility: Determinants and Consequences" (1998) 1 *Journal of Health Care & Policy* 353-373.

[72] Indeed, sometimes family members can have significant interests in their family members undergoing genetic testing as this can help reveal their own probability of suffering from certain genetic diseases. Linkage studies focus on families with a high number of individuals who suffer from a particular disease that is known to have a genetic component (*i.e.*, heart disease). Genetic analysis and statistical analysis can determine the statistical probability of an individual having a certain disease if they carry the genetic marker prevalent in the family. See Human Genetics Commission, *supra* note 11 at 15; Peter S. Harper, "Research Samples from Families with Genetic Diseases: A Proposed Code of Conduct" (1993) 306 *BMJ* 1391-94. See also the discussion of the interests of families in accessing genetic information in Jennifer Miller, "Physician-Patient Confidentiality and Familial Access to Genetic Information" (1994) 2 *Health Law Journal* (1994) 141.

> people, such as members of a particular family (parents, children, siblings), or even larger ethnic or racial populations.[73]

The fact that genetic information is familial and social is of paramount importance when considering who should have the right to access and control genetic information.[74] This feature means that traditional ethical principles require to take account of this fact when determining who ought to have access to genetic information.[75] Although there are other examples in a health care setting whereby the diagnosis of one person reveals a possibility or likelihood of another person having been infected with a disease (for example in the case of transmission of HIV), the fact that genetic information reveals actual information about other people's genetic makeup and not just a possibility of them having a certain condition distinguishes genetic information from other health information.

Participation in research by a large number of members of a community may reveal information about others in that society. For example research might reveal that a community has a high risk of mental illness. This has implications for the interests of those in the community who may not wish to know such facts or who fear the consequences of others knowing such information. The community may also have

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[73] Sirkku Kristina Hellsten, "Biotechnology, Genetic Information" and Community, From Individual Rights to Social Duties?" in Thomson and Chadwick, ed., *Genetic Information, Acquisition, Access and Control* (New York; Kluwer Academic/Plenum Publishing, 1999).

[74] See Fedder, *supra* note 12 at 560:

> Given that approximately 80% of human DNA, can be found in all living organisms, and that 98% of human DNA is shared with the great apes, it seems paradoxical to argue that knowledge of one's gene structure should be viewed as arguably personal and private information. The variance in DNA between any two human beings is less than 0.1%.

interests in having access to information about the genetic makeup of its members in order to more accurately identify genetic risks.

In sum, there are several compelling arguments for these distinctive features of genetic information influencing the sort of approach that the law ought to take towards its regulation. Although it is not necessary to go as far as Annas et al. in demonstrating that genetic information is unique and unlike any other sorts of information[76], it is the case that these features of genetic information ought to influence the law's approach for the reasons discussed. More will be said about the ethical importance of the fact that genetic information is familial and social in chapter three. Later chapters will consider how this fact may be taken into account in practice.

This chapter will now explain those features of databases of genetic information and material that make it important to focus on genetic databases as opposed to genetic information in itself. This chapter will conclude by explaining that there is an urgency for this issue to be considered because of the scale of current and planned genetic databases in the UK, and elsewhere and because of the distinct approach that requires to be taken to the regulation of genetic information and material.

1.5 Databases of Human Genetic Material and Genetic Information

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[75] See Tuija Takala and Heta Aleksandra, "Who Should Know About Our Genetic Makeup and Why?" (2000) 26 *J of Med. Ethics* 171-174.
[76] *Supra* note 33.

In this thesis, the term genetic database is used to include all large scale, ordered collections of genetic information or genetic material from which it is possible to derive genetic information.[77] Collections of genetic information include clinical health records as well as databases formed for genetic registries or for research purposes. This definition is intentionally all encompassing since the aim of this thesis is to consider the privacy issues raised by collections of genetic information and material, which exist in many forms. It is possible to infringe privacy by accessing, controlling and using collections of tissue, as well as genetic information.

Genetic databases raise distinct issues for privacy for three reasons. Firstly, privacy is no longer protected by the physical obstacles of gaining access to a biological sample for analysis. Where genetic material is already held on a database there is no need to invade the body for genetic testing to occur. The data and tissue is available for uses other than those originally intended.[78] As Fedder says, "First, DNA samples can be collected and stored for long periods of time. This means not only can a record of the results of past genetic tests be maintained, but also new tests can be conducted on an individual's DNA

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[77] The House of Lords Select Committee on Science and Technology Enquiry into Genetic Databases (2000), defined databases as "[c]ollections of genetic sequence information, or of human tissue from which such information might be derived, that are or could be linked to named individuals." The definition does not include medical histories which relate or may relate to genetically-determined syndromes. *Select Committee on Science and Technology Enquiry into Genetic Databases, Call for Submission and Written Evidence* (House of Lords Select Committee on Science and Technology, 2000) (hereinafter House of Lords Written Evidence) at 1. Online at <www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/115/115we02.htm>. See also Jean E. McEwan "DNA Databanks" in Mark A Rothstein, ed., *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era* (Yale University Press, 1997) at 231, defining DNA databases as

> [r]epositories of genetic information about individuals obtained from the analysis of DNA samples...Typically however, they involve the routine storage of genetic information about a large number of people, the information is generally maintained with individual identifiers and in computerised form, making it easy to access and potentially to share.

as the need arises."[79] As a result, the law of consent which protects against bodily intrusions will not prevent others having access to the genetic material.

With respect to information databases, they raise particular issues for privacy since large collections of data are held in centralised computers or other systems. A large number of people may have access to such information unrestricted by geographical location and the data can be accessed, copied and transferred with great speed. Where genetic information is stored in such databases and held by third parties and out of the physical control of those to whom they relate the ethical arguments concerning who should have access to these databases are distinct since the information is already in existence.

Some may argue that it makes no difference that the information is already in existence and held by a third party. However, that argument fails to appreciate that the existence of the information in itself changes the ethical landscape. As one commentator has put it, 'Despite the view of the BMA that "biotechnology and genetic information are in themselves morally neutral" I would suggest that, while the uses to which that information are put may be the more problematic situation, the mere holding of the information is in itself of great ethical concern."[80]

A second point to note is that in some cases the information will not be known by the individual from whose genetic material it was derived. In the context of a research

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[78] See Marie Hirtle, "International Policy Positions on the Banking of Human Genetic Material" in Timothy Caulfield, Bartha Maria Knoppers and Douglas Kinsella, eds, *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996).
[79] See Fedder, *supra* note 12 at 580.

database the information may be subject to a one way coding system and the individual may not be informed of the results of the genetic analysis carried out. In such a case the individual could not be required to disclose the information to others since he is not aware of it. In addition, other parties will not be able to access genetic information from some databases regardless of their interests in it since this may be physically impossible. In other forms of database the information may be completely identifiable and the individual may know such information.

Thirdly, research undertaken on databases of large sectors of any population will reveal information about others in that community who share their genetic heritage in some form. The privacy of the community, and its members will be at issue, whereas individual genetic testing does not raise issues for group privacy. Therefore, there are certain features of databases that make it important to consider their implications for privacy.

Developments in information technology and the capacities of computers have added to the urgency of considering privacy of genetic information since information technology has made it possible to match data, process, analyse and transfer it at greater speed and with increasing accuracy that ever before. Prior to these developments in information technology, the lack of ability to transmit, store and analyse information readily, provided a barrier to sharing and accessing information and hence a certain protection for privacy. Where information was stored on paper files, for example, in local doctors surgeries it was largely only accessible to those who could physically access it. Anticipated future

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[80] See Maddox, *supra* note 19 at 167.

developments in each of the fields of information technology and genetic technology are likely to mean that the number and scale of databanks and databases of information and material will increase.[81] This is part of a general trend towards computerising medical records.[82]

1.6 Why Databases Are Important

The establishment of genetic databases is not an entirely new phenomenon and many databases containing genetic information or genetic material from which DNA can be extracted have existed for some time. For centuries, samples of tissue from cadavers and living bodies have been taken and stored. These tissue stores have been used for invaluable research.[83] As Blatt says, "Repositories of biological samples have existed for decades in public and private research laboratories, pathology departments, and clinical health care settings."[84]

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[81] As Bell says, "The ability to characterize large amounts of genetic information efficiently and cheaply is likely to increase dramatically over the next 5 to 10 years." *Supra note 77, House of Lords Written Evidence* , Memorandum by Professor John Bell, Nuffield Prof of Clinical Medicine, University of Oxford.

[82] See Hoeffel, *supra* note 1 at 13:

> The future ideal, from the "informatics true believers" perspective, comprises patient health care record systems that are: comprehensive (as opposed to scattered by incidents, specialities, or institutional settings); cumulative throughout lifetimes; standardized as to data coding and formatting (to be universally interpretable); networked and inter-operable (to allow effective data transfer among diverse units and data systems); and secure (to prevent their being interpreted or corrupted, and to control access).

[83] Databases have a particular importance in monitoring public health and the safety of medicines and devices including disclosures to cancer and other registries. Professional organizations and government regulatory bodies that monitor the public health or the safety of medicines or devices as well as cancer and other registries, rely on information from patients records for their effectiveness in safeguarding the public health.

[84] Robin J. R. Blatt, "Banking Biological Collections and Digitalizing DNA: Data Warehousing Data Mining, and Data Dilemmas in Molecular Medicine and Public Health Policy" (OECD Workshop Vienna 2000 on Genetic Testing Policy Issues for the New Millennium Abstracts, 23-25 February 2000). Online at <www.oecd.org/dsti/sti/s_t/biotech/prod/genetic_testing.htm>.

There are tremendous benefits for medical research in accessing large databases of this sort.[85] Epidemiology, the scientific method which investigates the occurrence of disease in populations in order to identify the causes of disease has played an important role in public health research for some time and has involved the use of databases of tissue and information.[86] Tissue databases have the potential to be analysed and tested for genetic research since they contain DNA. In addition, databases of health information have been established in the clinical context, in hospitals and for use in medical research. However, genetic developments and other commercial incentives have resulted in increased plans to create large-scale databases[87]. There is no doubt that genetic databases will increase in size, number and sophistication in the near future.

That the establishment of an increasing number of large databases is likely and raises important issues for privacy does not mean that their establishment ought to be discouraged. The Human Genetics Commission discussion document on genetic information commented that a failure to develop databases of this sort would have significant costs in terms of "prolonged human suffering from disease."[88] The Medical Research Council[89] reaffirmed the importance of databases in the context of research in

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[85] See Ruth Chadwick, "The Icelandic Database; Do Modern Times Need Modern Sagas?" (1999) 319 *BMJ* 441 at 444: "Both sides of the database debate, however, seem to agree about the value of the science."

[86] Epidemiology is defined in Samet and Bailey, "Environmental Population Screening" in M. A. Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997) 197-211 at 197.

[87] The approach of the law and international agreements towards the patenting of gene sequences and cell lines and products from genetic research will inevitably have an impact upon the commercial incentives behind genetic research. See E. Richard Gold, "Biomedical Patents and Ethics: A Canadian Solution" (2000) 45 *McGill Law Journal* 413-435.

[88] See Human Genetics Commission, *supra* note 11 at 22.

[89] The Medical Research Council is the U.K.'s principal public-sector funder of genetics research relevant to human health. See *supra* note 77, Memorandum by the Medical Research Council:

their submission to the Select Committee of the House of Lords Enquiry into Genetic Databases.[90] Studies of actual tissue and genetic information are necessary to make use of the information derived from the Human Genome Project to correlate discoveries about our genes with actual diseases suffered.[91]

> The research will mean looking for answers through large-scale data analysis by computers without knowing what the actual questions are. Researchers are looking for links and correlations that cannot necessarily be foreseen at this stage. From those links, they hope to learn more about how the diseases develop and how they may be prevented.[92]

It should also be noted that the extent to which privacy can be protected by anonymising genetic databases is restricted by the fact that much genetic research requires to be carried out by matching it with other information about an individual's health, age, sex and lifestyle. In some cases the research necessitates keeping identifiers on the data so that this information can be updated over time. The Medical Research Council has repeated this assertion. "Such data collections usually need to be large, and to collect detailed

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> Human Genetic Databases play an important role in medical research and will do so increasingly over the coming years. The major benefits of knowledge of the human genome sequence for public health will come from the discovery of genetic factors predisposing people to develop the common, multi-factorial diseases of later life, and those affecting an individual's response to treatment of such disorders. Knowledge will allow the possibility of more effective use of existing treatments and also the development of new treatments and interventions to prevent the progression of disease. Databases bringing together health information and genetic information are one of the key tools we can use to make these advances.

[90] *Human Genetic Databases, Challenges and Opportunities*, (House of Lords Select Committee on Science and Technlogy, 4th Report, Session 2000- 2001).

[91] An example of such a study is a linkage study described in the submissions to the House of Lords Enquiry which involves databases of genetic material from families with a history of heart disease to try to search for novel genetic variants which may be linked to heart disease. Heart disease kills over 25,000 individuals younger that 65 years old in England and Wales each year. House of Lords Written Evidence, *supra* note 77.

[92] See Human Genetics Commission, *supra* note 11at 23.

information about people's health, lifestyle and medical care over a long period of time."[93]

If such databases are valuable in terms of the benefits that they may bring to medicine and science, and society decides that these benefits are important,[94] then it falls on the law to determine an acceptable way of regulating genetic databases to ensure that there are no unacceptable infringements of privacy. A successful regulatory policy about which members of society feel confident will assist rather than inhibit genetic research.

1.7 Databases in Practice

The remainder of this chapter will highlight the urgency for this issue to be considered by detailing current and future planned databases in the UK and elsewhere. The written evidence of the House of Lords Select Committee Enquiry into Genetic Databases

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[93] The Medical Research Council gave an example of one such study in their submission to the House of Lords Select Committee Enquiry into Genetic Databases, 2000-2001. 'The Avon Longitudinal Study of Parents and Children (ALSPAC) was specifically designed to analyse the interplay between genes and environment in areas such as childhood, infection, allergy, asthma, growth and development. The project is based on information about 14,000 children born in 1991 and 1992, and their parents. Information is derived from the analysis of questionnaires completed by their parents, measurement of the environment in the home, non-genetic assays of biological samples, and tests at age seven and eight, as well as analysis of DNA. Over 127,000,000 items of information are already on the main database, and some 70-research papers have been based on the survey. House of Lords written evidence, *supra* note 77.

[94] Some commentators question whether databases are important and necessary. For example, Burris and Gostin argue that we should not be too quick to make certain assumptions about the collection of genetic data and genetic screening programs for public health purposes. Scott Burris and Lawrence O Gostin, "Genetic Screening from a Public Health Perspective: Some Lessons from the HIV Experience" in M A Rothstein Ed *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997) 137-157 at 138:

> Putting aside the assumption that widespread collection of genetic data is both desirable and inevitable sets a very different agenda for public health law. As a preliminary matter, we are required to ask, what criteria need to be satisfied to justify a particular genetic intervention in public health terms and to what extent have they been satisfied?

indicates some examples, of current genetic tissue and information databases in the UK.[95] It reported on the challenges and opportunities posed by genetic databases in 2001 and found that there is a significant number of tissue banks and genetic databases of all sizes including a large number of small-scale databanks.[96] These were largely established for research to be conducted on them. The written evidence also highlighted a proposal for the establishment of a large-scale genetic database referred to as the UK Population Biomedical Collection, which consists of a joint project between the National Health Service, the Medical Research Council and the Wellcome Trust. This is intended to involve a large national sample of between 500,000 and one million patients identified from general practice who will donate DNA samples. This will build upon the NHS infrastructure for tracking patients and will use electronic medical records. This collection is to increase understanding of the interactions between genes, environment and lifestyle. This means that the database also requires ongoing collection of data from research subjects.[97]

Certain collections of health records and other health information can form genetic databases.[98] The written evidence also confirmed that databases are commonly

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[95] For a discussion of the extent of databanking in the United States of America see Phillip R Reilly, "DNA Banking" (1992) 52 *Am J Hum Genet* 1169-1170. He found that "[i]n sharp contrast to commercial DNA Banking, state based forensic DNA Banking is growing rapidly."

[96] For example, the Medical Research Council's submission to the House of Lords Written Evidence, *supra note 77* said that a survey of Medical Research Council and Cancer Research Campaign-funded scientists in 1998-99 suggested that there are well over 300 collections of cell or tissue samples in use, within that research community alone. Two thirds of the collections involved samples from 500 people or less, and only five exceeded 10,000 samples of DNA.

[97] This point is made in Jane Kaye and Paul Martin, "Safeguards for Research Using Large Scale DNA Collections" (2000) 321 *BMJ* 1146-1149.

[98] Glaxo Wellcome highlighted the value of NHS records in their written evidence by saying that "[t]he UK has the opportunity through the National Health Service system of tracking patients and using electronic medical records to establish a valuable genetic research database." House of Lords Written evidence, memorandum by Glaxo Wellcome, *supra* note 77.

established in an adhoc way in the context of clinical care whereby samples of tissue are taken for testing of some sort (not necessarily genetic testing) and retained. Some of these can be extremely large scale, for example, collections of Guthrie cards which contain samples of blood taken from new-borns in screening programs.[99] Gostin points out that databases of this sort can be problematic since consent was not normally given for such tissue samples to be retained and used for secondary purposes and yet they provide a useful resource for subsequent research. He says:

> One problematic source of information is previously stored tissue samples. Stored tissue samples may be regarded as inchoate data bases because the technology exists to extract from them a vast amount of current and future health data. The public health and research communities have shown increasing interest in using existing tissue samples for genetic testing and for creating new genetic databases. In some cases genomic information is being extracted from large collections of tissue samples which were stored well before the advent of genetic testing: any consent that may have been obtained originally for tissue samples did not even envisage future genetic applications. [100]

The UK also has a large forensic database of approximately 750,000 DNA samples, which is to be used for identification purposes in the detection of crime.[101] Recent plans

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[99] Indeed, the Government Commissioned Report into the scale of organs held without consent in the UK by NHS trusts and medical schools found that, at the end of 1999, 210 NHS trusts and medical schools were holding 104,300 organs, body parts, and entire bodies of still born babies and foetuses. There are many more collections of this sort in and around the UK. See 'Shocking Body Parts Scandal Revealed" *The Times* (30 Jan 2000).

[100] Lawrence O. Gostin, "Health Information Privacy" (1995) 80 *Cornell Law Review* 413 at 467.

[101] See Dea Birkett, "Guilty as Predicted" *The Guardian* (Tues Dec 19, 2000); M. Guillen, M. V. Lareu, C. Pestoni, A. Salas and A. Carracedo, "Ethical-legal problems of DNA databases in criminal investigation" (2000) 26 *J. of Medical Ethics* 266-271.

in the UK have been made to vastly increase the number of DNA samples held on the database and funds have also been made available for this purpose.[102] Further databases have been established elsewhere for identification purposes in the army and for other purposes.[103] These types of databases will not be considered within the ambit of this thesis.[104]

The evidence presented to the House of Lords enquiry indicates that plans for wide scale expansion of genetic databases are mirrored elsewhere in the world. For example, wide scale databases of large sectors of the population are already established or are planned to be established in Iceland,[105]Tonga and Estonia[106]. The Icelandic Health database which was established to enable population genetic research to be carried out is probably the best known and most commented on database. It is helpful to briefly mention some

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[102] "Human Genetics Commission to Promote a Wider Public Debate on DNA Database Proposals" (Human Genetics Commission Press Release, 1st Sept 2000). Online at <http://www.hgc.gov.uk>.

[103] See generally *supra* note 96. Reilly points out that DNA banking by the military in the USA has been undertaken for some time to assist in the rapid resolution of identification of human remains. In addition, commercially based repositories in the United States have been offering DNA banking as a service to researchers and individuals who may have some reason to store their DNA in anticipation of the development of a linkage test that might benefit their children and grandchildren.

[104] Although it is worth mentioning forensic databanking of genetic information since a major concern for privacy is that databases established for one purpose may be used for another. For a discussion of DNA banking for identification in the criminal context, see Warren R. Webster, "DNA Database Statutes & Privacy in the Information Age" (2000) 10 *Health Matrix* 119-140; Jean E. McEwan and Phillip R. Reilly, "A Review of State Legislation on DNA Forensic Data Banking" (1994) 54 *Am. J. Hum. Genet.* 941-958; Andrea de Gorgey, "The Advent of DNA Databanks: Implications for Information Privacy" (1990) 16 *American Journal of Law and Medicine* 381-398.

[105]Henry T Greely, "Iceland's Plan for Genomics Research: Facts and Implications" (2000) 40 *Jurimetrics Journal* 153-191.

[106]It was reported in November 2000 that the Estonian Genome Foundation was looking for investors to fund a database of medical and genetic data from its population of about 1.3 million people. According to that article, 90% of Estonians have willingly accepted the idea and are willing to participate by allowing samples of genetic material to be stored on a database together with a detailed medical history. Michael Gross, "Estonia Sells its Gene Pool" *The Guardian* (Thursday, 9 Nov 2000). Similarly, in Tonga the Government has negotiated with an Australian biotechnology firm to establish a similar database of a smaller scale. The population of Tonga is 108,000 and is especially homogenous making it an ideal place for the conduct of genetic research of this sort. The Tongan government will retain ownership over the DNA samples collected and will benefit from Royalties from successful commercial ventures from the

features of the scheme here since it may indicate the trend towards the establishment of databases of this kind.[107]

A private company in Iceland called deCODE established a wide scale database of health information as a result of legislation[108] passed by the Icelandic parliament in December 1998 which enabled them to collect this information under the terms of a license for a specified period of twelve years. Unless Icelanders specifically chose to opt out of the scheme, deCODE was given access to their health records (although certain security measures and anonymising of data occurs under the scheme). DeCODE, then cross references this health information with genealogical information about the Icelandic population (which is publicly available) together with samples of genetic material from those in the population who wish to donate it. This information is used for research that intends to discover correlations between genes and certain genetic conditions.

The population of Iceland is approximately 270, 000 and a large majority of the population chose not to opt out of the scheme making the database of health information (including genetic information available in their medical records) fairly large.[109] It is not clear how many Icelanders have chosen to donate samples of genetic material. In any

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scheme. See Patrick Barkham, "Faraway Tonga cashes in on its gene pool secrets" *The Guardian* (Thursday November 23, 2000).

[107] *Ibid.*; George Annas, "Rules for Research on Human Genetic Variation, Lessons From Iceland" (2000) 342 *New England J of Medicine* 11830.

[108] *Act on a Health Sector Database, Reykjavik: Ministry of Health, 1998* (No 139/1998).

[109] The scheme was heavily criticised because individuals were presumed to consent to participation unless they withdrew their consent. This meant that consent was not really informed consent and that some individuals who could not exercise their right to withdraw would have their records included automatically. In addition, individuals were not informed of the particular research that would be performed using their records and consented only in general terms to having their information used. See discussion in Annas, *supra* note 107.

event, this serves to show that an increasing number of genetic databases of entire populations or parts of populations are highly probable.

1.8 Conclusion

This chapter has argued that one major consequence of the genetic revolution is the ability to produce extraordinary amounts of personal, sensitive information from the molecular analysis of a cell. This chapter sought to explain why genetic information in general and genetic databases in particular are thought to raise important legal and ethical issues for privacy.

Genetic information was argued to be personal and sensitive, and warranting distinct consideration from other information for a number of reasons, including because it relates not solely to one individual but reveals information about the genetic makeup of the proband's family and community at the same time. Genetic databases have several properties that mean that they raise particular issues for privacy. For example, the information is in the hands of a third party, the information may be accessible, and can be transferred with great speed. In addition, the information may not be known by the person to whom it relates. Research on genetic databases can reveal information about the predisposition of a certain group to genetic conditions and can therefore impact upon group privacy.

The final part of this chapter set out some reasons why it is important to consider the issues raised by genetic databases. There is a trend in society for the establishment of an increasing number of large-scale population databases, which are important for the conduct of research. One imminent plan for the establishment of such a database in the UK, that of the UK Biomedical Collection, means that it is important to consider and debate the issues raised now.

The next stage of this thesis in chapters two and three will suggest an approach that ought to underlie the legal regulation of genetic databases. The first stage in this process is to consider what is meant by genetic privacy and why privacy and genetic privacy are important. This discussion will explain why the law ought to adopt a rights approach to the regulation of privacy. Chapter three will then complete the outline of the approach argued for by suggesting how it should be modified to take account of the special features of genetic information discussed.

Chapter Two

What Is Genetic Privacy and Why Is It Important?

2.1 Introduction

The previous chapter argued that the law ought to adopt a distinct approach to the regulation of genetic information because of *inter alia* its familial and social nature and it explained why genetic information might be thought of as sensitive and personal. It also discussed why certain parties might want access to it, why this information may be useful to them, and some of the potential uses and misuses of such information. In addition, it was argued that certain features of databases result in them raising particular issues for privacy. This chapter will consider the interests and rights, which the proband[1] and others to whom genetic information relates may have in keeping private their genetic information and genetic material.[2]

Part 2.2 will begin by examining the meaning of genetic privacy and the interests which it seeks to protect. Part 2.3 will demonstrate the value to society of a legal recognition of a right to genetic privacy. This part will also consider the potential consequences for society and for individuals, of a failure to take confidentiality and privacy of genetic and

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[1] The proband is the person from whom the genetic information was obtained although it will reveal information about relatives of the proband.

[2] Although some of the discussion in this chapter refers to databases of genetic information, it should be noted that for the foreseeable future, only a very small proportion of each individual's genetic data will be available on databases and that most databases will consist of original samples from which genetic data can be obtained. See for example, *Human Genetic Databases, Challenges and Opportunities*, (House of Lords Select Committee on Science and Technlogy, 4th Report, Session 2000- 2001) at Ch. 3.4. Discussions will refer to the information derived from samples bearing in mind that access to such samples enables access to genetic data.

other information seriously. This discussion of the ethical underpinning of genetic privacy is essential since there are competing views on this issue. It is often asserted, for example, contrary to the stance of this thesis, that genetic privacy is only important as a means of preventing certain uses to which genetic information may be put, or that it is important to protect confidentiality only because of its functional value in facilitating research and treatment and that there is no value in protecting the confidentiality and privacy of genetic information in se.

It will be argued that whilst there is a powerful pragmatic case for recognising a strong degree of confidentiality and privacy over genetic information, in that without such recognition the public would be more reluctant to undergo genetic testing, to consent to participate in genetic registers which assist in public health monitoring and planning, or to participate in research where their records might be held on a database, the importance of protecting privacy goes beyond this since it is essential to human dignity. The arguments in this chapter will be built upon in the next chapter, which will evaluate and take account of communitarian criticisms of an individualistic approach to privacy.

2.2 The Meaning of Genetic Privacy

In order to understand the arguments in support of a right to privacy over an individual's genetic information, it is necessary to explore what is meant by privacy and to make explicit the values that underlie the importance that is placed on privacy, and in particular genetic privacy. The UK did not traditionally adhere to a rights model of jurisprudence in developing its laws, and as a result the concept of a right to privacy did not feature in its domestic law until the *Human Rights Act 1998* came into force in October 2000.[3] Certain legal measures were in place to protect confidentiality and these will be discussed in later chapters. When considering the definition of privacy and the values that underpin it, it is helpful to look at the privacy jurisprudence and commentary of the United States, which has developed further than that of the UK.

Various commentators have argued in favour of the importance of respecting a degree of privacy, although they offer different reasons why privacy is important and define privacy in many different ways.[4] For example, in a seminal article in the Harvard Law Review in 1890, which formed the cornerstone of modern privacy jurisprudence in the United States,[5] Warren and Brandeis[6] called for the law to give protection to a right of privacy[7] which they defined in terms of the "right to be let alone."[8] They argued that solitude and privacy were essential to the individual and that the individual ought to have a right of action in order to prevent interference with one's 'inviolate personality'.[9] Subsequently, a powerful 'right to privacy' developed in the United States. Prosser also

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[3] This Act will be discussed in detail in chapter 4.

[4] Tony McGleenan reports that one writer (Flaherty, 1989) has identified 13 different legal senses by which the term is understood. See Tony McGleenan, "Right to know and not to know: Is there a need for a genetic privacy law?" in R Chadwick, M Leveitt and D Shickle eds., *The Right to Know and the Right Not to Know* (Aldershot: Avebury, 1997) at 43.

[5] Tony McGleenan describes the article in this way. *Ibid.*, at 44.

[6] Samuel Warren and Louis Brandeis, "The Right to Privacy" (1890) 4 *Harv. L. Rev.* 193.

[7] Interestingly, it was technological innovations such as instantaneous photographs and developments in the newspaper industry, which gave impetus for this call for the law's intervention. What was once protected by the physical limitations of science became threatened by technology and required the law's intervention to preserve a field of personal privacy that had previously been taken for granted. Similarly with regard to genetic privacy, it is technological innovation that has required a re-examination of the importance of privacy. *Ibid.*, at 211.

[8] Judge Cooley had used this phrase. *Supra* note 6.

[9] Warren and Brandeis, *supra* note 6 at 196.

discussed the concept of privacy and identified four distinct interests[10] that the tort of privacy in the United States of America, seeks to protect.[11] One of these consists of the right to be free from intrusion upon one's seclusion or solitude. This raises the question of what the right to be let alone might mean in the context of genetics.

There are three separate ways in which the right to be let alone can be interpreted in relation to genetic information. Firstly, it may simply mean that others should not be able to use our genetic information in ways which interfere with 'how we live our lives' and this may only relate to the uses of genetic information. On this basis, it might be argued that privacy is safeguarded by putting in place provisions to prevent certain inappropriate uses of genetic information such as discrimination legislation. On the same basis, it might be argued that disclosure of coded genetic information that cannot be identified with an individual poses no threat to privacy, since it cannot be used against an individual.

Secondly, the right to be let alone may have a wider meaning in that it may prevent others from having unauthorised access to one's genetic information regardless of the uses to which it is put. For example, Balint adopts this definition, by saying that privacy of genetic information is "protection against unauthorized access to personal medical information by individuals or organisations."[12]

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[10] These include (1) intrusion upon the plaintiff's seclusion or solitude, or into his private affairs, (2) public disclosure of embarrassing private facts about the plaintiff, (3) publicity which places the plaintiff in a false light in the public eye, and (4) appropriation for the defendant's advantage of the plaintiff's name or likeness. William L Prosser, "Privacy" (1960) 48 *California Law Review* 383 at 389.

[11] *Ibid* at 383.

[12] John Balint, "Issues of Privacy and Confidentiality in the New Genetics" (1998) 9 *Alb L.J. Sci & Tech.*27 at 30.

This definition implies that there is an interest in the confidentiality of genetic information held in databases and in preventing others from accessing it regardless of the uses to which it may be put. This definition relies on a view of privacy which considers that one's solitude or dignity is interfered with when another party acquires knowledge of one's personal genetic information without permission. This explains why individuals might feel a sense of intrusion if their diary or medical records have been disclosed to someone, regardless of whether such information was used to his or her advantage or used in any way at all.

The third sense in which the right to be let alone may be interpreted is that one's privacy has been interfered with if one is given information about one's genetic makeup without consent. This right has been invoked by some to argue that the right to genetic privacy ought to include a right not to know one's genetic constitution.[13] This argument has considerable force when one considers the psychological harm that might result by exposing an individual to information about a future illness[14] or a genetic disability affecting his or her child. Leon Kass has discussed the harm that can be done by knowing genetic information and concludes that the deepest problem connected with learning one's own genetic makeup and unhealthy predispositions is "the various hazards and

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[13] See for example, Graeme Laurie, "In Defence of Ignorance: Genetic Information and the Right Not to Know" (1999) 6 *European J. of Health Law* 119-132. Laurie argues that there is a notion of privacy which he describes as "spatial privacy" which protects one's sense of self and that receiving information about oneself which we did not previously have and about which we can do nothing may invade our spacial privacy.

[14] It has been estimated that only between 10 and 20% of people at risk of Huntington's disease choose to be tested. S Bundey, "Few Psychological Consequences of Presymtomatic Testing for Huntington's Disease" (1997) 349 *The Lancet*, 4. This shows the importance of recognising a right not to know in certain circumstances.

deformations in living your life that will attach to knowing in advance your likely or possible medical future."[15]

In practice this interpretation of privacy poses ethical dilemmas. There will sometimes be a conflict between someone's right to know their own genetic constitution and other genetically related parties' rights not to know because it may be difficult in practice for someone to keep information about their own genetic constitution secret from others.[16] Moreover, in some circumstances it will not be known in advance whether someone does not wish to know certain information. The decision as to whether they would wish to remain ignorant of a condition may depend on their knowledge of the risk of that condition. Genetic screening programs which involve contacting individuals at risk of particular conditions to determine whether they want to be screened can be seen as a breach of privacy, in that the heightened risk of a condition is highlighted by the invitation to participate.

Although these examples illustrate the practical difficulties of balancing a right not to know with other interests, and in exercising this right in some circumstances, there are cases where recognising a right not to know genetic information, may conflict with arguably less important interests. If an employer or insurer asks someone to take a genetic test, the assertion of such a right may allow the individual 'to be let alone' in the

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[15] Leon Kass, "Triumph or Tragedy? The Moral Meaning of Genetic Technology" (2000) 45 *Am. J. Juris.* 1 at 4.

[16] In addition, Murray makes the point that linkage analysis which is required for the accurate testing of certain conditions, "relies on DNA samples from affected/ unaffected relatives of the person wishing to know. The tests may yield information about the risks of other family members who may not wish to know their own status; family members may not wish to participate, which yields conflict." Thomas H Murray, "Ethical Issues in Human Genome Research" [1991] *FASEB J* S 55-60 at 56.

sense of not being subject to such information. As Mclean says, arguments made by employers and insurers that assert that it is essential to know genetic information can result in a situation where the right not to know is infringed, "The right of the individual to privacy is seriously threatened if this logic is followed. Equally, any right not to know is washed away."[17] Although it is difficult to balance this right against others in some cases, it is nevertheless important to recognise it as a right.

A fourth meaning of genetic privacy can be described as a positive right to privacy since it goes beyond the right to be let alone in the senses outlined above. It can be argued that in order to enjoy privacy one needs to have control over one's information and genetic material. Informational privacy is not just about controlling access to genetic information. It can extend to control over how it is used and what is done with it. Petersen describes informational privacy in terms of control. Thus, "Informational privacy is the right to control how information about oneself is used by those to whom it is disclosed" [18] and genetic privacy can in some cases be seen as a form of informational privacy. This right is described as positive since it does not just prevent others from infringing a right but it gives the individual additional claims on their genetic information.

Of course, control can be exercised in order to protect the right to be let alone, in that control over information allows one to determine who has access to it. However, this

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[17] Sheila A. M. McLean, *Old Law, New Medicine, Medical Ethics and Human Rights* (Pandora, 1999) at 177.

[18] S. B. Petersen, "Your life as an Open Book: Has Technology Rendered Personal Privacy Virtually Obsolete?" (1995) 48 *Federal Communications Law Journal* 163 at 164.

right encompasses more than controlling access in that one is able to rely on this right to decide what uses may be made of one's information or genetic material. For example one might want to control what research is carried out using one's genetic information. In addition, such a right may enable an individual to determine how long his or her genetic information is to be stored and what should happen to it after death.

There are clear parallels between this concept of privacy and a view of genetic information as 'property' which is 'owned' by the individual.[19] Space does not permit a detailed exploration of this perspective on genetic information in this thesis but there are clearly ways in which the ideas of ownership, control and property interact[20].

It is important to note in this discussion of the meaning of privacy that not only individuals but also groups can be holders of a right to privacy. Research on families communities or sectors of society can result in information being known about members of such groups regardless of whether they participated in such research. Therefore, collective privacy interests have also to be taken into account in determining where the balance should lie between various rights and interests. Collective genetic privacy will be discussed further in chapter three.

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[19] The status of medical information in Canada was discussed in the case of *McInerney* v *MacDonald* (1992), 93 D.L.R. (4th) 415 (S.C.C.) where Justice La Forest said, "[t]he fiduciary duty to provide access to medical records is ultimately grounded in the nature of the patient's interest in his or her records. Information about oneself revealed to a doctor acting in a professional capacity remains in a fundamental sense one's own." This case is discussed in Bernard M. Dickens, "Conflicts of Interest in Canadian Health Care Law" (1995) 21 *Am. J. L. and Med* 259-80 at 261.

[20] See the discussion in Moe Litman and Gerald Robertson, "The Common Law Status of Genetic Material" in Timothy Caulfield, Bartha Maria Knoppers and Douglas Kinsella eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 51-84.

It is useful to be clear on the distinction between confidentiality and privacy, both of which will be discussed in the course of the following chapters. Gostin defines confidentiality as:

> [A] form of health information privacy that focuses on maintaining trust between two individuals engaged in an intimate relationship, characteristically a physician-patient relationship. Confidentiality is a person's claim to keep private the secrets exchanged in the course of that relationship, enforced not simply to respect the person whose confidences are divulged but also to underscore the importance of relationships of trust.[21]

Whereas, he defines informational privacy as, "An individual's claim to control the circumstances in which personal health information is collected, used, stored, and transmitted."[22] Therefore, although confidentiality is a subset of privacy, each concept has a distinct meaning. This thesis will look at privacy in all of the senses outlined above and will also examine confidentiality.[23]

The extent to which the law protects genetic privacy will be considered in a later chapter. Before this is discussed, it is helpful to understand the values, which underpin the need to protect privacy. The discussion of the value of privacy is divided into two sections dealing with firstly, its instrumental value and secondly its inherent value.

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[21] Lawrence O Gostin, *Public Health Law, Power Duty Restraint* (U of California Press, 2000) at 128.

[22] *Ibid.*

[23] An alternative discussion of the meanings of genetic privacy can be found in Anita L Allen, "Genetic Privacy: Emerging Concepts and Values" in *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era* (Yale U. Press, 1997) at 31-59.

2.3 The Value of Privacy

Most people would agree instinctively that individuals ought to have a certain degree of privacy over their lives in the sense of having a realm of their lives protected from interference by the state or others in which they can live without others knowing certain information about them, and in which they can make decisions, according to their own values. In the context of genetics, recent evidence supports this contention. In a Mori Poll conducted for the Human Genetics Commission in the UK which was published in March 2001,[24] 70% of respondents thought it inappropriate for an employer to see the results of an existing or potential employee's genetic test results; 85% thought that genetic information should not be used to set insurance premiums, 90% thought that consent should always be sought prior to blood or tissue being used in genetic tests; 90% agreed that information should only be included in a database where an individual had given consent, and half of the respondents said that they feared that if others have access to their genetic information they would know too much about them.

This indicates a strong consensus that:

- individuals ought not to have their genetic information shared with others without their permission in certain circumstances;
- individuals ought to have a degree of control over their genetic information; and

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[24] Public Attitudes to Human Genetic Information (Human Genetics Commission, March 2001) Online Human Genetics Commission: at <www.hgc.gov.uk/business_publications.htm>. It is acknowledged that opinion polls such as this are limited in value since the answers that people give can be manipulated by the wording or mode of questioning. Nevertheless, the results are still worth noting.

- certain uses of their information should be prohibited.

The reasons why people feel that there is something private about their genetic information are complex and varied. Evolutionary urges towards self-protection may encourage wariness towards giving information about ourselves to others. Personal experiences and notions of insecurity and trust undoubtedly play their part in our caution about what others know about us and our wish to control our privacy.

2.4 Instrumental Value

(a) Prerequisite for the Enjoyment of Other Rights

One persuasive explanation as to why privacy is valued is that without protection of a right to privacy, the existence of other human rights becomes meaningless since a realm of privacy is a prerequisite for the enjoyment of other human rights. '[I]f we concede the existence of individual human rights of any kind, then it is almost tautologically self-evident that there must be a "right to privacy" for without it there would be no private individuals to have or exercise those rights'.[25] Privacy may therefore satisfy a facilitating purpose by enabling the enjoyment of other human rights.

(b) Confidentiality

The recognition of a right to privacy also serves broader utilitarian concerns since there is a general acceptance of the principle that genetic information disclosed in the context of clinical care, for research, for genetic registers or for public health purposes should be regarded as confidential. It is necessary to respect confidentiality because genetic information may include highly sensitive information, for example about an individual's mental and physical health. Therefore, the widely accepted arguments for respecting confidentiality of medical information also apply to genetic information. Often genetic information will be revealed as a result of a screening program or because a particular individual undergoes genetic testing and such information will often form part of a genetic database. Individuals may not participate in genetic testing or screening programs if they are not confident that such information will be kept private.[26] Arguments for respecting confidentiality are therefore partly based on pragmatic considerations.

Thompson highlights three reasons why confidentiality is necessary in the doctor-patient relationship.[27] Firstly, the patient approaches the doctor under duress, pain or need and so the patient is inherently vulnerable and disadvantaged in relation to the doctor. Secondly, the situation of treatment is by its very nature private in that it can involve touching and the disclosure of intimate information. Thirdly, "[t]he sharing of intimate information in the activity of truth telling involves the implicit rules of reciprocal confidence, otherwise the process could not get started."[28]

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[25] I. E. Thompson, "The Nature of Confidentiality" (1979) 5 *Journal of Medical Ethics* 57 at 59.

[26] There is some evidence to support the fact that individuals would not come forward for genetic testing if they were not confidant that their information would be kept confidential. For example, it has been reported that in a study conducted in 1998, for the US Centre for Genome Resources, almost two thirds of the respondents said that they probably would not take genetic tests if health insurers or employers could get access to the results. See "Employers should be Barred from Accessing Genetic Information, Americans Say in NCGR Survey" (March 4, 1998), located online at http://www.ncgr.org/about/news/archive.html, as cited in Eugene Oscapella, *Genetics, Privacy and Discrimination* (Canadian Biotechnology Advisory Committee Commissioned Paper, Oct 31, 2000.)
[27] See Thompson, *supra* note 25.
[28] *Ibid.*

In addition, in the case of research, some of the same considerations apply and individuals may not go for diagnosis, treatment or participate in research for certain conditions where they may be stigmatised or discriminated against, if they are not confident that this information will be kept confidential.

This interest in creating a climate where individuals are assured of the confidentiality of genetic information, whether stored in a database or not has been described as a public interest in confidentiality.[29] The instrumental value of confidentiality was given judicial recognition in the case of *X* v *Y* when it was said that, "in the long run, preservation of confidentiality is the only way of securing public health; otherwise doctors will be discredited as a source of information, for future patient will not come forward if doctors are going to squeal on them."[30]

This benefit will only transpire if the principle of confidentiality is respected in all but a minority of exceptional cases. Indeed, Kottow has argued for an absolute principle of confidentiality in medicine on the basis that it "collapses unless strictly adhered to, for even exceptional or otherwise limited leaks are sufficient to discredit confidentiality into inefficiency."[31] One consequence of such an approach is that there may be specific cases in which there is more harm done than good in adhering to the principle of

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[29] See Graeme T. Laurie, "The Most Personal Information Of All: An Appraisal of Genetic Privacy in the Shadow of the Human Genome Project" (1996) 10 *International J of Law, Policy and the Family* 74-101 at 80 (arguing that "[a]lthough it is recognised that individuals have a private interest in personal information, it is generally accepted that the true justification for protection [of confidentiality] is an appeal to 'the public interest'.").

[30] *X* v Y, [1988] 2 ALL ER 648 at 653 (per Rose J.).

[31] Michael H Kottow, "Medical Confidentiality: An intransigent and absolute obligation" (1986) *J of Medical Ethics* 117 at 122.

confidentiality, but this is justified by the greater, long-term 'general good' to society of strictly adhering to it. If individuals would not come forward for genetic testing, or would refuse permission for genetic data to be kept on public health genetic registers, or would decline to participate in research which involved such databases, because there was no established and well-adhered to principle of confidentiality, then this would be extremely detrimental to society. The practice of medicine and research would be severely hindered. However, Kottow's takes his argument for an absolute principle too far. It is possible for confidentiality to serve a useful function in medicine as long as exceptions are kept to a minimum and are required to be justified.

It is even more important to respect confidentiality in the context of research. Individuals agree to participate in research for altruistic reasons since there are usually no incentives in terms of benefits to their health from participating in such programs. Without assurances that their information will be kept confidential, many individuals would not take part in such research.[32] In order for society to benefit from research, there must be a high degree of confidentiality and any exceptions to it should be transparent. McCall Smith, the Vice Chairman of the Human Genetics Commission emphasises this point.

> If, as our Mori poll suggests, there is a fair degree of public distrust about the security of genetic information, then we need to deal with this so that people can volunteer for this research in full confidence. The alternative - a situation where people were frightened to participate because they thought they would be in some

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[32] For this reason it has been suggested that genetic material is entitled to a higher degree of protection of confidentiality, even from court ordered disclosure, in exchange for allowing samples to be used for research. See Ellen Wright Clayton et al., "Informed Consent for Genetic Research on Stored Tissue Samples" (1995) 22 *JAMA* 1786 at 1792 (Working paper for NIH – ELSI).

way compromised or disadvantaged - is not an attractive option for the United Kingdom.[33]

(c) Discrimination

An important practical reason to protect privacy is to prevent discrimination on the basis of genetic makeup. Discrimination refers to the practice of using genetic information to make decisions about areas such as access to employment, promotion, services and insurance. Maintaining confidentiality is the most effective means of preventing discrimination. Although, the use of genetic information can be justified as legitimate in some cases, in those situations where certain uses of genetic information are considered to be unfair, preventing access to it is an important function of privacy.

It is often argued that there are alternative methods of preventing or tackling discrimination other than by protecting privacy. For example, one could allow employers, insurance companies and others access to genetic information and enact certain legislation to prevent certain uses of it. However, there are significant practical and theoretical problems with such an approach. Firstly, in practice discrimination is extremely difficult to prove. In the UK, legislation prohibiting discrimination on the basis of sex, race and disability in employment and other areas has been in force for some time.[34] Although this can provide some individuals with a means of redress against discrimination, there are many cases where it is difficult to demonstrate, for example, that

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[33] Alexander McCall Smith, Vice Chairman of the Human Genetics Commission, *The Guardian* (27 Nov. 2000).

the reason that someone was not given a job, was because of a disability rather than for some other reason. Of course, in the areas of sex, pregnancy, race and disability discrimination law, the characteristic which is the object of discrimination is readily observable, whereas it may not be overt in relation to genetic information. There are many cases where the law does not provide an effective remedy for these individuals. Secondly, even where an individual has sufficient evidence to convince a court or tribunal that the reason for particular treatment was his genetic constitution, there will be many for whom access to the law is too costly. Even for those who can afford to pursue their cases, this can involve considerable time and effort. It is preferable, therefore to prevent discrimination by limiting access to information rather than tackling discrimination once the information has been used inappropriately.

This discussion has shown that there are significant practical benefits to respecting the confidentiality of genetic information in some cases. However, these arguments are based on pragmatic considerations relating to the doctor-patient relationship and to medical research rather than the principled view that privacy is valuable as a human right. It is on this basis that this thesis will argue that the law ought to recognise a right to genetic privacy and not on the basis that it serves other practical concerns, important as they may be. The next section will make a case for the recognition of a right to privacy by highlighting the ethical basis underlying such a right and by considering its inherent, rather than its instrumental value.

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[34] The *Sex Discrimination Act 1975*, the *Race Relations Act 1976*, and the *Disability Discrimination Act 1995*.

2.5 The Inherent Value of Genetic Privacy

(a) Dignity

A central theme in the literature which discusses the value of privacy and the interests, which it protects is that privacy is essential to protect the human dignity of the individual. The report of the Danish Council of Ethics supports the view that personal integrity which is integral to a human being is at the heart of the value of privacy of genetic information. It says, "The notion of having certain aspects of one's life which one wishes to "keep to oneself", which "do not concern others", etc can also be claimed in some elementary way to be integral to the essence of a human being."[35]

Bloustein supports this view of privacy, which he says ought to be protected in order to safeguard individual liberty and dignity because individuality may be lost in a society, which does not sufficiently respect privacy.[36] He writes colourfully:

> The man who is compelled to live every minute of his life among others and whose every need, thought, desire, fancy or gratification is subject to public scrutiny, has been deprived of his individuality and human dignity. Such an individual merges with the mass. His opinions, being public, tend never to be different; his aspirations, being known, tend always to be conventionally accepted ones; his feelings, being openly exhibited tend to lose their quality of unique

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[35] Report of the Danish Council of Ethics, *Ethics and Mapping of the Human Genome, Protection of Sensitive Personal Information* (Danish Council of Ethics, 1993).

[36] Edward J Bloustein, "Privacy as an Aspect of Human Dignity: An Answer to Dean Prosser" (1964) 39 *New York University Law Review* 962.

> personal warmth and become the feelings of every man. Such a being, although sentient, is fungible; he is not an individual.[37]

It is conceivable and even probable that behaviour and decision-making in society would be affected if each individual's genetic makeup was accessible by all. This would undoubtedly affect individuals' lifestyles and might result in a loss of individuality with a consequent loss of dignity. For example, without safeguards to protect the privacy of genetic information, individuals may no longer feel confident in applying for certain employment, or may experience social pressure not to reproduce, or may feel (an imagined or real fear) that others may not want to have children with them. Without control over access to one's genetic information, people may have different expectations for their lives since they may react differently to others who know information about their future health and may modify their life choices accordingly. This may result in a loss of individuality with a larger number of people conforming to popular views and established norms. This argument assists in explaining the value in protecting privacy of genetic information rather than simply preventing certain uses of it.

Rachels argues that privacy is important for distinct but related reasons to those offered by Bloustein.[38] He argues that privacy has an inherent value, which goes beyond keeping personal or medical information private because it may be embarrassing or because the public availability of such information may have certain undesirable consequences for the individual. He instances the fact that many individuals object to

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[37] *Ibid.*, at 1003.

others knowing certain information about them even though the information is harmless, is not embarrassing and does not result in any disadvantage to them by the information being known by others.[39] For example married couples usually wish to keep the details of their sex life private even although they have nothing to hide or to be embarrassed about and even though such information may have no adverse consequences for them if known.

Rachels argues that the inherent value in privacy derives from the fact that individuals define and manage their relationships with each other according to the sorts of information, which is shared with others. We discuss different matters with our partner or friend than we would with our employer. This level of control over our information explains why privacy is important. Without a degree of privacy, we lose the ability to develop and regulate different relationships with one another. A lack of privacy disrupts our valued control over important parts of our lives.

This account of the importance of privacy is convincing and enlightening as it explains why someone may value the ability to control access to their genetic information regardless of the uses to which it may be put. If an individual's employer had knowledge of his genetic information, this would affect the dynamics of power and nature of the employment relationship regardless of whether the employer actually used the information. An employee may not wish his employer to know information about a

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[38] James Rachels, "Why Privacy is Important" (1975) 4 *Philosophy and Public Affairs* 323. See also Charles Fried, "Privacy" (1968) 77 *Yale Law Journal* 474 at 782.

[39] Indeed, Helen Nissenbaum has gone as far as to argue that theories of privacy should recognise not only the importance of protecting intimate and sensitive information but should also recognise 'the systematic relationship between privacy and information that is neither intimate nor sensitive and is drawn from public spheres." See Helen Nissenbaum, "Protecting Privacy in an Information Age: The Problem of Privacy in Public" (1998) 17 *Law and Philosophy* 559.

particular genetic condition, although he may be happy to share it with his family or friends. Privacy over one's information therefore allows the individual to set the boundaries of different relationships to protect individuality and dignity.

It is necessary to make a case for protecting privacy as distinct from preventing misuses of genetic information because the extent to which the law is achieving certain aims will depend upon defining those aims precisely. McGleenan examines what it is that genetic privacy laws are designed to achieve and concludes that they are largely targeted at preventing discrimination.[40] In consequence, the value and viability of the laws must be measured according to their ability to minimise discrimination. If McGleenan's analysis is correct, then this would support an entirely different approach to the regulation of genetic information.

However, McGleenan, fails to identify accurately all of the interests which require to be protected by law. Although it is correct that protection of privacy will achieve the prevention of discrimination, McGleenan does not place sufficient importance on the other values served by protecting privacy and on the role of privacy in protecting human dignity, integrity and individuality. These values are legitimate and important ones for the law to protect and it is submitted that the best way for the law to protect these interests is by adopting a rights approach to genetic privacy. More will be said about this later.

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[40] *Supra* note 4 at 44.

(b) Autonomy

The paramount ethical justification for respecting certain forms of genetic privacy is the principle of autonomy or self-determination. This principle recognises the value of an individual's right to govern his or her life according to his or her own values and to exercise control over his or her body and information. This principle has particular importance in the context of genetic information where the information being discussed is often essential to one's sense of self. This principle highlights the importance of consent, as the mechanism by which an individual retains control over his or her body and information. Where confidentiality or privacy is breached without individual consent, this infringes the right of the individual as a self-determining being. Although autonomy and privacy do not have an identical meaning, and the term privacy best captures the values asserted as important in this thesis, the concepts are intimately linked, and the autonomy of the individual will often provide the main justification for protecting privacy.

In situations where information relates to one individual, the principle of autonomy supports the view that the individual should be able to determine what can be done with it. A failure to protect privacy interferes with autonomy in that autonomy also supports the view that one should be able to decide not to know certain information.[41] The law has

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[41] It is less clear whether autonomy can be said to underlie the concept of genetic privacy which allows an individual to regulate who has access to certain information. See, on this point, Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988) at 104:

> Privacy may be interfered with but not autonomy. If someone taps your phone conversations without your knowledge he interferes with your privacy. But your decisions, your actions, your values, are in no way changed or altered from what they might be otherwise. You are as self-determining as ever.

traditionally recognised that autonomy (in theory at least) means that it is important to recognise an obligation on doctors, health care professionals and others to keep medical and genetic information confidential and that only in exceptional circumstances should such confidentiality be breached. Autonomy also safeguards privacy in some respects since it recognises that individuals ought to be able to control what happens to their bodies in terms of allowing them to consent to or refuse treatment, and even allows individuals to determine what will happen to parts of their genetic material such as their gametes, once they are separate from the body.

However, in certain cases there is a difficulty in asserting the principle of autonomy as the ethical basis for a right to privacy over genetic information. If autonomy is used to justify the proband's right to keep the information private, it can also be asserted as an argument for all biological relations of the proband to have access to such information because the information also relates to them. Lemmens and Austin make the point well:

> In general, an individual has a right to know his or her own genetic constitution, based on the value of individual autonomy. This rationale can also be used to justify the right not to know one's own genetic constitution. But this rationale would also provide a reason for biological relatives to gain access to the genetic information of a family member: it is also information about their own genetic constitution.[42]

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[42] Trudo Lemmens and Lisa Austin, *Of Volume Depth and Speed, The Challenges of Genetic Information* (Commissioned Report for the Canadian Biotechnology Advisory *Committee*, 2001), located online at http://cbac.gc.ca/english/reports/listDocs.aro?type=42.

This dilemma has caused some commentators to call for a re-examination of traditional principles of medical ethics. However, it is submitted that traditional principles of medical ethics are equipped to determine the circumstances in which genetic privacy ought to be protected provided that account is taken of the familial and social nature of genetic information. The fact that privacy has been identified as an interest worthy of protection *in se* is reason for the law to adopt a rights approach to genetic privacy. It is submitted that this is the only means, which adequately protects an individual's interest in his or her genetic information, since it requires any infringement of such a right to be justified. Without the adoption of a rights approach, privacy and confidentiality may be set aside because of competing interests regardless of their importance or weight. The right to genetic privacy argued for ought not to be an absolute right, but instead ought to be balanced against competing rights and interests that society deems important. The next chapter will expand on how this ought to be done.

2.6 Conclusion

This chapter has explored the various meanings of genetic privacy. In addition, it has argued that genetic privacy ought to be protected because of its inherent rather than its instrumental value, (although its important instrumental value is acknowledged), and that as a result, privacy ought to be protected as a right. Finally, the fact that genetic information relates to the family and community of the individual being tested means that the rights approach should be modified to take into account this feature of genetic information. The next chapter will examine how this should be done and will determine the approach that ought to underlie the legal regulation of genetic databases.

Chapter Three

Community Rights, Social Duties and A Modified Rights Approach

3.1 Introduction

The previous chapter described the meaning and importance of genetic privacy and made an argument that the law ought to adopt a rights approach to genetic privacy. The first part of this chapter will evaluate some of the criticisms that the communitarian perspective makes of a purely individualistic, rights approach to the law. It will also evaluate the arguments of those commentators who argue that the nature of genetic information is incompatible with an individualistic rights approach. This section will argue that the social and familial nature of genetic information, and the arguments made by communitarians about the importance of social duties, calls for a rights approach to genetic privacy to be modified to take these factors into account. The fact that genetic information has these properties means that there ought to be certain limits on the extent to which a proband can keep his or her information private. Where such information can be used for the benefit of the health of the community, for example for use in research databases, such social goods may legitimately override the right of the individual to privacy over his or her genetic information and material, in certain circumstances.

The second section will consider a further criticism of approaches that place primacy on individual rights. It is the claim that the individualistic approach is largely a product of western culture, that it is less relevant to other cultures, and that it is incompatible with a pluralistic society.

The final part of this chapter will consider the available physical means to ensure that threats to privacy are minimised and to prevent access to genetic databases by those whom the law determines ought not to have access. It will be argued that an erosion of privacy is inherent in the development of large-scale databases of genetic information and material and that such information by its nature can never be truly anonymous. However, this loss of privacy must be balanced against the enormous benefits to health and medicine, which research and clinical databases are capable of bringing about. It will conclude that, provided that appropriate legal and technological safeguards are put in place, such a loss of privacy can be justified.

3.2 Communitarianism

This section will consider the implications of communitarian arguments for a right to genetic privacy. It is helpful at the outset to set out some of the principal tenets of communitarian ethics.[1] Communitarians have criticised the libertarian tradition, as

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[1] This brief explanation of the views of certain communitarians was taken from Sirkku Kristiina Hellsten, "Biotechnology, Genetic Information, and Community" in Alison Thompson and Ruth Chadwick eds., *Genetic Information: Acquisition, Access and Control*, (New York; Kluwer Academic/ Plenum Publishing, 1999) at 305.

placing too much emphasis on individualism and the formal rights of individual citizens.[2] They also argue that liberalism is generally inconsistent with the imposition of certain duties. For example, Rubenstein says, "Indeed, in a rights-based social construct in which the primacy of the individual is achieved by taking an instrumental view of society, individual rights neither imply nor extract from the individual any correlative obligation toward society."[3] Instead, they argue that society and its institutions ought to focus on the importance of community and of the social nature of persons.[4] Communitarians stress that individuals live as members of society and that their membership of society legitimately requires them to make certain sacrifices or concessions for the communal good. For example, Feinberg comments that "[i]t is impossible to think of human beings except as part of ongoing communities defined by reciprocal bonds of obligation, common traditions and institutions."[5] Individuals require to have duties as well as rights in order for society to function effectively for the benefit of its members.

Sandel distinguishes between communitarians and liberals by the fact that communitarians see the community as the end whereas liberals see it, as being "one contender among others within the framework defined by justice."[6] In the context of

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[2] See, for example, Alisdair MacIntyre, *After Virtue* (University of Notre Dame Press, 1981).
[3] Helena Gail Rubinstein, "If I Am Only For Myself, What Am I? A Communitarian Look At the Privacy Stalemate" (1999) 25 *Am. J. L. and Med.* 203 at 225.
[4] Wellman, for example, asserts that "[t]he most formidable attack on liberalism in the last fifteen years has been the communitarian complaint that liberals insufficiently appreciate the social nature of persons." Christopher Heath Wellman, "Liberalism, Communitarianism, and Group Rights" (1999) 18 *Law and Philosophy* 13-40 at 13.
[5] In Joel Feinberg, *The Moral Limits of the Criminal Law* (1986) at 47, cited in Rubinstein, *supra* note 3 at 224.
[6] See Michael Sandel, *Liberalism and the Limits of Justice, 2nd edition* (Cambridge; Cambridge University Press, 1982) at 64.

genetic information, communitarians might argue that the interests of the community are paramount in determining social policy whereas liberals may concede that community interests have a part to play but regard the rights of the individual as the most important consideration.[7] Liberals would accept the limitation of individuals' rights for the benefit of the community to varying degrees.[8]

This thesis has recognised that individuals' rights can in limited circumstances be overridden and that it is legitimate to impose certain obligations on members of society which limit their freedom.[9] It has taken the view, however, that individual rights to autonomy and privacy generally take precedence over community interests and has placed the burden on those who would override such rights for the interests or benefit of the community, to justify such infringement. So how persuasive are communitarian criticisms of a rights approach and what does the communitarian approach have to add to the arguments made thus far?

3.3 Criticism of Individualism

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[7] Lawton notes that this approach is central to the European Convention on Biomedicine, "The primacy of the individual is the second key theme of the Convention on Human Rights and Biomedicine" since Article 2 states that the interest and welfare of the human being shall prevail over the sole interests of society or science. Lawton, Anne, "Regulating Genetic Destiny: A Comparative Study of Legal Constraints in Europe and the United States" (1997) 11 *Emory Int'l. L.R.* 365 at 384.

[8] Some commentators argue that communitarianism is compatible with privacy protection. For example, Anita L Allen says "[t]heories that base the value of privacy on the importance of promoting individual personhood and relationships presuppose highly individualistic understandings of human flourishing. Yet communitarian and care-based understandings also entail privacy protection." She says that this is because a degree of privacy is necessary for facilitating the flourishing of responsible members of families and communities. See Anita L. Allen, "Genetic Privacy: Emerging Concepts and Values" in Mark A. Rothstein, ed,, *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era* (Yale UP, 1997) 31-59 at 35.

[9] See Wellman, *supra* note 4 at 13, noting that liberals have recently responded to communitarian criticisms "by emphasising liberalism's ability to recognise the importance of groups and group rights." He cites Allen Buchanan, *Secession* (Boulder: Westview Press, 1991) as an example.

Some communitarians would argue in favour of social duties to share and use information for the benefit of the community regardless of its nature. However, the communitarian viewpoint takes on particular significance when applied to genetic information. It was stated in chapter one that one of the special features of genetic information is that it is familial and social and cannot be said to belong or relate exclusively to one person. Potentially, the most compelling criticism of a purely individualistic approach is that it fails to take sufficient account of the moral importance of this fundamental feature of genetic information. Communitarians might argue that this feature lies uneasily with the rights approach so far advocated. Wachbroit writes that, "[t]he standard approach to medical confidentiality does not seem able to accommodate the problems raised by the non-individualistic character that some genetic information can have."[10] Another author has said that the rights of the community and family must be taken into account in discussing duties relating to genetic information:

> While such a communitarian approach to privacy and genetic information has scarcely been contemplated, it is a self- evident and natural corollary to the recognition of the range of claims surrounding this sort of information. If the 'family' is to come to be seen as 'community 'in microcosm, the collective claims and interests of that community must also be determined and weighed in any balance of values when assessing the appropriateness of any dealings with familial genetic information. [11]

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[10] Robert Wachbroit, "Rethinking Medical Confidentiality: The Impact of Genetics" (1993) 27 *Suffolk University Law Review* 1391 at 1398.

[11] Graeme Laurie, "Genetics and Patients' Rights: Where are the limits?" (2000) 5 *Med. Law Int.* 25-44 at 40.

Two sets of opinion, therefore, object to individualism regarding genetic information. One group would apply communitarian values to all information regardless of its nature, whereas the second regards community values as important because of the special nature of genetic information. It should also be noted that communitarianism is a spectrum of views rather than a single position: different communitarians argue for varying degrees of social duties.[12] Each set of criticisms will now be addressed.

Criticisms of individualism have been made on ethical and practical grounds. Some commentators have criticised its ethical basis by arguing that the, "liberal emphasis on subjective values and formal rights in fact tends to justify and consequently increase egoism, moral indifference, political alienation and moral fragmentation in a pluralistic society."[13] In the context of genetics it may be argued that a rights based approach sets members of society and even families in opposition to one another. This may affect relationships within communities and discourage a spirit of sharing.

This view is evident in the case of *Moore* v *Regents of University of California.*[14] The judgement rejected the concept of genetic material as property on the grounds that this individualistic approach and categorisation may commodify human tissue and make

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[12] In Israel, a moderate communitarian approach is evident in the *Patient's Rights Act* whereby patients are entitled to the right to informed consent but denied the right to informed refusal since committees are entrusted with the option to override a person's decision to refuse treatment in certain circumstances. Gross describes this approach as "A uniquely communitarian autonomy" which is "both underwritten by and deferring to the collective voice." Michael L Gross, "Autonomy and Paternalism in Communitarian Society: Patients Rights in Israel" (1999) 29 *Hastings Center Report* 13-20 at 14.

[13] Hellsten sums up communitarian critiques of liberal political theory and practice in this way in *supra* note 1 at 301.

[14] *793 P 2d, 497 (Cal 1990).*

individuals more reluctant to share their genetic information in research. Justice Arabian posed two key questions cogently:

> Does it uplift or degrade the unique human persona to treat human tissue as a fungible article of commerce? Would it advance or impede the human condition, spiritually or scientifically, by delivering the majestic force of the law behind plaintiff's claim? I do not know the answers to these troubling questions.

It is difficult to evaluate criticisms relating to political alienation and social fragmentation. However, even if these consequences could be established, they would require to be balanced against the safeguards provided by a rights approach, which may enable individuals legitimately to refuse to participate in such research. This question is particularly poignant in cases where genetic samples and information are anonymous, and therefore pose a minimal threat to individual identification.

Communitarians also argue that there are substantial practical benefits to society of an approach that requires information and resources to be shared with families or communities instead of a model, which entitles each member of society to refuse to volunteer their information to be used for the benefit of the whole of society, or for genetic research. They justify limiting or infringing privacy by the substantial benefits to society as a whole and consequently to individuals as members of that society. Population genetic research, which uses stored tissue and genetic information from databases may result in important improvements to public health through the increased knowledge provided by the science of genetics and the eventual development of therapies.[15] Therefore, it is argued that it is legitimate for the state to impose obligations and duties on members of society which, may include a requirement that individuals allow their genetic information to be used for research and statistical purposes, or for residual genetic samples to be stored and used for purposes other than those for which they were taken.

John Harris stresses the important contribution that research has to make, "It is important to be clear that unless human tissue and human genetic information continues to be available for research, the costs in terms of continued human suffering from disease will be incalculable."[16] He goes on to argue that individual control over genetic material ought to be limited and in circumstances in which people are not in a position to consent to or have not consented to participate in genetic research, we should presume that "they are decent, well motivated people who would wish to help others when doing so costs them little or nothing."[17] Concerns have also been expressed by the research community that unduly restrictive regulation of tissue banks will impede research unnecessarily.[18]

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[15] Gostin describes the important public health function of health information, which would include genetic information:

> Health information is indispensable for virtually all public health activities including identifying, monitoring, and forecasting health threats; response and intervention; program evaluation; and population-based research. It is for this reason that biostatistics and epidemiology are the foundational sciences of public health.

See Lawrence O Gostin, *Public Health Law: Power, Duty, Restraint* (U of California Press, 2000) at 113.

[16] John Harris, 'Ethics and Research in Human Genetic Material', (2001) *Genetics Law Monitor* Vol 1 Issue 4.

[17] *Ibid.*

[18] For example, Stephenson points out that, "Some proposals concern pathologists because the stringent restrictions for the use of archival tissue, such as anonymizing it would hinder even biomedical research having little to do with DNA analyses or genetic research." See Joan Stephenson, "Pathologists Enter Debate on Consent For Genetic Research on Stored Tissue" (1996) 275 *JAMA* 503(2).

A purely rights based approach may discourage the sharing of one's information for the benefit of research and for others and may result in a situation where some people may wish to profit from their DNA. If important research could not be undertaken as a consequence of the adoption of a rights approach then this practical criticism would be persuasive. However, the recognition of a right to privacy will not necessarily impede research. Instead, it ought to ensure that privacy rights are taken into account in determining what research ought to be undertaken.

An additional practical criticism of a rights approach that enables individuals a high degree of control over their information and material is that it may cause distortion of research results caused by missing data from individuals.

> [I]f patients are given the right to decide who may use their data for purposes of medical and health policy research, researchers studying diseases that first afflict or disproportionately afflict a vulnerable population may find fewer individuals willing to supply their data than could those researchers studying illnesses afflicting a broader population. Requiring consent for each use of medical records will result in biased studies, thus delaying if not foreclosing the possibility of research and disease detection as well as possible cures or treatments.[19]

Although the reluctance of individuals in vulnerable groups to participate in research by sharing their information is understandable, it is also important for these groups and for society as a whole to undertake effective research into such conditions. In sum these communitarian criticisms have something to commend them in terms of influencing policy in that the practical affects of a particular approach are important. However, maximising the benefits of research should not be the only consideration in determining policy and that is where communitarians may diverge from liberals.

It is difficult to establish empirically whether a rights approach does or does not encourage selfishness and whether people are less likely to want to participate in research or set aside their own interests for those of the community or the family where they have a right not to. However, it is evident that if people are given the right to refuse, then some will. As a result, the benefit to the community of genetic research is likely to be more limited where individuals have absolute autonomy over their information than in a situation, which obliges them to participate. Similarly some individuals will refuse to share information with family members even although the withholding of such information may benefit that person's health.

A question which requires to be addressed is whether the law should shift its emphasis from protecting individual rights to enforcing social duties. There are powerful reasons for not accepting a communitarian approach even if it might result in increased efficiency and reduce selfishness in society.

Firstly, although it may be legitimate in limited circumstances for the law to permit the use of information without consent or to require individuals to have their genetic material used in certain research, rights remain important in ensuring that certain restrictions limit these duties. To replace rights with a communitarian view that gives precedence to social

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[19] See Rubinstein, *supra* note 3 at 224.

gains without limits would have undesirable consequences. Individual interests could be set aside because of a benefit to the community, regardless of the extent of that benefit. It is a trite but important objection that this approach uses individuals as a means to an end without regard for their individual dignity. John Rawls and many others have made this point, "Each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override. For this reason justice denies that the loss of freedom for some is made right by a greater good shared by others."[20] To disregard rights and focus on community benefits may result in the sacrifice of the interests of a few, for the benefit of others. Moreover, those groups whose interests are likely to be sacrificed are those without substantial political power such as minority groups, or groups that have traditionally been oppressed such as women.

A second criticism of the communitarian approach is 'the slippery slope' argument: there are no limits to where it might end or to the consequences of such an approach. Communitarian arguments could extend well beyond an obligation to participate in research. It could be argued on the same basis, for example, that individuals have an obligation to undergo genetic testing, to know and use their genetic knowledge to minimise burdens on health care by not having children with certain genetic conditions and traits. Hellsten makes the wise point that we should be aware of the consequences of accepting a communitarian perspective. For example:

> If we follow this communitarian logic in the matter of genetics, it can easily be concluded that there would be a similar obligation to obtain and share the genetic information with anyone affected one way or another, and that it is our duty to

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[20] John Rawls, *A Theory of Justice* (Harvard U Press, 1971) at 3-4.

> choose a life style which prevents the outbreak of a particular genetic (or other) probable disease.[21]

Whilst it may be the case that an individualistic approach may result in fewer benefits to health and to the community because some people will refuse to share their information, a large number of people may voluntarily share their genetic information and material given the choice and the right social climate. In this context, it is unlikely that the social goals or benefits achieved by a voluntary approach and compulsory communitarian approach will be substantially different. Further, where individuals retain autonomy, those who do share their information will be making an altruistic gesture. Where research participation is voluntary:

> Society benefits both from the knowledge gained and from the individual affirmation of commitment to the public good and the needs of others. But no matter how great the benefit may be, the investigator does not have the right to force the individual to take part. Moreover, to require participation rather than permitting voluntary enrolment would itself be costly because it would eliminate the social benefits of altruism.[22]

Put simply, enforced sharing is not really sharing at all. In addition, a liberalism that accepts that there ought to be certain limits to autonomy which this writer subscribes to, can remain open to limitations on the rights of individuals to keep private their information where the benefits to the community justify such limitations. A third criticism which is more pragmatic, is that there are difficulties in determining how the

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[21] See Hellsten, *supra* note 1 at 304.

communitarian approach can be put into practice. Assuming that it is possible to agree what constitutes a community or group, in what way should the rights of such groups be taken into account?[23]

3.4 A Modified Rights Approach

In sum, there are certain fundamental difficulties in adopting a purely communitarian approach. However, it is essential to integrate the important contribution of communitarian ethics to the formulation of policy on genetic databases. Although this thesis has stressed the importance of privacy and individual rights, it has also consistently maintained that privacy ought to be balanced against societies and other parties' rights and interests in accessing and using genetic information and material. It is legitimate to assert that citizens have a moral obligation to participate in certain research or to allow others access to their genetic information for defined purposes. In addition, it may also be legitimate for the law to impose certain duties. The communitarian perspective therefore has an important contribution to make to the debate on for example, the social importance of particular research where the process of obtaining consent for use of archived samples could be difficult or impossible. Where the interests of the community in such research outweighs any minimal interests in autonomy or privacy then individual

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[22] Ellen Wright Clayton, "Informed Consent and Genetic Research" in Mark A. Rothstein, ed., *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era*, (Yale U. Press, 1998) 126-137 at 128.

[23] This discussion has not defined what is meant by the community. In some contexts, this simply means the political society within which we live, which might mean that individual interests ought to be limited by the interests of the whole of society as represented by the state. However, community can also refer to smaller groups defined by their common religion, ethnic group or even extended families. Such groups may also have interests which some may argue ought to limit individual rights. There is a debate highlighted in the literature which focuses on whether groups can have morally significant interests. See Wellman, *supra* note 4 at 15 (wondering "Are Group Rights Conceptual Nonsense?").

rights may be overridden legitimately. In addition, the familial and social nature of genetic information has prompted this writer to re-evaluate her perspective in the light of communitarian values.[24]

Those who advocate the primacy of individual privacy should have regard for the important values which communitarianism espouses. Although privacy is important, and human rights ought to be respected, they are not and should not be the absolute or the sole consideration. We should therefore heed Knoppers' warning when considering the balance between the right to privacy and the benefits to the community of genetic databases. She says that, "[i]t could well be that with DNA sampling, we have reached the epitome (if not epiphany) of the informed consent process. We are in danger of losing sight of the larger goals of medicine and of public health. Offering increased choices and control respects the contribution of the person but where will it end?"[25] Although communitarian arguments stress that individuals ought to have social duties, these duties should operate alongside the safeguards offered by rights. This will ensure that an individual's privacy and autonomy are set-aside only in certain circumstances in order to contribute to the important social goods of society. This will guarantee that such research is not undertaken at the unacceptable expense of individuals' rights.

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[24] This writer originally took the view that ethical importance attached to the fact that information derived from testing a particular person, and that they ought to have a strong degree of privacy over it. After further consideration, through the process of writing this thesis, this writer recognises that others do have legitimate claims on such information because it relates to them.

[25] Bartha Maria Knoppers, "Preface" in Knoppers, Laberge and Hirtle, eds., *Human DNA: Law and Policy, International and Comparative Perspectives*, (Kluwer Law Int, 1997) at xvi.

Mann notes a growing acceptance of this modified individualism that stresses the compatibility both of respecting rights and of the importance of limiting rights for the public good. He argues, "[w]hile modern human rights explicitly acknowledges that public health is a legitimate reason for limiting rights, more recently the underlying complementarity rather than inherent confrontation between public health and human rights has been emphasized."[26] This is a middle ground, which both respects rights and recognises circumstances in which it is legitimate to limit those rights for the benefit of the community.

3.5 Reflecting Community Involvement in Practice

So far, this discussion has focused on the arguments of communitarians in having genetic information and material shared for the benefit of the community. However, the community's interests in privacy with regard to large-scale databases are also relevant in determining what genetic research is and is not undertaken. What place should communities have in decision-making about research?

Some commentators argue that communities have interests, which ought to be taken into account in preventing or consenting to certain research being undertaken. Genetic research involving anonymous tissue samples or genetic information may pose minimal threat to the rights of the individual while having major implications for the privacy of a group. One of the most important reasons for understanding the interests and rights of

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[26] Jonathan M Mann, "Medicine and Public Health, Ethics and Human Rights" (1997) 27 *Hastings Center Report* 6-13 at 9.

communities and of societies is that genetic research can potentially lead to considerable stigmatisation and discrimination for groups. As Gostin explains:

> Release of anonymous data usually does not entail significant privacy concerns because individuals cannot realistically be identified……Anonymous data can raise concerns about "group" privacy – the sometimes contested idea that ethnic, racial, or religious groups possesses privacy interests. Suppose that a researcher does not collect personally identifiable data but publishes information that stigmatises a particular group, as with genetics research on sickle cell anaemia (African Americans) or Tay-Sachs disease (Ashkenazi Jews). Or think about a study in a small Native American village finding that the population has extraordinarily high rates of drug abuse, mental illness, or STDs. In each of these cases, members of the group may feel that they have diminished reputation and social standing.[27]

These examples of genetic research are not fictional. Recent genetic research provides vivid illustration of such issues surfacing. Since certain genetic variants are more common in some populations than others, researchers can estimate the disease risks of entire populations.[28] For example, genetic research revealed that a gene indicating a predisposition to breast, ovarian and colon cancer was prevalent in a large percentage of Ashkenazi Jews.[29] This resulted in a situation where people could be discriminated

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[27] See Gostin, *supra* note 15 at 129.

[28] Richard R. Sharp and Morris W. Foster, "Involving Study Populations in the Review of Genetic Research" (2000) 28 *J of Law Med. and Ethics* 41-51.

[29] Karen H Rothenberg, "Symposium: Workshop On the BRAC1 Breast Cancer Gene in the Jewish Population: Breast Cancer, The Genetic "Quick Fix" And the Jewish Community" (1997) 7 *Health Matrix* 97.

against in a number of areas of life, not because they actually carried the mutant gene but on the basis that as Jews, they had a higher risk of carrying the mutation. Such research therefore carries with it serious implications for communities upon which it is conducted. That is not to say that such research should not be conducted[30]since it may have significant value for the communities and their members.[31] However, it does strengthen the case for community involvement in deciding whether or not such research should be undertaken, and in developing research protocols. Some commentators also argue that community interests ought to be recognised by requiring their involvement in evaluating research. Indeed the policy of the Human Genome Diversity Project is that consent to the taking of genetic samples must be provided by both the individuals being sampled and the First Nation of which the individual is a member. [32] In an interesting article which considers the guidelines for protecting aboriginal communities participating in biomedical research, Weijer et al., explain that some have argued for the adoption of a principle of respect for communities which, "confers in the researcher an obligation to respect the values and interests of the community in research and, whenever possible, to protect the community from harm." [33]

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[30] Although in the case of research that was being undertaken between a possible correlation between men who had an extra copy of the Y chromosome who were supposedly predisposed to violence, it was decided that such research ought to be stopped. See Clayton, *supra* note 22 at 128.

[31] Such research may lead to resources being devoted to certain diseases that affect certain populations. For a general discussion see A Caplan, "Handle with Care: Race, Class and Genetics" in T. F. Murray and M. A. Lappe, eds., *Justice and the Human Genome Project* (Berkley: University of California Press 1994) at 30-45.

[32] The Human Genome Diversity Project's aims have been described as "to gain insight into human origins, evolution, patters of migration and reproduction and the global distribution of genetic disease. It was set up in 1991 by HUGO. See British Medical Association, *Human Genetics, Choice and Responsibility* (OUP, 1998) at 195.

[33]Charles Weijer, Garry Goldsand and Ezekiel J Emanuel, "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation" (Nov 1999) 23 *Nature Genetics* 275-280 at 275.

Recognising that communities have interests or rights will result in conflict with individuals' interests. The modified rights approach recognises the legitimate interests of the community in such cases and therefore accepts that these ought to be taken into account in determining policy.[34] This principle can be put into effect by ensuring a process of consultation with the group, in addition to the usual process of individual consent. In addition, particular communities may be involved in drafting guidelines themselves[35] and also may be involved in the design, conduct and publication of any studies.

In sum, one of the main strengths of the modified rights approach advocated is the account taken of the familial and social nature of genetic information and the affects of its use and disclosure, not only for individuals but also for communities and groups. The privacy interests of groups and communities in knowing, not knowing and not having others know genetic information must therefore be considered where genetic information is likely to be discovered or revealed. An exclusively individualistic approach ceases to make sense in an era of genetics where information cannot be said to belong to an individual in any ethical sense. What is required is a practical response that features and balances the rights of individuals with the interests of society and which works in practice. Knoppers makes this point well:

> Legitimate concerns for the protection of privacy or for the possible stigmatisation that accompanies gene identification with particular population regions or ethical groups, require valid and workable responses that do not

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[34] For a general discussion on community involvement in genetic research see Sharp and Foster, *supra* note 28.

> undermine the possibility of undertaking genetic epidemiology but instead recognise the specificity and the need for research.[36]

It is also important to be aware of the extent to which legal rights can be undermined by unofficial communitarian policies. For example, Hellsten describes the operation of a communitarian approach to genetics in Cyprus which emphasises that reproductive decision-making should be voluntary while at the same time, choice is undermined by other policies that emphasise the importance of community involvement in reproductive decision-making.[37]

Similarly, communitarian ethics might undermine individual rights in practice in the UK. For example, codes of practice, of the medical profession, sometimes advise non-disclosure of genetic information to family members of the proband without permission, but encourage the individual to disclose it. Such an influence may well be legitimate and society may determine that this position strikes an appropriate balance by giving individuals the final choice while encouraging sharing of information. However, this example illustrates how both explicit and implicit policies of the medical profession can influence the extent to which rights are protected in practice. As a result, communitarian ethics ought to be fully debated even in a context where rights are protected by law. As Hellsten says, "[w]e now have to start discussing seriously the questions of social duties

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[35] See Weijer et al., *supra* note 33 at 277.

[36] See Knoppers, *supra* note 25.

[37] The Cyprus Thalassemia Program emphasises the importance of community involvement in genetics in controlling Thalassemia. The state has made an agreement with the church to not interfere with premarital testing and certificates, and genetic screening so that the church, which opposes termination, does not have an opportunity to interfere in decision-making. Couples are also given genetic counselling. Hellsten says

and responsibility as well as the influence of social pressure on individual decision-making, even in a situation in which the political and legal rhetoric still functions within the language of individual rights and autonomy."[38]

3.6 Limiting and Balancing the Right to Privacy

Elements from libertarian and communitarian ethics, therefore fuse to support a modified rights approach to genetic privacy. This balances the right to privacy of an individual against the interests of other parties to whom the information relates, and against the interests of the community. Determining how this balance ought to be struck in practice is a more difficult matter. Balint says that addressing the balance is extremely challenging:

> It is not clear where the line should be drawn between permissible and impermissible breaches of privacy and confidentiality. Who should have the right to decide what information presents significant risk to the larger community. Who defines what is a significant risk? Should there be an absolute requirement that the subjects involved be informed that certain medical information will be passed on to those in authority?[39]

Wherever the balance may lie, it is important that a sufficient degree of privacy is maintained so that individuals feel confident that their genetic information will be

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that it is important to ask how much autonomy is left after these other social pressures and propaganda are taken into account. See Hellsten, *supra* note 1 at 304.

[38] *Ibid* at 305.

safeguarded. This may encourage them to have their information stored in genetic databases. The Mori poll conducted for the Human Genetics Commission shows that the public are currently concerned about the dangers of genetic information and a right to privacy may go some way towards reassuring those who have concerns. There is also the possibility that individuals may resort to secret and private testing[40] if they do not trust the law to protect their interests.[41]

In any event, as Mclean and Giesen correctly argue, the extent and limitations of a right to privacy ought not to be determined by medical professionals or researchers but should remain in the hands of the legislature or the courts. "The potential limitations of the individual's right to informational self-determination must not be left to the option of medical professionals whether in the clinical context or before the courts as expert witnesses."[42] The law faces the challenge of striking this balance in a way which respects human rights but which does not create significant difficulties for medicine and research.

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[39] John Balint, "Issues of Privacy and Confidentiality in the New Genetics" (1998) 9 *Alb. L.J. Sci. & Tech.* 27 at 36.

[40] Eugene Oscapella "Genetics, Privacy and Discrimination', A Survey Prepared for the Canadian Biotechnology Advisory Committee Project Steering Committee on Genetic Privacy (Canadian Biotechnology Advisory Commission; Ottawa, October 31, 2000) at 2.

[41] It may be possible for people to identify their genetic traits using commercially available testing kits These kits that will undoubtedly be developed for a greater number of conditions and will become cheaper. This will mean that individuals will be able to find out genetic information about themselves and keep the fact that they have been tested private. This possibility is relevant to the approach, which the law ought to take to the protection of privacy where a third party holds such information. If the privacy of individual's test results held in databases is not adequately protected, then this may result in an increasing number of individuals carrying out tests themselves. This is not a desirable consequence given the paramount importance of genetic counselling in order to prepare individuals for the results, which such a test may produce.

[42] McLean, Sheila AM, Giesen, Dieter, "Legal and Ethical Considerations of the Human Genome Project" (1994) 1 *Medical Law International* 159-175 at 164.

In sum, communitarian ethics which focuses on duties rather than rights is fundamentally flawed in that it fails to protect individuals from being used for the benefit of their community since there are no limits on the extent to which individuals or their genetic information and material can be used for certain purposes. This may result in humans being treated in a way that is unacceptable to contemporary society and which overrides the principle of respect for persons. However, communitarian ethics acts as a useful counterbalance to the focus on individual rights in this thesis, in reminding us of the importance of our interdependence in society and our moral social duties. Indeed, most would accept specific limitations on their privacy as necessary and justified in order to achieve certain social gains in medicine and research and in the detection and prevention of crime. Provided we accept the central role of rights in the law of privacy, communitarian ethics can enrich the debate about how the law ought to balance these important rights whilst achieving certain social aims. The communitarian viewpoint ought to be acknowledged and widely debated because it may influence and limit individuals' choices in practice and we ought to be aware of social factors that enhance or restrict individuals from exercising truly free choice.

3.7 Individualism is a Western Concept

This section will now consider a criticism, that the individualistic approach is largely a product of western culture, that it is less relevant to other cultures and that it is incompatible with a pluralistic society.

Individualism is not universally accepted by all societies and cultures[43] and arguments about the importance of individual rights, autonomy and privacy are not universally acceptable or applicable to other cultures or jurisdictions. Laurie describes this objection in commenting that, "Post modernists in particular, reject any claims that values can 'apply across the board' preferring instead to varying degrees a philosophy of relativism."[44] This criticism does not apply only to the debate about genetic privacy but it is an important point which requires to be addressed.[45]

This thesis has not argued that a model based on respect for individual rights ought to be followed in all societies or cultures. It has focused exclusively on recommending an approach for the law in the UK. It is accepted that values such as autonomy and privacy, which are central to the thesis, are not valued in exactly the same way across cultures. Therefore, this thesis ought to be confined to this context.

It is more difficult to counter the criticism that it is difficult to justify a single approach in an increasingly pluralistic and multi-cultural society such as the UK, because any laws will impose certain values on some who may not accept them or who may object to them.

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[43] See for example a more communitarian approach evident from the laws in Israel discussed by Michael Gross, *supra* note 12 at 13 where he says that Israel has tried to meet the demands of social justice and its rebirth within the framework of a communitarian state – "that is within a society imbued with a high degree of collective consciousness, mutual concern, and interdependence. The result, in the field of health care, is a unique blend of universal health insurance paternalism, and limited patient rights."

[44] *Supra* note 11 at p29.

[45] There are those who argue against the view that values cannot apply universally. However, this argument will not be evaluated in full as it is not necessary for the purposes of this thesis. See Ruth Macklin, *Against Relativism. Cultural Diversity and the Search for Ethical Universals in Medicine* (OUP, 1999).

Why should autonomy and privacy be endorsed by law, when this may reflect values regarded as unimportant by cultures or individuals within the UK?

In practice our society requires to adopt a pragmatic, democratic position, which respects pluralism in so far as is possible whilst achieving a workable, political compromise when consensus proves impossible. A rights approach takes respect for autonomy as an underlying axiomatic value since it generally enables individuals to make decisions about their own lives in accordance with their own values, within certain limits.

Moreover, it is evident that autonomy is highly valued in western culture and in the UK.[46] The current acceptance of autonomy and the importance of individual rights in the UK, means that an approach that diverges from this emphasis would require a fundamental cultural and political change. Any major legal departure from this value would raise, therefore, enormous practical problems in enforcing values on a society, which does not hold them to be important. Rubenstein discussing individualism and privacy in American society says, that the influence of individualistic culture on the debate about privacy is so ingrained that it is difficult to think about it objectively. "One of the biggest challenges in reaching consensus on the instant issue is caused by our culture. We live in a social environment of increasing distrust and hostility. Further, other aspects of our culture ensure that the privacy issue is addressed in a venue that almost guarantees that the issue's costs and benefits cannot be thought through carefully by American society."[47]

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[46] Laurie makes this point when he says that the communitarian approach "stands in stark contrast with the more autonomy driven view which is represented, *inter alia* by Anglo-American legal systems." See Laurie, *supra* note 11 at 41.

[47] *Supra* note 3 at 227.

Alternative approaches are unlikely to succeed, therefore, without significant cultural change. This is not to say that it is fruitless to consider other approaches. The law has the potential and an obligation, to reflect changes in society's values and in some cases to instigate such changes. This is more likely to prove effective where it involves a modification of social values rather than a complete shift in values.

3.8 Physical Measures to Protect Genetic Privacy

This section will briefly examine the extent to which privacy can be protected in practice before moving on to the next tranche of this thesis in chapters five and six, which will evaluate the law as it currently applies to genetic privacy.

It is important to examine these physical aspects since laws which give individuals certain rights to restrict other parties' access to certain information are of little value without the technological means necessary to implement such laws. In addition, in situations where privacy can be protected by technology, whilst achieving the necessary aims of research for example, the threat to individual privacy may be significantly lessened without the need for recourse to the law.

In the digital era where information technology has made it possible to collect, disseminate and transfer genetic information quickly and without trace, it becomes extremely important to have clear legal measures in place, which determine the rights of individuals to privacy. This is particularly acute where a third party holds information in databases when they may have strong financial or other incentives in selling or revealing the information to other parties. Reliance can no longer be placed on personal relationships to safeguard the interests of individuals in keeping private their genetic information.

Although it is often argued, that privacy and confidentiality are threatened by information technology and by the gathering of large amounts of data that can be transferred easily and matched, information technology can also be utilised to protect personal information.[48] For example, it is possible for security measures to be built into the software of computerised information systems, which prevent access to certain individuals, and which can log attempts at security breaches in a way that is impossible with paper records. Other measures to assure confidentiality include locking files, destroying the data and genetic samples when they are no longer required. The use of these technologies in databases of genetic information can ensure that risks to privacy are minimised.

Oscapella makes the point that one of the most effective ways of protecting privacy of genetic information is to prevent its initial collection:

> The ultimate protection [of privacy and prevention of discrimination], however, may often lie in more strictly limiting the initial collection of personal genetic information. For example, the greatest protection against state interference with

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[48] See Barbara von Tigerstrom, "Protection of Health Information Privacy: the Challenges and Possibilities of Technology" (1998) 4 *Appeal* 44 at 52.

> human reproduction will come from keeping personal genetic information from the state in the first place.[49]

Although this approach may appear to be extreme, it is not likely to result in the disintegration of all genetic databases. It is possible to envisage circumstances in which the collection of data does not appear to be adequately justified, for example if a research project does not appear to have a sufficient likelihood of achieving significant benefits to medicine. In such a case, the threat to privacy caused by the collection of data should be taken into account. It is the case that any collection of data or genetic material poses some risk to privacy. However, provided that the establishment of such databases are likely to result in benefits in medicine and research then such inherent loss is adequately justified. Further, the use of identifiable tissue or information should be restricted to studies that require identification. Anonymous data and samples should be used whenever possible.[50]

There are various ways of removing identifiers from data so that it cannot be linked to named individuals. De-identified data has been described as data that has had all explicit identifiers, such as social insurance numbers, names, addresses and other information removed, generalised or replaced with an invented alternative.[51] Anonymous data on the other hand implies that the data cannot be manipulated or linked to identify an individual.

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[49] See Oscapella, *supra* note 40 at 3.

[50] This point was made by Health Council of the Netherlands, Committee on Human Tissue for Special Purposes, *Proper use of Human Tissue* (The Hague: Health Council of the Netherlands, 1994) at 14.

Although some commentators have argued that, "If anonymity is guaranteed, DNA banking should not present any problems"[52] anonymous data is not entirely free from threats to privacy. Sweeney argues that the problem with data considered to be anonymous is that the person releasing the data is unaware of the knowledge, which the viewer of the data may bring to bear on the 'anonymous' data.[53] For example, depending on the coding scheme used, someone may be able to decipher it and link it to named individuals. She says that medical records, which are distributed with a code or number are not typically anonymous since hundreds of administrators typically have directories that link the number to a named individual.[54] Gostin makes the point that regardless of its status, genetic material such as tissue samples can never be anonymous because of the possibility of analysing this data and identifying it with a person.[55] This is a special quality of genetic information and although it may be costly in terms of time and money to link a tissue sample with an individual, it nonetheless remains a theoretical possibility. He says, "Genetic data bases are especially problematic because they are often termed non-identifiable despite the existence of technology that can link genetic data to a unique individual."[56]

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[51] Latanya Sweeney, "Weaving Technology and Policy Together to Maintain Confidentiality"(1997) 25 *Journal of Law, Medicine and Ethics* 98 at 98.

[52] See B. Godard and M. Verhoef "DNA Banking, Current and Ideal Practices" in Timothy Caulfield, Bartha Maria Knoppers and Douglas Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 30.

[53] See Sweeney, *supra* note 51 at 98.

[54] She gives examples of coding schemes that use post-code and dates of birth to render data anonymous. Such data can often be deciphered relatively easily. For example, in the 1997 voting list for Cambridge Massachusetts which contains over 54,000 voters, birth date can identify the name and address of 12% of the voters, and 97% can be de-identified with a full postal code and birth date. *Ibid.*

[55] Lawrence Gostin, "Health Information Privacy" (1995) 80 *Cornell Law Review* 451 at 504.

[56] *Ibid.*

Similarly anonymous databases of genetic information will often have a number of people who have access to the code that can link named individuals to the assigned number or code. In particular, when the data stored reveals that someone has an unusual genetic condition, then it may be possible to link such a record to a relatively small number of individuals. This is particularly the case where the database is relatively small or where some other data is known about the geographic location or sex of the contributor. Therefore, although anonymous data is not free from risk of identification, it is preferable to use it where possible to ensure that privacy is infringed to the least extent possible. One unfortunate consequence of anonymisation is that it is not possible to contact an individual if information is revealed during the course of the research, which may greatly improve his or her health.

Making data anonymous is not always practical since, some databases require the data to be identifiable so that it can be linked with other information about health and lifestyle[57] or because it may be useful to update the data from time to time with new health information or for clinical medical records. An increased risk of inappropriate identification is included in such databases.

One possible way to minimise the risk of identification is to follow the approach of the Icelandic Population database in which the data is coded with a one-way identifying

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[57] See George J. Annas, "Rules for Research on Human Genetic Variation – Lessons from Iceland" (2000) 342 *The New England Journal Of Medicine* 1830 at 1830:

> Research on genetic variation aims to understand how genes function and requires the comparison of DNA samples from groups of individuals to identify variations that might have importance for health and disease. The work is easier if samples are linked to accurate medical records and genealogical information...

scheme so that the information on file can be updated but the identity of information relating to an individual cannot be revealed from the database.[58] Regardless of the technology employed it is unlikely to be perfect in preventing security breaches. Such risks have to be taken into account in any database.

3.9 Conclusion

It has been argued so far, that there are certain features of genetic information and databases that warrant distinct consideration for privacy in law and ethics. It has also been argued that there ought to be legal recognition of a right to genetic privacy so that any infringements of privacy must be substantially justified. This is necessary to safeguard an individual's privacy interests in his or her genetic information when held on a database. This right ought to be modified to take into account the fact that genetic information is familial and social and benefits to the community ought to be balanced against the right of the proband to genetic privacy. The criticisms of an individualistic rights approach were addressed and the physical means of protecting privacy were briefly explored.

The following two chapters will examine the law in practice and measure it against the modified rights approach argued for so far. The current legal provisions concerning privacy, confidentiality, access to and control of genetic information and material stored in databases will be critically evaluated. Chapter four will consider the common law

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[58] This is discussed in Henry T. Greely, "Iceland's Plan for Genomics Research: Facts and Implications" (2000) 40 *Jurimetrics Journal* 153 at 183.

action for breach of confidence and the following chapter will look at a new approach implemented by the *Data Protection Act 1998* and the *Human Rights Act 1998*.

Chapter Four

Breach of Confidence and Genetic Information

> If the individual is to retain any meaningful control over information affecting his life and if society is to avoid becoming enveloped in an Orwellian miasma, the law may have to employ administrative and legislative controls that will impose direct responsibilities and limitations on information system managers and data users. If we fail to do this, Everyman's life history will be recorded, centralised, and made available to wider audiences as the "experts" wield increasing power through their data banks and computer networks. [1]

4.1 Introduction

The previous chapters of this thesis have established an argument for the legal recognition of a modified right to genetic privacy. This argument is partly based on the nature of genetic information, which is sensitive and personal, familial, able to predict health well into the future and has a history of possible abuse for eugenic purposes. It is also premised on the argument that privacy is underpinned by the ethical principle of self-determination and recognition of the need to protect human dignity. Chapter three argued that the rights approach ought to be modified to take account of the familial and social nature of genetic information and because of the importance of communitarian arguments that assert that individual rights ought to be overridden for the good of the community in

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[1] Prof Arthur Miller, *Assault on Privacy, Computers, Data Banks and Dossiers*, 142 (U of Michigan Press, 1971) at 209.

some cases. As a result, it has also been argued that this right to genetic privacy is necessarily limited. In strictly defined circumstances, it may legitimately be outweighed by the interests of third parties who also have a right to access and know their own genetic constitution, and by the interests of other third parties including society in knowing such information.

In the opening quotation, Arthur Miller, writing in 1971 called upon the law to "impose direct responsibilities and limitations on information system managers and data users."[2] Chapters four and five will assess the extent to which the law in the UK has imposed such controls, their adequacy in protecting the rights and interests of individuals and groups over genetic information, and how far the law has taken account of the concept of genetic privacy set out in chapters two and three.

No legislation has been enacted specifically to deal with privacy and confidentiality of genetic databases.[3] There are, however pre-existing areas of legislation and common law which protect an individual's interests in keeping personal genetic information private and confidential and in regulating who ought to have access to it. This chapter will examine the common law action for breach of confidence, prior to the *Human Rights Act 1998*. It will argue that this action was inadequate in protecting confidentiality and genetic privacy. The next chapter will consider the implications of the *Human Rights Act*

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[2] *Ibid.*

[3] The House of Commons Science and Technology Committee (Shaw Committee) 3rd Report, 'Human Genetics: The Science and its Consequences', Report and Minutes of Proceedings, London, HMSO July 1995, recommended that misuse of genetic information should be both a criminal offence and that it should be the subject of privacy rather than anti-discrimination legislation (para 226). However no specific legislation has been enacted.

1998 and the *Data Protection Act 1998* since these statutes are likely to have a profound impact upon actions for breach of confidence and the protection of a right to genetic privacy. The following chapter will also consider how the common law may change as a result of this legislation.

4.2 The Obligation of Confidentiality

The courts in the UK have not recognised a cause of action for infringement of privacy per se.[4] The common law action of breach of confidence makes unlawful the unauthorised disclosure of certain information, including confidential genetic information[5], in defined circumstances. This action arises out of a common law duty to keep confidential information private when it has been disclosed to someone under the understanding that it ought to be kept confidential.[6] The circumstances of disclosure place the confident in a position of trust and for this reason the law applies equitable principles to import this duty into a legal one.[7] The nature of this obligation was discussed in the case of *A-G* v *Guardian Newspapers Ltd (no 2)*[8] in which the Court of Appeal concluded that there was a public interest in a legally enforceable protection of confidences received under notice of confidentiality. Breach of this obligation can be

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[4] *Kaye* v *Robertson* [1991] FSR, 62 (CA) cited in Andrew Grubb, 'Breach of Confidence: Anonymised Information', *Medical Law Review* (8 Spring 2000) p115-119, where Grubb says that although infringement of privacy *per se* is not protected by English law, it does usually protect a specific aspect of an individual's privacy which is their interest in excluding others from personal information about them.

[5] It should be noted that not all genetic information is in itself confidential since some of it may be obtained from external observation of characteristics such as eye colour or it may be public knowledge such as information about family history of disease. See *Human Genetics Commission, Whose Hands on Your Genes? A discussion document on the storage, protection and use of personal genetic information,* (UK: Human Genetics Commission, 2000) at 3. Online at *www.hgc.gov.uk* at 4. However genetic information disclosed in the clinical or research context will have the necessary quality of confidence.

[6] See general discussion in Francis Gurry, *Breach of Confidence* (Oxford; Clarendon Press, 1984) at 3.

[7] It has been said that there is uncertainty as to the jurisdictional basis of the action for breach of confidence. See Harry Lesser and Zelda Pickup, 'Law Ethics and Confidentiality', (Spring 1990) *Journal of Law and Society* Vol 17, No 1 17-28 at 18.

justified in certain circumstances when it is considered to be necessary in the public interest or for a number of other reasons which will be discussed below.[9]

4.3 Legal Requirements for An Action For Breach of Confidence

Megarry J described the three necessary requirements to establish an action for breach of confidence in *Coco* v *A N Clark (Engineers) Ltd:*

> First, the information itself...must have the necessary quality of confidence about it. Secondly, that information must have been imparted in circumstances importing an obligation of confidence. Thirdly, there must be an unauthorised use of that information to the detriment of the party communicating it. [10]

At first sight, according to this test, the law appears to provide a significant degree of protection for an individual over his or her genetic information. However, a detailed examination of these three elements together with a consideration of the potential circumstances in which non-consensual disclosure of confidential information is permitted by law, reveals that prior to the *Human Rights Act 1998*, the law of breach of confidence failed to protect confidentiality in a wide range of circumstances. Considerable exceptions to the principle were permitted without substantial justification and without significant legal control over such exceptions. Moreover, it will become apparent that this law developed out of the need for expediency in medicine rather than

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8 [1990] 1 AC 109.
9 However, once the breach is established, it is for the confidant to justify disclosure. See *W* v *Egdell [1990]1 ALLER 835 at 845e.*
10 *[1969] RPC 41 at 46-48.*

from a recognition of the importance of confidentiality as a principle and of privacy as a right.

4.4 Requirement that the Information be Confidential

The courts have endorsed the view that all medical information is confidential and this includes identifiable genetic information.[11] However, not all databases contain identifiable genetic information since databases used for research or genetic registers will sometimes contain anonymous or coded data. In such circumstances, following the recent judgement of the Court of Appeal in the case of *R* v *Department of Health, Ex parte Source Informatics Ltd*[12] it is unlikely that an unauthorised disclosure of such information would be considered to be actionable as a breach of confidence.

This case was an application for judicial review as a result of a view expressed by the Department of Health in a policy document. Pharmacists were selling information obtained from prescription forms about doctors' prescribing practices to companies which gather the information for marketing purposes. The Department of Health had opined that this practice was a breach of the patients' confidence, notwithstanding that the pharmacists removed the patients' names or identities from the data before passing it to the company. In the court of first instance Latham J held that there was a breach of confidence which could form the basis of a successful action since what was proposed

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[11] In *Hunter* v *Mann* the court considered the duty of confidence in respect of medical information and said, "[t]he doctor is under a duty not to [voluntarily] disclose, without the consent of the patient, information which he, the doctor has gained in his professional capacity." [1974] QB 767 at 772.
[12] *R* v *Source Informatics Ltd*, [2000] 1ALLER 786.

would "result in a clear breach of confidence unless the patient gives consent, which is not part of the proposal at present."[13]

He reasoned that anonymising the data did not remove the duty of confidence towards the patient, that there remained a risk of identification despite anonymisation, and that the patient would not have been aware of, or have consented to, the information being given to the data company. He also held that such disclosure could not be outweighed in the public interest. In effect, this endorsed the view of genetic privacy supported in chapter two that privacy can extend beyond meaning simply that information ought not to be used in a way that is contrary to an individual's interests, but that it also can involve a significant degree of control over their information regardless of whether it is used in a way that is contrary to the person's interests.

This decision was overturned by the Court of Appeal, which held that the information is confidential to the patient only if it can be identified with him. The absence of confidential information meant that one of the three elements necessary for an action for breach of confidence was absent, so the action could not succeed. The Judge also said that the pharmacist's own conscience was the touchstone by which to judge the scope of the duty of confidentiality and to decide whether it had been breached. He held that on the facts a reasonable pharmacist ought not to be troubled by a scheme where identity is protected since the patient's privacy is safeguarded. The court also made it clear that the patient had no proprietary claim to the information contained on the prescription form

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13 *R* v *Source Informatics Ltd* [1999] 4ALLER 185. See also the discussion in Deryck Beyleveld and Elise Histed 'Case Commentary, Anonymisation is Not Exoneration' (1999) *Med. Law Int.* Vol 4, pp69-80.

and that the sole concern of the law was to protect the confider's claim to personal privacy. "In my judgement the answer is plain. The concern of the law is to protect the confider's personal privacy. That and that alone is the right at issue in this case. The patient has no proprietorial claim to the prescription forms or to the information it contains." [14]

This judgement appears to rule out the possibility of a successful action for breach of confidence where genetic data is anonymised, unless the courts accept the argument that genetic data, unlike other medical information, is always identifiable.[15] This is unlikely since in the Source Informatics case, the court determined that although there was a theoretical risk of identification from the prescription forms, this was not a real risk in practice. Genetic information is more likely to be linkable to named individuals (and in future, this will become increasingly possible), than patient information on prescription forms. However, it still seems unlikely that disclosure of anonymised genetic information held on a database, even for commercial purposes, would enable an individual to bring a successful action for breach of confidence.[16] The court appeared to be concerned only with preventing patients' information being used contrary to their interests rather than with giving them privacy rights over their information which would enable them to control who could have access to it or how it could be used. By explicitly rejecting the view that information could be viewed as property in some way, the court rejected the

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[14] *Supra* note 12 at paragraph 34 per Simon Brown LJ.

[15] Gostin for example has argued that there is always a risk that certain genetic information and genetic samples can be linked to an individual because certain genetic information and samples, can be used to identify individuals by genetic fingerprinting. See Lawrence Gostin, 'Health Information Privacy', (1995) *Cornell Law Review* Vol 80:451 at 504.

sense that information might "belong" to the patient. Although the court claimed to be protecting the privacy interests of the patient, by arguing that "the concern of the law was to protect the confider's personal privacy" it was protecting only an extremely narrow concept of privacy.

Latham J's analysis which considered that privacy was infringed when coded genetic information was disclosed without permission is, in my opinion, a preferable approach to that of the Court of Appeal since it gives patients a significant right to informational privacy and it recognises that there are interests at stake in the use of anonymous genetic information. The court's analysis in this case will be examined further below in an attempt to explain why it took such a narrow view in determining whether the scheme might constitute a breach of confidence. It is important to note that the courts did not conclude that there had been a breach of confidence, which was justified. The court did not find a prima facie breach of confidence and so no justification was required. As a result of this case, an action for breach of confidence is only likely to be relevant in cases of disclosure of identifiable information.

4.5 Importing an Obligation of Confidence

The second requirement of an action for breach of confidence is the existence of some sort of relationship of trust in that one party must show that (s)he imparted an obligation of confidence to another person. This does not mean that it is necessary to establish a pre-existing relationship between the parties such as, a marital or employment

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[16] This will of course depend on a court's assessment of when it becomes a "real risk" that genetic information can be linked with named individuals. This case was decided before the *Data Protection Act*

relationship, in order for there to be an obligation to keep the information confidential.[17] Where genetic information stored in a database is disclosed to a doctor or to a researcher, the courts could find the presence of such a relationship. It will be implied that such information was imparted by the patient or research subject under an obligation of confidence. In some cases there may be an explicit undertaking that the information will be kept confidential.[18]

Where it is not possible to establish an undertaking of this sort, there will be no legally enforceable obligation of confidentiality. Family members of a patient or research subject would not have imported any obligation of confidence over such genetic information and they would not have any remedy in law were such information to be disclosed without the consent of the patient or research subject. For example, if X has undergone genetic testing, and has found out that he has cystic fibrosis and has consented to have that information stored in a database and disclosed it to certain parties, X's parents have no remedy if the information is wrongfully disclosed even although it reveals information about their genetic makeup.

A further example which demonstrates the limitations of linking confidentiality to the existence of a relationship is that the disclosure of confidential genetic information from a database may not be a deliberate disclosure by the person or body (such as the doctor,

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1998 was in force, and as a result the Act will impact upon the regulation of similar databases.

[17] Although Wilson argues that plaintiffs successfully suing for breach of confidence have normally been able to establish some form of pre-existing relationship with the original confidant, this is not necessary as long as one can establish that one party imparted an obligation of confidence on another party. This means that although it is not necessary that there has been some long-standing relationship, there must have been some pre-existing link between the parties and this fact can be described as a relationship in itself. William Wilson, 'Privacy, Confidence and Press Freedom' (1990) *Modern Law Review* Vol 53, 43-56 at 47.

researcher or controller of the database) who undertook to keep the information confidential. In the event of a security breach or computer error, a third party may gain access to the information from the database without permission whether deliberately or accidentally.[19] This would mean that there would be no cause of action for breach of confidence for the person whose information had been disclosed.

4.6 Detriment

In most cases it is not difficult to establish detriment, the third requirement of the action. There are many reasons why the consequences of disclosure of personal medical information or information about identity may be detrimental. Further, it is possible that the unauthorised disclosure of identifiable genetic information would be considered a detriment in itself.[20]

4.7 Limitations of Breach of Confidence

This discussion has demonstrated that there are certain situations whereby an action of breach of confidence prior to the *Human Rights Act 1998* would not provide any redress for disclosure of sensitive genetic information for either the proband or the proband's relatives. It underlines the lack of the individual's control over anonymous or coded data under common law. This highlights the approach of the common law to privacy which does not recognise privacy as something inherently worthy of protection. Instead the law

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18 In such circumstances an action for breach of contract might also be possible.

19 For example a New York Times article recently reported that in 2000, a Dutch computer hacker broke into a computer at the University of Washington Medical Center and downloaded thousands of files containing patient information in order to make a point about the lack of security of medical information. Katie Hafner 'Privacy's Guarded Prognosis', (New York Times, March 1, 2001).

is only willing to prevent disclosure of certain information where an obligation of confidence arises out of specific limited circumstances or relationships. In addition, the action for breach of confidence does not recognise the familial nature of genetic information.

There is a wide range of circumstances in which a prima facie breach of confidence has occurred but where disclosure of confidential information is permitted by law and these will be discussed below. The permissible exceptions may differ according to whether the information was collected as part of the patient's treatment or whether it was collected in a research or other context since the practice of the profession, for example the medical profession, has a significant impact upon the exceptions permitted by law. [21]

4.8 Confidentiality of Genetic Information in the Medical Context

Confidentiality of medical information has always been considered to be an essential element in the doctor-patient relationship. Professional codes of ethics have stressed the importance of confidentiality for 3000 years and this is apparent from the Hippocratic oath which says,"[a]nd whomsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be

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[20] Support for this proposition is found in the case of *X* v *Y and Others* [1988] 2 ALLER 648 in which the disclosure of medical records of two doctors who were HIV positive was made to the press in breach of confidence. The court held that even without their publication by the newspaper, detriment occurred.

[21] As Hirtle notes, "policy positions and recommendations on banking lie within, and are complicated by the wider normative framework applicable to the patient- physician relationship, to genetic research and to research involving human participants." Marie Hirtle, 'International Policy Positions in the Banking of Human Genetic Material', in Timothy Caulfield, Bartha Maria Knoppers and Douglas Kinsella eds, *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996).

published abroad, I will never divulge, holding such things to be holy secrets."[22] More recently, the Declaration of Geneva repeated this assertion," I will respect the secrets which are confided in me, even after the patient has died." [23]

Professional codes of practice also recognise permissible exceptions to the principle of confidentiality. The General Medical Council's most recently published guidance[24] indicates the circumstances in which the medical profession is permitted to disclose medical information.[25] These rules apply when the information has been derived from a patient undergoing clinical testing.

Although professional codes of practice do not have the force of law, they provide a useful starting point for discussion of the current legal position for two reasons. Firstly, as Mason and McCall Smith point out in the context of medical law in particular, it is difficult to disassociate the moral content of confidentiality from the legal common law duty.[26] Professional codes of practice give substance to the content of the common law duty of confidentiality of genetic information in medical practice. Secondly, adherence to professional codes often establish professional norms of practice and a failure to adhere to such norms can form the basis of an action for negligence. This is because the

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[22] The Royal College of Psychiatrists notes that this provision has remained unaltered for 300 years. See Ian E Thompson, 'The Nature of Confidentiality' (1979) *J. of Medical Ethics*, 57.

[23] The World Medical Association, Declaration of Geneva, Physician's Oath adopted by the General Assembly of the World Medical Association, Geneva, Switzerland, September 1948. Amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968, and by the 25th Assembly in Venice, 1983.

[24] General Medical Council, *Confidentiality: Protecting and Providing Information*, (General Medical Council, August 2000).

[25] The World Medical Association and the World Health Organisation have announced that they will be drafting guidelines on databases. Abbusi, K, 'WMA to produce guidelines on health databases', (2000) *BMJ*, 320:1295.

grounds for establishing medical negligence in England and Scotland, set out respectively in the cases of *Bolam* v *Friern Hospital Management Committee*[27]and in *Hunter* v *Hanley*[28], endorse the custom test, whereby the defendant's conduct is tested against the normal usage of the profession.

4.9 General Medical Council's Guidance

The General Medical Council's guidance describes a number of exceptions to the obligation of confidentiality although only those relevant to genetic databases will be discussed here.[29] The first exception applies where the individual consents to disclosure, for example, to a family member, an employer or insurer.

The second exception to the duty of confidentiality applies when it is in the interests of the patient to breach confidentiality and when it is undesirable on medical grounds to seek such consent.

Thirdly, information may be disclosed for a medical research project that has been approved by a recognised ethics committee. The General Medical Council guidance says that disclosure of information for purposes such as epidemiology, public health safety, or the administration of health services or for use in education or training, clinical or medical audit, or research is unlikely to have personal consequences for the patient.

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[26] Mason & McCall Smith, *Law and Medical Ethics*, 4th Ed (Butterworths, 1994) at 167. They base this view on Lord Coleridge's CJ comment that, "A legal common law duty is nothing else than the enforcing by law of that which is a moral obligation without legal enforcement."

27 *Bolam* v *Friern Hospital Management Committee* [1957] 2 ALL ER 118.

28 *Hunter* v *Hanley* (1955) SC 200.

[29] *Supra* note 24.

Therefore anonymised data can be given without consent, although consent should be sought for disclosure of identifiable information. Where it is impracticable to obtain consent or impossible to anonymise data, then data may be disclosed without express consent.

This approach considerably limits the extent to which the individual can control the use of his or her information. Whether or not this is justified will depend upon the facts including the case that can be made for benefits to public health and research as weighed against the privacy rights of those involved. The modified rights approach ought to involve an analysis of these factors to ensure that rights are not overridden without sufficient justification. This does not appear to be the approach of the General Medical Council, however.

Fourthly, confidential information can be disclosed as required by statute (which is often concerned with the protection of public health[30] or for statistical purposes) or non-statutory disclosure, which includes where information is required to be disclosed in the course of legal proceedings.

A final and controversial exception to the rule of confidentiality is when a breach of confidence is said to be justified in the public interest. It is difficult to predict the circumstances in which courts will accept that disclosure of genetic information stored in

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[30] For example the *Public Health (Control of Diseases) Act 1984* and the *Public Health (Infectious Diseases) Regulations 1998* that require a number of diseases to be reported. None of those diseases is specifically a genetic one. See also Charles Foster, 'Confidentiality and Genetic Information', *Genetics Law Monitor* (Sept/ Oct 2000) Vol. 1 Issue 2 which discusses this subject.

databases is justified in the public interest, and no cases have directly addressed this issue. Instead, analogous case law will be analysed. In practice it will be at the discretion of the doctor or researcher to decide whether a disclosure is justified in the public interest and the courts will make a determination after the fact as to whether such disclosure was justified. As a result, the advice of medicine's professional bodies such as the General Medical Council will have an important bearing on the circumstances in which such disclosure will occur.[31]

The case law on actions for breach of confidence and advice of the General Medical Council will be analysed from two perspectives. Firstly, it will be examined to consider how the public interest exception may apply to disclosure of genetic information held in databases.[32] It is submitted that in practice, disclosure of genetic information to family members, reproductive partners, employers and others may be justified in limited circumstances in accordance with the case law. In addition, it is possible that the medical profession will interpret such exceptions more widely than the courts intended, as the General Medical Council guidance indicates.

Secondly, analysis of the case law will demonstrate the interests underlying this area of law. The law is concerned with protecting the interests of expediency in medicine and research rather than individual rights. These powerful interests explain why there are

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[31] Where it is not practicable to seek patient consent or where the patient is not competent, the General Medical Council recommends that it be for the doctor to consider whether the disclosures are justified in the public interest by weighing the benefits to public health against the possible detriment to the patient.

[32] There have been no cases directly in point in the UK. However, as Brahams says, "The law is basically reactive rather than prospective and problems posed by futuristic medico- scientific discoveries are likely to be dealt with by reference to established legal principles and analogies made with decided cases." Diana

numerous and widely drawn exceptions to the principle of confidentiality. They result from the failure of the courts to recognise and protect privacy as a human right and a failure to recognise the importance of self-determination and human dignity. Prior to legislative developments such as the *Human Rights Act 1998* and the *Data Protection Act 1998* (which are discussed below), individuals, relying only on the protection of the common law action for breach of confidence had limited control over their personal and sensitive information.

4.10 Case Law

This section will examine the circumstances in which the case law might justify disclosure of genetic information. One of the primary cases[33] in which the courts considered the circumstances in which disclosure of medical information could be justified in the public interest is *W* v *Egdell*.[34] In this case, W had been convicted of manslaughter on the grounds of diminished responsibility and was diagnosed as suffering from paranoid schizophrenia. He was ordered to be detained in a secure hospital without limit of time. A consultant psychiatrist, Egdell, was asked by W's lawyers to prepare a report on W which they hoped to put before a tribunal asking for W's transfer to a regional secure unit. However, Egdell's report concluded that there were potentially dangerous features of W's personality, which had previously been insufficiently appreciated and explored. As a result, W's application to the tribunal was withdrawn and W's lawyers intended to keep the contents of the report private. Dr Egdell thought that

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Brahams, 'Human Genetic Information, The Legal Implications', in *Human Genetic Information, Science, Law and Ethics*, Ciba Foundation Symposium 149 (Chichester; Wiley, 1990) p111-132 at 111.

[33] Mason and McCall Smith comment that this case crystallised the public interest as applied to medicine. *Supra* note 26 at 171.

his examination had cast new light on W's condition and that it ought to be known by those responsible for W's care and discharge. He sent copies of the confidential report to the medical directors at W's hospital, to the Home Secretary and to the Department of Health and Social Security. W brought an action for breach of confidence against the doctor. The Court of Appeal held that Dr Egdell was entitled to breach confidentiality in circumstances in which non-disclosure posed a real risk of serious harm to a third party even if that third party was unidentifiable.

In the Egdell case, there was a clear danger to the public. If the information had been kept confidential, aspects of W's condition would not have been taken into account by the authorities in making decisions about his discharge and security. Bingham LJ said, "...only the most compelling circumstances could justify a doctor in acting in a way which could injure the immediate interests of his patient as the patient perceives them without consent."[35]

Certain principles can be drawn from this case which can be applied to determine the circumstances in which disclosure of genetic information may be justifiable. It seems clear that in some circumstances it may be permissible to disclose genetic information without consent where this may prevent serious harm to others. For example, disclosure to employers may be justified where serious harm or death may result from failure to take account of a particular genetic condition of an employee. It is more difficult to determine

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34 *W* v *Egdell,* [1990], 1 ALLER 835.

[35] *Ibid at 851j.*

the exact circumstances in which disclosure may be justified since it is often difficult to predict harm and an assessment of the level of harm that justifies disclosure is subjective.

Disclosure for the purpose of preventing or detecting crime would also be justified provided that there was a substantial risk of harm or substantial damage to the public interest if such information was not disclosed. Disclosure to insurers or others would unlikely be justified in accordance with this test as it is difficult to envisage how serious harm could be prevented by such disclosure.

Some commentators have argued that the Egdell case gives authority for the disclosure of confidential genetic information to family members of the proband in order to prevent harm. For example, Ngwena and Chadwick write:

> It is apparent from decided cases that the public interest exception can be invoked to protect an open rather than closed category of interests of which the physical and mental health of an identified individual or class of subjects is but one. What is crucial is the establishment of tangible anticipated harm to a third party. In principle, therefore, the interest in preventing the deleterious effects of genetic disease in a genetically related third party prima facie falls within the public interest exception.[36]

However, the Egdell precedent may be interpreted in an alternative way. Egdell does not necessarily give authority for disclosure to biological relatives of the proband in order to

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[36] Charles Ngwena and Ruth Chadwick 'Genetic Diagnostic Information and the Duty of Confidentiality, Ethics and Law'(1993) *Medical Law International* Vol. 1 pp73-95 at 81.

enable them to prevent or minimise the consequences of genetic disease. There is a significant moral distinction between justifying disclosure of information to prevent harm and justifying disclosure to allow someone to take steps to minimise or prevent the consequences of an existing condition. This can be compared to the distinction between the obligation not to cause harm and the obligation to rescue. In the Egdell case the non-disclosure of information may have resulted in W causing harm to the public whereas a failure to disclose genetic information to a family member would simply not enable the person to prevent or avoid existing harm. This distinction is significant and if this interpretation is correct there may be no authority in law for the disclosure of genetic information in order to prevent harm of genetic disease to biological relatives.[37] In addition, the genetic condition would presumably have to be very serious to come within the parameters of the Egdell case.

In sum, the Egdell case does not necessarily offer authority for the view that disclosure of genetic information can be made to relatives of the proband. However, this practice is authorised by the British Medical Association and as a result it is likely to occur in any

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[37] A number of cases in the USA have addressed this issue. In *Pate* v *Threllsel* 661 So2d 278 (Fla 1995), Florida's supreme court held that a doctor should have warned his patient that one of his relatives might also be at risk of developing the same disease which had a genetic component to it. The doctor did not have a duty to seek out and warn family members, but the case did not address whether the doctor could have informed them contrary to his patient's wishes. An appellate court in New Jersey reached a different conclusion in *Safer* v *Pack* 677 A 2d 1188 (NJ Super Cr App Div 1996). The plaintiff's father was diagnosed with colon cancer in 1956 and the father's doctor's estate was sued because he had not told her that she was at increased risk of developing colon cancer. The court said that if evidence was adduced in the course of the case which indicated that the doctor had been told not to disclose details of illness or genetic risk, the court would have to decide whether confidentiality ought to have been breached in such circumstances. The court obviously thought that it could be overridden in some circumstances. These cases are discussed in Ellen Wright Clayton, "What Should the Law Say About Disclosure of Genetic Information to Relatives Genetic Disclosure to Relatives" (1998) *Journal of Health Care Law and Policy* 373-391 at 383; and Angela Laing, "The Argument Against a Physician's Duty to Warn For Genetic Diseases: The Conflicts Created by *Safer* v *Estate of Pack*" (1998) *Journal of Health Care Law and Policy* Vol 1: 437-453.

event[38] and the courts may be influenced by this practice. Further, disclosure is unlikely to be justified in cases where knowledge of the genetic condition concerned could not reduce or prevent illness or death.

It is possible to perceive the Edgell case as leaving the principle of confidentiality relatively unscathed in that this was an extreme case.[39] However, the case may be used in practice to justify disclosures of confidential genetic information which the courts may not have foreseen or intended.

The British Medical Association's view is that as a general rule genetic information should not be disclosed without consent.[40] If an individual refuses to share information with relatives, after strong encouragement and counselling, this refusal should be respected unless failure to disclose may result in a risk of death or serious harm. In deciding when genetic test results ought to be disclosed to relatives of the proband, the

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[38] The Nuffield Council on Bioethics Report, 'Genetic Screening: Ethical Issues', (Nuffield Council on Bioethics, December 1993), suggested that confidentiality ought not to be absolute where family members are at risk. On the other hand the House of Commons Science and Technology Committee (the Shaw Committee) reported that, "the individual's decision to withhold information should be paramount." *Supra* note 3 at para. 227-228.

39 *Supra* note 26 at 173.

[40] Compare the view of *the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research* which said that disclosure of genetic information without consent was ethically defensible if, (1) reasonable efforts to elicit voluntary consent to disclosure have failed; (2) there is a high probability both that harm will occur if the information is withheld and that the disclosed information is withheld and that the disclosed information will actually be used to avert harm; (3) the harm that identifiable individuals would suffer would be serious; and (4) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and /or treatment of the disease in question is disclosed. *The Ethical, Social and Legal Implications of Genetic Screening,* Counselling and Education Programs 44 (Presidents Commission for the Study of Ethical problems in Medicine and Biomedical and Behavioural Research, Screening and Counselling For Genetic Conditions: 1983).

British Medical Association advise that the following factors should be taken into account[41]:

- the severity of the disorder;
- the level of predictability of the information provided by testing;
- the action that relatives could take to protect themselves or to make informed reproductive decisions, if they were told of the risk;
- the level of harm or benefits of giving and withholding the information; and
- the reason given for the proband refusing to share the information.

Applying these criteria, such disclosure may be permissible, for example, if testing reveals a serious or life-threatening genetic condition for which treatment is available.[42] However, these guidelines are sufficiently broad that they may be interpreted more widely than intended. Ngwena and Chadwick say that the courts have not always employed a risk model to evaluate the probability and magnitude of harm, but the case of *X* v *Y* (discussed below) suggests that judges do appeal implicitly to such considerations[43]. For example, some doctors argue that it is permissible in the public interest to disclose to a patient's sister the chance that she may also carry the BRAC1 gene as she may have an increased chance of developing breast cancer. Breast cancer is a

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[41] These factors are listed in BMA, *Human Genetics, Choice and Responsibility*, (OUP, 1998) at 72.

[42] The Royal College of Physicians have argued that relatives ought to have such information disclosed in some circumstances on the basis that it is their information, "Blood relatives have an interests in knowing the truth which has nothing to do with influencing their behaviour towards affected individuals in their families, but as a necessary means of finding out the truth about themselves." Royal College of Physicians (1991) *Ethical Issues in Clinical Genetics: A Report of a Working Group of the College of Physicians Committees in Ethical Issues in Medicine and Clinical Genetics*, prepared by Janet Radclife Richards with Martin Bobrow, Royal College of Physicians, London, para. 4.19 cited in Ngwena and Chadwick, 'Genetic Diagnostic Information and the Duty of Confidentiality: Ethics and Law',(1993) *Medical Law International* 1(1): 73-95.

[43] *Supra* note 36 at 82.

serious condition. However, if the presence of the BRAC1 gene only indicates a 70% chance of developing breast cancer during lifetime, and there are limited steps which may be taken to minimise its onset some may argue that disclosure to relatives in such circumstances is not justified unless the relative has a higher chance of having a genetic condition which is more easily treatable. Clearly the lines are fuzzy and difficult to draw.[44] The way in which doctors[45] choose to draw these lines is fundamentally important as this will be extremely influential in the standard that is set by which the courts will judge whether a particular disclosure was or was not justified in the public interest.

The British Medical Association also takes the view that disclosure to one's sexual partner may be justified in some circumstances as being in the public interest. This argument is based on the public interest in preventing the birth of children with genetic conditions, or enhancing the reproductive choice of individuals. This appears to be an extremely weak argument since the birth of a child with a genetic condition is unlikely to be equated with a serious risk of harm to the public as in the Egdell case.

In conclusion, the case law demonstrates that prior to the *Human Rights Act 1998*, non-consensual disclosure of genetic information to employers, other parties and in limited circumstances, to relatives of the proband is likely to be justified in order to prevent

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[44] As Beauchamp and Childress argue, even if it is possible to determine on a numerical scale the statistical probability and magnitude of risk, there still remains the problem of deciding objectively what risks are and are not acceptable. See Beauchamp and Childress, *Principles of Biomedical Ethics*, 3rd ed, (New York, OUP 1989) cited in Charles Ngwena and Ruth Chadwick, 'Genetic Diagnostic Information and the Duty of Confidentiality: Ethics and Law'(1993) *Medical Law International* Vol 1 pp 73-95.

[45] Ngwena and Chadwick point out that "Generally speaking, the medical profession and the lay do not always evaluate risks from the same standpoint." *Supra* note 36 at 83.

significant harm. This is in addition, to the other exceptions to the principle of confidentiality set out above.

In the USA, the courts have gone one step further in permitting the disclosure of confidential medical information in the public interest. The case of *Tarasoff* v *Regents of the University of California*[46] held that when a medical professional determines that his patient presents a serious danger of violence to another he incurs an obligation to protect the intended victim against such danger. Justice Tobriner delivered the majority opinion of the California Supreme court, which held that, "[W]hen a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to protect the intended victim against such danger."[47]

This means that in the USA, medical professionals are not only permitted to disclose confidential information where it is in the public interest, they are under a duty to do so. A failure to do so can result in them incurring legal liability and as a result may promote disclosure when not required by law to safeguard against such liability. It is fortunate that the UK courts have not taken this approach since this may seriously undermine patient privacy without substantial justification.[48]

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46 *Tarasoff* v *Regents of University of California*, 551 P 2d 334, 1976.

[47] This was the second time that the case reached the California Supreme court after the American Psychiatric Association filed an amicus curiae brief. In this judgement the duty of the psychiatrist was defined more broadly. This judgement is reported at *Tarasoff* v *Regents of University of California*, 551 P 2d 334, 340, 1976).

[48] But see R D Mackay, 'Dangerous Patients. Third Party Safety and Psychiatrists Duties - Walking the Tarasoff Tightrope',(1990) *Med. Sci. Law* Vol 30, No 1, 52-56 at 56 where it is argued that "in an extreme case, where an identifiable victim's life could clearly have been saved an adventurous court might not be

So far, most of this discussion has focused on the disclosure of identifiable genetic information held in databases. This applies to databases of identifiable information regardless of whether the databases are for clinical, research or other purposes. However, a number of research and other databases would include non–identifiable genetic information or genetic material and in that case, the action for breach of confidence is not relevant.

Kaye and Martin summarise the position for the regulation of research databases:

> Medical research in the UK is governed primarily by a system of regulation through guidelines issued by the Department of Health, the Medical Research Council, and professional bodies such as the royal colleges.....Currently no guidelines relate specifically to population collections. The operational guidance for the UK Biomedical Population Collection has not yet been drafted, although the Medical Research Council's guidelines on the use of biological samples and personal medical information will probably be used as source documents. [49]

A discussion of the system of regulation of research exceeds the scope of this thesis. However, it should be noted that such guides exist.

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deterred from erecting the Tarasoff Tightrope, and imposing a duty to protect upon mental health professionals in appropriate circumstances."

[49] Jane Kaye and Paul Martin, 'Safeguards for research using large scale DNA collections', *BMJ* (2000); 321: 1146-1149 at 1148.

4.11 Evaluation

Three main arguments support the view that the action for breach of confidence only protects confidentiality in so far as it has a functional value. Firstly, the number of vague and widely drawn exceptions to the principle indicates that confidentiality is only protected in so far as it serves the interests of the medical profession in medicine or research. Secondly, the judgements of the courts balance the public interest in protecting confidentiality against the public interest in disclosure rather than the private rights of the individual concerned. Thirdly, the way that the courts in this and other areas of medical law traditionally defer to the medical profession to determine legal standards (most notably the standard of care in medical negligence cases) indicates a disregard for patients' interests in privacy and confidentiality.[50] Each of these arguments will be considered briefly.

Firstly, the principle of confidentiality appears to have a considerable number of fairly elastic and wide-ranging exceptions. Thompson discussing the exceptions says aptly, "what, one might ask, remains of the patient's right if the doctor's discretion is so large?"[51]. The large number of exceptions tends to indicate that confidentiality is not thought of as an important ethical principle. Examination of the exceptions shows that confidentiality it is only protected where it serves a functional value.

Mclean and Maher support this analysis. They argue that the reason for such a significant number of exceptions in law to the principle of confidentiality is that confidentiality has

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[50] There are many examples of this. For example, Doctors and not the individual woman is given the power to decide when a woman is entitled to an abortion according to the terms of the *Abortion Act 1967*.

only been recognised as having instrumental value in assisting the doctor-patient relationship and that the ethical value of privacy, is not given priority by the courts.[52] Thomson has explained this approach by hypothesising that confidentiality is as much concerned with protecting trade secrets as with the individual's interest[53]. He goes on to suggest that, "if it were not in the doctor's own interest to maintain a relationship of confidentiality, one wonders if the reaffirmation of the patient's right to privacy (by the BMA) would amount to more than pious rhetoric."[54]

He argues that the caveats to the principle emphasise the autonomy of the medical profession in deciding what 'the common good' is and stress the doctor's right to independent judgement where the doctor considers it undesirable to seek the patient's consent for his own good. This analysis is interesting because history indicates that the interests of the medical profession in practicing medicine effectively and in protecting 'trade secrets' were at the heart of the development of confidentiality as a principle.

Secondly, it is apparent from case law that the duty of confidentiality arises out of a public interest that confidences be preserved. This is clear from the case of *AG* v *Guardian Newspapers Ltd (No 2)*[55] in the House of Lords where Lord Goff, discussing the public interest justification, said:

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[51] *Supra* note 22 at 58.
52 McLean, SAM and Gerry Maher eds, *Medicine, Morals and the Law*, (Aldershot; Gower 1983) at chapter nine.
[53] *Supra* note 22 at 57 where, discussing the Hippocratic oath, he says, "We should remember that the oath originated in what was an esoteric cult, and the obligations of secrecy were as much concerned with protecting trade secrets and maintaining control over initiates as they were concerned with the patient's interests."
[54] *Supra* note 22 at 58.
[55] [1998] 3ALLER 545 HL.

> [A]lthough the basis of the law's protection of confidence is that there is a public interest that confidences should be protected by the law, nevertheless that public interest may be outweighed by some countervailing public interest which favours disclosure. This limitation may apply as the learned judge pointed out, to all types of confidential information. It is this limiting principle, which may require a court to carry out a balancing operation, weighing the public interest in maintaining confidentiality against a countervailing public interest favouring disclosure.

Therefore, the approach does not balance the private rights of the individual against a public interest in disclosure. Rather the public interest in disclosure is balanced against the public interest in having a legally enforceable duty of confidentiality. A rights approach to privacy is not followed at all.

The public interest in maintaining confidentiality was again referred to in *X* v *Y*[56] which concerned an intentional disclosure to certain newspapers that two doctors who had contracted AIDS, were continuing to practice medicine. Rose J held that confidentiality was necessary in order to secure public and private health. He focused on the practical need for confidentiality since those infected would not come forward for treatment unless confidentiality was secured. He did not consider the rights of the doctors to keep their HIV status private to be paramount, although this was a relevant consideration in the case. The court's decision to prevent publication of HIV status was based on the public interest in encouraging treatment. Again the public interest in preserving confidentiality as a means of expediency was the justification for confidentiality rather than the rights of the individuals to privacy.[57]

A third important argument which illustrates the values underlying the protection of confidentiality of medical information and the extent of the public interest justification is apparent from *W* v *Egdell* which was discussed above[58]. The Egdell case explicitly considered which interests ought to be balanced in determining whether there had been a breach of confidence. The court of first instance had held that the private interests of W in having the information kept confidential had to be balanced against the public interest in disclosure. This decision was overturned, however, by the Court of Appeal. The Court said:

> In so far as the judge referred to the 'private interest' of W, I do not consider that the passage in his judgement accurately stated the position. There are two competing public interests and it is clear by his reference to *X* v *Y* [1988] 2ALLER 648, the judge was fully seized of this point. Of course, W has a private interest, but the duty of confidence owed to him is based on the broader ground of public interest described by Rose J in *X* v *Y*. I do not consider that this

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[56] [1988] 2 ALLER 648 at 653.

[57] The previous chapter highlighted this fact which is embodied in the following quotation by Rose J, "[i]n the long run preservation of confidentiality is the only way of securing public health; otherwise, doctors will be discredited as a source of information , for future individuals will not come forward if doctors are going to squeal on them." *X* v *Y*[1988] 2ALLER 648 at 65 3a-b.

58 *Supra* note 33. See also the cases of *R* v *Crozier*[1990] 8 BMLR 128 and *Re C* [1991] 7BMLR 138. Both consider the public interest which justifies breaching individual patient confidentiality. Re C concerned contested adoption proceedings whereby the biological mother's doctor disclosed confidential information relevant to her suitability as a parent. The Court of Appeal held that such a disclosure was justified in the public interest since it enabled the court to make a proper decision as to what was in the child's best interests. In *R* v *Crozier*, a breach of confidence was held to be justified in the public interest when a psychiatric report was disclosed to the prosecution and court during sentencing, since the report revealed that the patient was mentally ill and constituted a danger to the public.

> is a case of legal professional privilege although it is, however, relevant as part of the background which gave rise to the issue of confidentiality.[59]

It is clear that the courts did not apply a rights approach in coming to their decision. The third argument which supports the view that confidentiality is protected mainly for its functional value is that confidentiality is typical of many areas of medical law where the courts defer to the medical profession to set the standards for law, instead of adopting a rights based approach.

The Source Informatics case discussed above[60] reinforces the view that, prior to the *Human Rights Act 1998*, the courts failed to protect confidentiality out of a recognition of the importance of patients' rights. This is illustrated by the reasoning of the Court of Appeal in holding that the appropriate test for determining a breach of confidence was whether the conscience of the pharmacist was troubled by the scheme. Grubb criticised the court's approach as flawed because " the issue turns on the scope of the patient's interests and not as the Court of Appeal thought, the "conscience' of the reasonable pharmacist."[61] Grubb is correct to assert that it is the patients' interests that ought to determine whether it is appropriate for the information to be used in a particular way. This approach is typical of the way that courts tend to defer to medical or health care professionals in determining what the law should say about a particular issue in medical law. Instead they ought to define what is appropriate in light of the patient's rights and interests.

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[59] *Supra* note 34 per Sir Stephen Brown at p846.
[60] *Supra note 12.*

In order to safeguard privacy it is necessary to balance the rights of the patients over their information with other interests including those of society. Where the rights of the patients do not even feature in the equation, such as in the *Source Informatics case*, the medical profession's standards are given significant if not determinative weight and information is likely to be disclosed and used in whatever circumstances the medical profession considers appropriate. When applied to databases of genetic information there is no guarantee that individuals' rights will be given due consideration.

Another example of the courts failing to adopt a rights approach is the authoritative test laid down by the courts in setting the standard of care in relation to medical negligence. This test states that a doctor is not negligent if he acted, "in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular area."[62] This approach, described as the *Bolam* test, indicates a lack of respect for individual rights since the medical profession is entrusted to determine what standard of practice constitutes negligence. The law simply endorses current medical practice and leaves itself little room to set or improve standards by holding that current practice falls short of what is required by law.[63]

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[61] *Supra* note 4 at p118.

[62] *Bolam* v *Friern HMC* [1957] 1WLR 582, 587-8. For a discussion of the standard of care see Margaret Brazier, *Medicine, Patients and the Law* (Penguin Books, 1992) at chapter 6.

[63] But see the discussion of developments in the common law since Bolam. It is argued by M Brazier and J Miola in 'Bye-Bye Bolam: A Medical Litigation Revolution', (2000) 8 Med. L. Rev. 85-114 that a House of Lords Judgement, *Bolitho* v *City & Hackney HA*, 1998, AC 232 HL, will limit the deference paid to the medical profession. Brazier and Miolo say at 114, "The decision does, however, signal judicial deference will, at the highest level, to return Bolam to its proper context." This case accepted that the standards of the medical profession could determine how much information requires to be disclosed to a patient to avoid a claim of negligence, instead of considering how much information ought to be disclosed from the viewpoint of patients' rights. The House of Lords endorsed the Bolam test in determining how much

Ngwena and Chadwick accept that it is the prevailing custom of the medical profession that will determine the extent to which confidentiality is respected in genetics. They say,

> In so far as ascertaining the legal standards, however, much will depend on the prevailing custom of the geneticist. Courts do not require mathematical accuracy in the exercise of clinical discretion. The crucial consideration is whether a particular practice has the confidence of the profession or a section of it.....Although the courts have reiterated the point that ultimately it is for the law rather than the medical profession to set the requisite standard, decided cases demonstrate not only consistent but also a remarkable judicial deference towards standards set by the profession. [64]

4.12 Conclusion

This chapter first of all outlined the extent of the action for breach of confidence and also some of its limitations, when applied to genetic databases. Secondly, it discussed the number of exceptions to the principle of confidentiality that are permitted in law, discussed the public interest exception in considerable detail, and examined how this may be applied to allow genetic information to be disclosed to certain parties without consent.

It was argued that the common law action for breach of confidence, which forms one major part of the law with regard to genetic privacy, does not protect confidentiality or privacy out of a recognition of their importance as rights. In addition, a rights model is

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information ought to be disclosed to a patient in order to make an informed decision about treatment in the case of *Sidaway* v *Bethlem Royal Hospital Governors and others* [1985] 1ALLER 643 HL.

not adopted in the approach of the courts, which appear to defer considerably to the medical profession in making and interpreting the law. This resulted in a law that was full of exceptions. Further, the law of breach of confidence was premised on a relationship of sorts since it had to be established that one party had imported an obligation of confidence on another. This mode of law does not adequately regulate confidentiality with regard to genetic databases where such a relationship may not exist. Neither does this law recognise the familial nature of genetic information.

Why is it problematic to defer to the medical profession in deciding the circumstances in which confidentiality can be breached? In the context of genetics, the ethical issues involved in determining when such information ought to be disclosed are extremely complex and it may be argued, therefore, that the medical profession with its experience in such areas is in the best position to decide such matters. Why do rights need to feature in the determination of the law at all?

Orentlicher has made a similar argument in the context of genetic privacy. He says, "The genetic privacy of patients can be protected by effective enforcement of professional ethical standards", and that "the medical profession can do much to preserve the genetic privacy of patients; it merely needs to use its existing powers effectively."[65]

This view of the medical profession as adequately protecting patients' rights by a process of self-regulation is flawed. Although the medical profession could do much to secure

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64 *Supra* note 36 at 84.

patients' privacy, it is not an appropriate mechanism to protect rights including the right to privacy. This is properly the function of law. Importantly, reliance on the medical profession leaves individuals without any means of enforcing their rights if they are breached.[66] Moreover the medical profession will tend to respect confidentiality and privacy only where this serves some useful function in medicine and research.

John Harvard, Secretary of the British Medical Association wrote about confidentiality in 1985 that, "No longer can these questions be answered by referring to Hippocrates. They have to be answered by rational argument appropriate to the second half of the 20th Century, and they must take full account of the recent developments which threaten the doctor patient relationship."[67] This point still applies today.

Rights require to be protected and balanced against other interests. It is for this reason that this thesis has set out an alternative approach for the law to take. That of the modified rights approach discussed in earlier chapters. It is trite to say that the issues raised by the genetic revolution require careful thought and analysis. Such matters cannot be left to outdated tradition, or the medical profession's codes of practice. By adopting a modified rights approach, the law would succeed in ensuring that rights were

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[65] David Orentlicher, 'Genetic Privacy in the Patient- Physician Relationship', in M A Rothstein, *Genetic Secrets, Protecting Privacy and Confidentiality in the Genetic Era*, (Yale UP, 1997) 77-91 at 88.

[66] The tradition of entrusting the medical profession with protecting the interests of patients may be influenced by a change in the public's perception of the medical profession. Kaye and Martin write that, "Public trust in the medical profession and the conduct of medical research has been seriously eroded in the wake of events at Bristol Royal Infirmary, Alder Hey and Staffordshire Hospital and the scandals caused by Harold Shipman and other doctors recently struck off for malpractice. Although the characteristics of these cases differ from each other, the cases have become joined in the public mind, leading to sustained criticism of the system of professional self-regulation centred on the General Medical Council. This criticism has even come from within the profession itself, most notably from the BMA." *Supra* note 49 at 1146.

respected whilst allowing room for debate on the circumstances in which rights ought to be limited or overridden by some other interests.

The next chapter will consider the impact of the *Data Protection Act 1998* and the *Human Rights Act 1998* on the law and it will be argued that these two pieces of legislation signal a change of approach in the law, which appears to be moving towards the recognition of the importance of rights. It is to be hoped that the modified rights approach argued for in earlier chapters ought to influence this transition.

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67 John Harvard, 'Medical Confidence', (1985) *Journal of Medical Ethics* 11, 8-11 at 11.

Chapter Five

The *Data Protection Act 1998* and the *Human Rights Act 1998*

– The Right(s) Approach to Genetic Privacy?

5.1 Introduction

The discussion in the previous chapter has argued that the common law has traditionally deferred to the medical profession to set the limits of the circumstances in which confidentiality is and is not protected and, that the law has failed to adopt a rights approach to adequately recognise or protect patients' rights in general and a right to genetic privacy in particular. This resulted in a law of confidentiality that was piecemeal, ambiguous, and riddled with exceptions. Central to the law of medical confidentiality was the relationship between doctor and patient and as a result, this law was inadequate and ill equipped to deal with the challenges faced by the genetic revolution and by large-scale genetic databases, which are not always centred on relationships of that sort. Further, it was argued that it is preferable for the law to adopt a modified rights approach to genetic privacy and that a right to privacy ought to be balanced against social and other interests, rather than to follow the approach that had been taken by the common law.

This chapter will first of all consider two major pieces of legislation that also impact upon genetic privacy law. It will be argued that the influence of European Union law through the *Data Protection Directive*, imported into domestic law by the *Data*

Protection Act 1998, has strengthened rights of individuals to informational privacy. This legislation signals a new approach to the protection of privacy since it recognises privacy as something inherently valuable. It will be argued that this legislation, and the *Data Protection Principles* contained therein have the potential to significantly enhance privacy protection. However, there are certain undesirable exceptions to the *Data Protection Principles* contained in the *Act*, and some of these appear to conflict with the underlying ethos of the legislation.

This chapter will go on to consider the *Human Rights Act 1998* and in particular the right to respect for private and family life of the *European Convention on Human Rights* which is now directly enforceable in the domestic courts. It will examine how this right may be interpreted by the courts in relation to genetic information by considering some case law from the European Court of Human Rights in Strasbourg and some of the cases that have been brought so far in the domestic courts. It will argue that the *Human Rights Act* together with the *Data Protection Act 1998*, have the potential to bring about a sea change in the approach of the law towards the protection of genetic privacy. The extent of this change will depend to a great extent, on the willingness of the judiciary to adopt a rights jurisprudence in the interpretation and application of the *European Convention on Human Rights.* With regard to the regulation of genetic databases in particular, it is hoped that the courts will adopt a modified rights approach in the interpretation and development of laws in this area, respecting the rights of the individual whilst bearing in mind other social goods that justify privacy rights being overridden.

5.2 Data Protection Legislation

One important area of law that impacts upon privacy and control of data is the *Data Protection Act 1998*, which implements the *European Union Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data* ("*the Data Protection Directive 1995*").[1] This *Act* gives individuals a significant degree of control over the processing of their personal data.[2] The *Act* is much wider in its impact than the common law action for breach of confidence in that it regulates the processing of all personal data. The ideological underpinning of the *Act* is out of recognition of the need to protect individual rights and in particular the right to privacy. The *Data Protection Act* recognises the importance of giving individuals a significant degree of control over, not only who has access to their data but also over what happens to it. This is wholly at odds with the approach that the common law of the UK had taken to privacy and confidentiality and the *Act* signalled a change in direction and significant strengthening of privacy protection in the law. The *Data Protection Principles*, which form the core of the *Act*, will be explored below. First of all, it is interesting to note where this change in approach of the law came from.

The *Directive* was enacted out of recognition of the need for "Member States to protect the fundamental rights and freedoms of natural persons, in particular their right to privacy with respect to the processing of personal data."[3] The influence underlying the *European Directive* was the 1980 Organisation for Economic and Cultural Development (OECD)

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[1] *Directive 95/46/EC.*

[2] For a comparative analysis of Data Protection and Privacy regulation as it applies to genetic information, see Deborah Crosby, *Protection of Genetic Information: An International Comparison*, (Human Genetics Commission, 2001). Online Human Genetics Commission at ,*www.hgc.gov.uk*> at 51-79.

"Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data" which conceived the fundamental principles of data protection.[4] The principles contained in that document were then embodied in the 1981 Council of Europe "Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data" which was then ratified by 20 nations and which now forms the core of the Data Protection Directive. The *Data Protection Act* implements these provisions into domestic law.

The preamble to the *Act* describes it as, "An Act to make new provision for the regulation of the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information." It is concerned with ensuring that individuals have a significant degree of control over processing, storage, transfer and access to data, which relates to them and also tries to ensure that data is accurate and not kept for longer than is necessary. This legislation arose out of a recognition of the need to protect informational privacy[5] and for uniform standards to be adopted in the memberstates of the European Union in order to protect these rights.

(a) Personal Data

The *Act* sets out a number of data protection principles that apply to the processing of personal data in general and other more stringent provisions that apply to the processing

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[3] From the preamble of the *Directive 95/46/EC.*

[4] See the Organisation for Economic Co-operation and Development, 'Working Party on Biotechnology, Health Policy Brief, Data Protection in Transborder Flows of Health Research Data', (OECD, 13 Dec 1999).

[5] The General Medical Council's Guidance, *Confidentiality: Protecting and Providing Information* (General Medical Council, Sept 2000) seeks to comply with the Act. Online: General Medical Council at

of sensitive personal data. The ambit of the *Act* is extremely wide reaching since the provisions apply both to information held on computer and to information held in manual files, and because the definition of personal data is broad. Genetic information comes within the definition of personal data if the data controller can link it to an identifiable living person taking account of information that the data controller has or is likely to come into possession of.[6] Importantly, in circumstances where genetic data could be linked to a named individual, for example, if the information and technology are available to identify someone by DNA analysis, then the *Act* will cover even data described as anonymous. However, the *Act* does not apply to genetic material, until it has become genetic information by some means.

The fact that the provisions in the act apply to all personal data, and that there is no requirement for such information to have been imparted under an obligation of confidence is also a significant distinction from the action for breach of confidence. Therefore there is no need for the establishment of any particular relationship, or confidential undertaking in order for the provisions of the *Act* to apply. Anyone who intends to process personal data is bound by the *Act's* provisions.

For example, in the context of genetic databases, all data is covered, and all individuals have a level of control over such data regardless of their relationship with the holder of the information. For example, if someone has sufficient information in their possession (about family relationships for example) to link data held in a database to them, even

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<http://www.gmc-uk.org/standards/secret.htm>. See B Mahendra, "Medical Disclosure and Confidentiality", (2001) *New Law Journal* Vol. 151 No 6966 p10.

although the data was derived from someone else, there is a presumption (unless one of the exceptions is relevant) that all parties who may be affected by disclosure of such data must consent to it being processed.

(b) The *Data Protection Principles*

The *Data Protection Principles* are set out in schedule one of the *Act*. It should be noted however, that there are a number of detailed and specific exceptions to certain of the principles. These will be considered below. The principles are as follows:

- personal data should be processed fairly[7] and lawfully.

- Data has to be obtained only for one or more specified and lawful purposes, and cannot be further processed in any manner incompatible with that purpose or those purposes.

Genetic information must not generally be taken for one purpose and used for another (unless one of the exceptions discussed below applies). In the context of research, such provision may lead to genetic information and not being able to be used in circumstances

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6 See s1 of the *Data Protection Act 1998*.

7 It has been said that the processing of genetic data may also raise some fundamental problems of making the processing fair to individuals since it is questionable whether individuals understand the implications of genetics sufficiently well to allow them to make informed decisions about whether to take a genetic test or to disclose its results. Iain Bourne, Compliance Manager (Health), Office of the Data Protection Commissioner, Written Evidence submitted to the Select Committee on Science and Technology of the House of Lords Enquiry into Genetic Databases. *Select Committee on Science and Technology Written Evidence (House of Lords Select Committee on Science and Technology, 2000) hereinafter House of Lords Written Evidence, at 1, online: House of Lords Select Committee* < *www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/115/115we02.htm*>.

in which individuals would not have objected to its use.[8] On the other hand, this provision may simply lead to all encompassing descriptions in consent forms that include all sorts of research. If this provision is commonly evaded by standard and widely drawn descriptions of the uses to which genetic information and material may conceivably be put, this provision will fail to enhance the individual's control over his or her information.[9]

- Personal data is required to be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.

This means that unnecessary information should not be requested from the data subject or stored in databases. In a research project, knowing in advance what information will be necessary may be difficult depending on the type of research to be conducted. Some research takes place on the basis that researchers try to correlate the presence of certain genes with other factors such as information about health, lifestyle and behaviour. They may not know exactly what information may be relevant. However, a common sense interpretation of this provision ought to minimise the keeping of unnecessary

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[8] The Medical Research Council suggests that in respect of historical collections of genetic material, it will be legitimate to use them, if consent cannot be obtained, and if samples have been coded or anonymised and there is no potential harm for the donors of the material, either individually or as a group. House of Lords Evidence *ibid.*

[9] In the context of post mortem use of tissue, this type of practice occurred when standard consent forms were developed which did not give relatives of the deceased any real choice about the sort of research to be carried out. This approach was subsequently subject to substantial criticism. See the Gillam Elam, "Consent to Organ and Tissue Retention at Post Mortem Examination and Disposal of Human Materials", (Health Service Directorate, December 2000) at p6 where the drawbacks of the consent forms, in use were said not to provide relatives with an opportunity to limit the nature of the examination nor did they indicate to relatives that they could choose not to agree to retention of organs for uses other than diagnosis.

information, whilst ensuring sufficient information is available for medical and research purposes.

- Personal data is required to be accurate and, where necessary, kept up to date.
- Personal data processed for any purpose or purposes is not to be kept for longer than is necessary for that purpose or those purposes.

This provision does not apply where the data is processed, only for research purposes. Where this provision does apply, genetic data that is no longer required for the original purpose ought to be removed from the database. This provision can be important for securing privacy and encouraging individuals to consent to their information being held on databases. It reduces the chance of security breaches that may threaten privacy and will limit the likelihood of information being used for secondary purposes without consent, or substantial justification.

- Personal data is to be processed in accordance with the rights of data subjects under this *Act*.
- Appropriate technical and organisational measures are to be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

Therefore, adequate security measures are required to be put in place in databases to reduce the chances of unauthorised access to genetic information.

- Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.[10]

This provision will restrict the practice of databases being stored abroad in order to circumvent privacy regulations.

(c) Conditions For Processing Personal Data

The central tenet of the *Act* is that consent must be obtained for any processing of personal data unless one of the conditions set out in schedule two of the *Act* apply. The *Act* begins with an assumption that the data subject ought to be able to control his or her personal data unless one of the defined exceptions applies.[11] This recognises the importance of individuals having control over their information and does not simply

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[10] Currently the data protection laws of Switzerland and Hungary have been approved so that data transfers can be made there without breaching this principle and a review of Canada's privacy laws is being undertaken to determine whether they have given sufficient protection for data to be transferred there.

[11] The conditions in schedule two of the Act include: where the processing is necessary for the performance of a contract to which the data subject is a party; where processing is necessary for compliance with any legal obligation to which the data controller is subject; where the processing is necessary in order to protect the vital interests of the data subject; where the processing is necessary for the administration of justice; for the exercise of any functions conferred in any person under any enactment; for the exercise of any functions of the Crown, for the exercise of any other functions of a public nature exercised in the public interest by any person; where the processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject (the Secretary of State can specify conditions relating to this exception). Schedule two of the *Data Protection Act 1998.*

target inappropriate uses of certain information.

These exceptions will not be considered in detail since processing of most genetic information requires one of these conditions plus a further condition laid out in schedule three of the *Act* to be satisfied before it can be processed without consent. This is because most genetic information would be classified as sensitive personal information,[12]which includes data consisting of information as to the racial or ethnic origin of the data subject[13] or his physical or mental health or condition.[14]

(d) Sensitive Personal Data

Sensitive data can only be processed under stringent conditions, which normally requires the express consent of an individual (as opposed to being able to imply consent). If data is to be processed without express consent, one of the following conditions in schedule three must apply.[15]

Schedule three includes, where disclosure is necessary:

- For employment purposes;
- In the vital interests of the subject, or of another person where consent cannot reasonably be obtained;

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[12] Defined in *section 2 of the 1998 Act*. See also the detailed regulation in the *Data Protection (Processing of Sensitive Personal Data) Order 2000 (SI 2000/417)*.

[13] *s2(a) of the Data Protection Act 1998.*

[14] *s2(e) of the Data Protection Act 1998.*

[15] Lawful disclosure of personal medical data can be made if one condition in schedule 2 of the Act applies together with one from schedule 3 as amended by *Data Protection (Processing of Sensitive Personal Data) Order 2000 SI 2000 417.*

- For the exercise of functions of a government department or functions of a public nature exercised in the public interest by any person;
- If the information contained in the personal data has been made public as a result of steps deliberately taken by the data subject.
- If processing is necessary for the purpose of, or in connection with, any legal proceedings (including prospective legal proceedings)
- For medical purposes, (which includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services provided that the processing is undertaken by a medical professional or someone subject to the same duty of confidence as a medical professional;
- For the detection or prevention of crime in the public interest;
- To protect members of the public against dishonesty, malpractice, or incompetence;
- To enable confidential counselling;
- For insurance and pension purposes.

Some of these exceptions do appear to run contrary to the aim of the *Act*, which is to enhance autonomy and privacy. However, some of these exceptions are necessary in order to allow medicine and research to work in practice. Further, although it is acknowledged that it may be necessary in some cases for other interests such as the detection of crime to outweigh privacy rights, one exception in particular warrants some comment as it appears to undermine privacy without substantial justification.

The exception relating to medical purposes is fairly widely drawn and the fact that a medical professional is processing the data is seen to justify non-consensual processing of the data. The same deference to the medical profession that could be seen in the common law of confidentiality appears in the law through this exception. Although it may not be practical to seek express consent to all processing of medical information and a certain degree of consent could be implied for processing of medical information required in relation to the patient's treatment, it is not necessarily the case that a patient would consent to his or her information being used for research or other purposes. Consent to separate uses of information ought to be required, except in cases whereby the benefit to the community in terms of public health or otherwise is thought to override the importance of privacy. In such cases, the power of deciding whether information should be used ought to be in the hands of an independent body. A proposal for such a body will be discussed in chapter six.

In sum, this change in approach which is based on a recognition of rights is an improvement to the common law position. The *Data Protection Principles* set out good information practices, which give an individual a significant degree of control over data that relates to him or her. This endorses a notion of privacy which not only prohibits others from having access to one's data, but enables the individual to control what happens to it. Information is in some sense seen in a similar light to property. This concept of privacy is limited by some of the exceptions which have been briefly mentioned. These may require to be reconsidered in light of the values which underlie this legislation. The *Data Protection Act* also appears to reaffirm the importance of a modified rights approach which recognises the legitimate interests of the community in having access to certain information. The extent to which it balances the rights of the proband against these other interests requires to be reconsidered in some cases.

(e) Access By The Data Subject

The *Data Protection Act 1998* also gives the data subject the right to gain access to personal data of which he is the subject.[16] Typically this will involve supplying an individual with copies of records relating to him when asked to do so. Knowing what information is being held about oneself is vital to exercising privacy and control over one's information. A 'health record' is defined in the *1998 Act* as being any record which consists of information relating to the physical or mental health or condition of an individual, and has been made by or on behalf of a health professional in connection with the care of that individual and it includes manual and automated records. Therefore individuals have a right to access genetic information held on databases when the information was obtained during their treatment. An important exception to this is that an individual may be precluded from accessing medical information if in the opinion of a health professional, disclosure would cause physical or mental harm to the individual or would breach the confidence of third parties. Although it is understandable that where another's confidence may be threatened by a disclosure, this may limit the extent to which an individual may access his or her records, (and this provision may have

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[16] See section 7 of the *Act* and the *Data Protection (Subject Access Modification) (Health) Order 2000 (SI 2000/413)*. The right to access of health records relating to deceased individuals is provided for in the *Access to Health Records Act 1990.*

particular importance for genetic information)[17] it is more difficult to justify the exception that denies an individual access to his or her own information on the basis that it may cause harm to him or herself.

Gannon and Villiers also make this point:

> Despite these improvements to the law, there are still criticisms to be made. For example, in the context of heath care an individual may be precluded from accessing his or her medical information if in the opinion of a health professional, disclosure would cause physical or mental harm to the individual or would breach the confidence of other parties. [18]

Again, this appears to be medical paternalism creeping into the law. The result is to seriously threaten privacy. Not only is the individual prevented from deciding who else ought to have access to his or her information, since he or she can not make a proper determination of this without knowing the content of his medical record, he or she is not entitled to know such information him or herself. Individuals can make requests for information held in research databases but a number of exceptions may also apply to prevent access in certain circumstances.

(f) Evaluation of the *Data Protection Act*

In sum, the *Data Protection Act* complements and strengthens the law's protection of personal data by requiring individuals to consent to the processing of their personal data

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[17] Therefore, it is likely that family members will not be able to access data derived from the proband.

unless one of the exceptions apply. This entrenches informational privacy in law out of a recognition of the importance of rights and prevents others from having access to data. In addition, the *Act* recognises that privacy rights must be weighed alongside other community interests. However, some of the exceptions to the principles infringe autonomy and privacy, without substantial justification and re-examination of these exceptions is therefore required.

The *Data Protection Principles* set good practice for the storage and processing of personal data and any databases of genetic information would have to comply with these. The principles are quite general in their terms and the way in which they are interpreted by the courts will have a bearing on the extent to which they safeguard privacy. Further detailed guidance, or codes of practice would be helpful in order to determine how these principles apply to genetic databases in particular. However, the principles only apply to databases of actual information and not to tissue banks from which it is possible to derive such information.

One further point should be made in relation to the *Data Protection Act 1998*. The *Act* requires to be interpreted in accordance with the *Human Rights Act 1998* and therefore, the exceptions discussed may be subject to challenge if they are considered to infringe upon the right to respect for private and family life unnecessarily[19] or if they are found to

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[18] Phillipa Gannon and Charlotte Villiers, 'Genetic Testing and Employee Protection', (1999) *Medical Law International* Vol 4 pp39-57 at 51.

[19] Halford for example has argued that challenges under article 8 of the Convention will be critical in relation to health information since there are a number of situations not covered by the *Data Protection Act 1998* where rights of access to personal records are lacking. See John Halford, "Doctoring the Law", *Law Society's Guardian Gazette*, Vol 97, No 30 p32.

be incompatible with other rights. Moreover, if any exceptions are seen to be incompatible with the right to respect for private and family life, the courts may issue a declaration of incompatibility, which can lead to a fast track procedure amending the legislation. In practice, therefore, the provisions of the legislation can no longer be read in isolation.

(g) Future Changes

Certain legislation has been proposed that if enacted would also impact on genetic databases. *C.59 of the Health and Social Care Bill*, would limit patient privacy and, in particular, confidentiality by allowing disclosure of medical information without consent in even more circumstances than those already provided for in the *Data Protection Act*.

Clause 59(4), of the bill says that an order may require the disclosure of patient information to other parties without the patient's consent, may specify the persons to whom information must be disclosed and the manner of the disclosure, and may remove any obligation of confidence that might otherwise be breached. Patient consent would not be required for information to be used for research or other purposes when the same result cannot practicably be achieved by other means.[20] The Data Protection Commissioner[21] takes the view that it would generally be possible to obtain consent for processing medical data for research purposes, so in the majority of cases consent still would have to be obtained.

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[20] *c.59(5)* Specifies that regulations under *c.59(3)* in respect of confidential information may not be made where "it would be reasonably practicable", having regard to the cost and available technology, to proceed by less coercive means.

[21] Now the Information Commissioner. Online at <*www.dataprotection.gov.uk*>.

One commentator discusses these changes with some justified scepticism:

> Not content with the wide discretion given to the NHS by the *Data Protection Act*, the Secretary of State for Health now intends to use provisions in proposed legislation currently before Parliament to give himself powers to override the common law and extend the range of circumstances in which medical records and personal identifiable information from them can be divulged both within and beyond the NHS.[22]

It is not clear why it is thought to be necessary to further widen the exceptions outlined in the *Data Protection Act*. This provision would further erode the privacy of individuals and take the control of their information further out of their hands, without substantial justification. In response to this provision, the Data Protection Commissioner recommended that:

> [I]ndividuals should be given the right to object to the use of their data for research purposes where the individual objects to the purpose of that research. For instance, someone may have strong moral objections to genetic research and it would seem fair that a person should be able to object to the use of his or her information for such research.[23]

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[22] Marion Chester, Law Society Gazette (8 February 2001) Vol. 98 No 06 p 50. Chester also suggests that a challenge under article 8 of the Convention may be one means of preventing government powers from enabling records to be used without our consent.

[23] Comment on *c59 of the Health and Social Care Bill.* This is available on the website of the Data Protection, now " Information Commissioner", http://wood.ccta.gov.uk/dpr/dpdoc.nsf

The social interests in having certain research conducted may be said to outweigh the privacy interests of the individual in some cases. However, one might object to the use of one's information for certain types of genetic research and such objection may be justifiable unless some other pressing need outweighs such considerations. A preferable mode of balancing such interests is discussed in chapter six.

5.3 The *Human Rights Act 1998*

The final and arguably the most significant area of law to be considered which impacts upon genetic privacy is the *Human Rights Act 1998* [24] ("HRA"), which was passed in the UK on 2nd October 2000 marking a new era of human rights jurisprudence in the law.[25] The implementation of this *Act* means that the *European Convention on Human Rights* ("the Convention") is now directly enforceable by the domestic courts in the UK for the first time. This was a result of the Labour Government's commitment when it took office in 1997, of implementing the policy of "Bringing Human Rights Home."[26] The *Human Rights Act* will better safeguard the Convention rights and freedoms by making them more accessible[27] and giving the UK what is essentially a Bill of Rights.[28]

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[24] The *Human Rights Act 1998* came into force by the *Human Rights Act 1998 (Commencement No 2) Order 2000* which was signed by the Home Secretary on July 12 2000.

[25] It should be noted that the Convention has had an impact in Scotland from the date of the passing of the *Scotland Act 1998 s 1(1)* of which declared that "there shall be a Scottish Parliament" in that the Scottish Parliament and Scottish Executive are required by that Act to give effect to the Convention Rights and that anything done by them that is incompatible with Convention rights is beyond their competence. Therefore any legislation that is incompatible with the Convention rights could be set aside.

[26] Lord Hope of Craighead, "Human Rights – Where Are We Now?" (2000) *European Human Rights Law Review*, Issue 5, 439 at 442.

[27] "The main purpose of incorporating the Convention into UK law would be to make available a Bill of Rights that could be accessed more speedily, more cheaply and more easily than is now the case." Michael Zander, writing before the passage of the HRA in 'A Bill of Rights for the United Kingdom – Now', (1997) 32 *Tex Int'l L.J.* 441 at 442.

[28] The White Paper "Rights Brought Home: the Human Rights Bill" set out the rationale for incorporation of the Convention. This is to "give people in the United Kingdom opportunities to enforce their rights under the European Convention in British courts rather than having to incur the cost and delay of taking a

The Convention, which is a proclamation of civil and political rights with limitations and balancing safeguards, became the first convention signed under the Council of Europe that was founded after Second World War. Although the UK ratified the Convention in 1951, it was not adopted directly into the law of the UK, which is a necessary step in order for a treaty to have domestic effect. This meant that prior to the *Human Rights Act*, anyone seeking to enforce their Convention rights had firstly to exhaust all remedies in the UK domestic courts which could apply only domestic laws[29] before taking the case to the European Court of Human Rights in Strasbourg. If a case did reach Strasbourg and a petitioner received a favourable opinion, the UK was required to change its practices in order to implement the decision of the Court. This involved a considerable amount of time and money and in reality meant that those without sufficient resources or determination had no means of asserting their Convention rights. Now that the Convention forms part of UK law, the rights, which it safeguards, have real and not just theoretical value.

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case to the European Human Rights Commission and Court in Strasbourg. It will enhance the awareness of human rights in our society", Tony Blair, Rights Brought Home: The Human Rights Bill, 1997 Cmnd 3782.

[29] Prior to the *Human Rights Act*, the Convention had another means of influencing UK law in that the courts occasionally referred to it where language in a statute was unclear. Statutes were to be interpreted in accordance with the obligations under the Convention, and where the common law was unclear. In the case of *R v Secretary of State, ex p Brind*, [1991] 1 AC 696, 747H-748A for example, Lord Bridge said that the courts would presume that Parliament intended to legislate in conformity with the Convention and not in conflict with it. This approach was followed in Scotland in *T Petitioner* (1997), SLT 724. In the case of *Derbyshire Country Council v Times Newspapers Ltd* 919920 QB 770, 830B-C, Butler Sloss LJ, said that the Convention could be taken into account by the courts where the common law was uncertain unclear or incomplete. However, Jim Murdoch noted that prior to the Human Rights Act "The Convention has had little use in the domestic courts of Scotland, either as a tool for development the common law or as an aid in the interpretation of statute, in marked contrast to the position adopted by courts in England and Wales." See Jim Murdoch, "Scotland and the Convention", in Brice Dickson ed, *Human Rights and the European Convention*" (Sweet and Maxwell, 1997).

(a) Right to Respect for Private and Family Life

Section 1 of the *Human Rights Act* lists the Convention rights incorporated into UK law.[30] The most relevant provision of the Convention which relates to genetic privacy is Article 8, the Right to Respect for Private and Family Life[31], although other rights will be relevant where they conflict with or have to be balanced against it.[32] The wording of the Convention right is as follows:

> Article 8 Right To Respect For Private And Family Life
>
> 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.

The wording of the right is by its very nature wide, and paradoxically, there are many ways in which it could be invoked to either prevent others gaining access to genetic information or to argue for access to genetic information derived from others. This right can be invoked to argue that one has a right to privacy over one's genetic information. Article 8 may also be used in support of the argument that someone has a right not to

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[30] The actual Articles of the Convention are set out in schedule one of the *Human Rights Act 1998*.

[31] The extent of the right is set out in Article 8(1) and the limitations of the right are set out in Article 8(2).

[32] The Right to Privacy may often come into conflict with Article 10 – Freedom of Expression or others.

know their genetic heritage, [33] or even that they have a right to access genetic information derived from testing someone else but which relates to them.[34]

The right to private and family life is not an absolute right, and article 8(2) sets out the circumstances in which the right can be interfered with. Interference with the right can be justified if it is in accordance with the law and is necessary in a democratic society in the interests of one of the factors listed in Article 8(2). Although these exceptions appear at first glance to cut away much of the substance of the right[35], the right may still have considerable force. It should be noted that the scope of the rights in the Convention are extremely widely interpreted whilst the exceptions are narrowly construed. In the case of *Lustig -Prean & Beckett v United Kingdom*[36], the European Court of European Rights observed that, interference in the privacy rights protected by the Convention could be justified as necessary in a democratic society only if it addressed a pressing social need and if the restrictions were proportionate to the legitimate aim pursued. It also went on to

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[33] This point was made in *Human Genetics Commission, 'Whose Hands on Your Genes? A discussion document on the storage, protection and use of personal genetic information', (UK: Human Genetics Commission, 2000) at 19. Online: Human Geentics Commission at <www.hgc.gov.uk>.*

[34] An article in the Guardian Newspaper recently reported that a challenge was being mounted on the basis of Article 8 of the Convention by people conceived through donor sperm insemination who are arguing that a law which refuses them access to information about their biological father breaches their right to private and family life. It is possible to conceive of challenges to confidentiality laws that refuse children the right to have DNA tested to establish or refute paternity. See Claire Dyer "Call to Identify Sperm Donor in Human Rights Test Case" (The Guardian, 11th Sept, 2000).

[35] Indeed, Foster argues "the flurry of caveats in clause (2) means that the Article is unlikely to have much effect on the development of the domestic law of genetic confidentiality." Charles Foster, "Confidentiality and Genetic Information", (Sept/ Oct 2000) *Genetics Law Monitor,* Vol. 1 Issue 2.

[36] *Lustig-Prean & Beckett v United Kingdom*, Applications 31417/96 & 32377/96, *Smith and Grady v United Kingdom* Applications 33985/96 & 339896/96, ECHR Sept 27, 1999 and see comment Rhona K M Smith, ed Bernard H Oxman, "*International Decision: Lustig-Prean & Beckett V. United Kingdom, Applications 31417/96 & 32377/96. Smith & Grady V. United Kingdom, Applications 33985/96 & 33986/96* (April 2000), 94 American J. Int. Law 382. This case concerned the UK's policy of prohibiting homosexuals in the armed forces and the investigations which the army took into personnel in order to find out whether they were homosexuals. The UK argued that the policy was necessary for national security and the maintenance of discipline.

say that restrictions imposed on intimate private life could only be justified under Article 8(2) when there were particularly serious reasons for doing so.

These aforementioned exceptions raise the question of how they may be interpreted and applied to genetic databases. There have been a number of cases which have involved the interpretation of the Article 8 right to privacy before the court in Strasbourg[37] and in the domestic courts since the *Act* was passed. These cases give an indication of the extent to which this provision will impact upon an individual's right to privacy over his or her genetic information and material held on databases.

(b) Protection of Health or Morals

Some may argue that the exception relating to the protection of health or the protection of the rights and freedoms of others might form a basis for arguing that an infringement of the proband's privacy may be justified in order to disclose certain genetic information to the proband's relative. This would depend upon whether it was possible to prove that the relative's health was actually improved by the disclosure of such information. It would be necessary to demonstrate the availability of therapy for the genetic condition and presumably, the condition would have to be serious in order to justify the infringement of a right. In such circumstances it is possible that disclosure of information that may preserve the relative's life may be justified.

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[37] These cases are relevant since in interpreting the Convention rights, which are fairly broad and open ended, Judges are required to "have regard" to the jurisprudence of the European Court. See the *Human Rights Act 1998, s2(1).*

It could be argued that the health of the country relies on the establishment of genetic databases to be used for research purposes or for public health concerns. In such a case, the minimal infringement of privacy possible would have to be demonstrated and be in proportion to the benefits gained from breaching such privacy. This also may require that adequate security measures be in place to prevent the information being accessed by others.

(c)Prevention of Disorder or Crime

The exception dealing with the prevention of disorder or crime may also permit non-consensual disclosure of genetic information in limited circumstances. It is not clear how serious the crime would have to be to justify disclosure. However, in the *Egdell*[38] case, Bingham LJ said that the decision of the court that disclosure of the medical report was permissible, was within the terms of Article 8 of the Convention, and so disclosure in analogous cases in order to prevent a serious threat of harm would no doubt be justified.

This position is supported by the case of *Z v Finland*[39] which was decided by the European Court of Human Rights. That case concerned the extent to which reliance on article 8 could prevent disclosure of medical information that was being used in legal proceedings involving serious criminal charges. In this case the court found that there was no breach of a Convention right when the person's medical advisors were ordered to give evidence, nor when her medical records were seized in evidence in the course of those legal proceedings. The current legal position in the UK that justifies disclosure in

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[38] *W v Egdell 1990 1 ALLER 835*

[39] 9/1996/627/811

the context of legal proceedings is unlikely to be affected by challenges under Article 8, unless disclosures are related to for example, less serious crime.

A challenge under article 8 of the Convention arose recently, in the domestic courts in the *Attorney General's Reference (No 3 of 1999).*[40] The House of Lords, had to consider *inter alia* whether it was contrary to article 8 of the Convention for a DNA sample which had been properly obtained but which ought to have been destroyed and not retained in a DNA forensic databank could be used in the prosecution case for a rape trial which depended solely on DNA evidence. The outcome in this case depended upon the construction of a provision of the *Police and Criminal Evidence Act 1984*. However, it was also argued on behalf of the respondent that Article 8 of the Convention meant that the evidence could not be used since it was a breach of article 8 to fail to destroy the DNA sample after the accused's first acquittal. The court rejected this argument on the basis that it had decided that retaining the sample was within the terms of the legislation and was therefore lawful and that the interference with privacy was necessary in a democratic society to ensure the investigation and prosecution of serious crime. It was not therefore contrary to article 8. Although the challenge under Article 8, failed in this case, it does leave room for similar challenges regarding the use of DNA samples and genetic information from databases improperly obtained, or unlawfully retained, in particular when used for less serious crimes or other reasons.

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[40] In the *Attorney General's Reference (No 3 of 1999).*

There are indications in the case law that it may be possible to challenge compulsory genetic testing as an infringement of Article 8. In the case of *T – 10/93A v Commission*[41] Mr A had applied for a job with the European Commission as an Administrator and was turned down on the ground that he was HIV positive. He volunteered information about his condition and had voluntarily submitted to testing. He argued that the decision not to employ him constituted an infringement of Article 8 of the Convention and that the fact that the test was carried out was an infringement since he had volunteered information about his condition. The court said that the requirement to undergo a medical examination was "in no way" a violation of Article 8 since it was to avoid appointing unsuitable candidates in terms of the duties to be assigned to them.

Although in this case, the court found that compulsory testing required by an employer was justified under Article 8, compulsory genetic testing could be challenged under this provision and would have to be justified. Further, Convention rights are required to be interpreted in accordance with the mores of the day in the country in which they apply and as a result, it is possible that a court may find a regime of compulsory genetic testing instituted by an employer to be an unjustified infringement of Article 8.[42]

(d) The Right to Private Life is a Positive Right

The right to "respect" for the right to private life in Article 8 carries with it a positive obligation on the state to provide protection from interference with the right from other

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[41] [1994]ECR II - 179

[42] Noreen Burrows says "Any claims against compulsory medical testing would be subject to a two- stage investigation. Compulsory testing would be presumed to be contrary to *Article 8(1) of the Convention* and

parties.[43] Thus the European court has found that Article 8 is violated not only when the state itself violates the complainant's privacy but also when the state does not provide a mechanism whereby the right of "respect for privacy" can be protected against intrusion by others. [44] This was summarised by saying that Article 8 protects a complainant who argues "not that the State has acted but that it has failed to act."[45]

This positive obligation was discussed in a private family law case *Glaser v United Kingdom*[46], where the European Court, sitting as a Chamber, considered the potential breach of the father's rights under Article 8 (the right to respect for family life) and Article 6. At paragraph 63 the court said:

> The essential object of Article 8 is to protect the individual against arbitrary interference by public authorities. There may, however, be positive obligations inherent in an effective "respect" for family life. Those obligations may involve the adoption of measures designed to secure respect for family life, even in the sphere of relations between individuals, including both the provision of a

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would therefore have to be justified under the second paragraph of that Article." In Brice Dickson, ed *Human Rights and the European Convention* (Sweet and Maxwell, 1997) 27-47.

[43] This was recognised in two cases prior to the *Human Rights Act* coming into force. See *Re F (adult patient)*, [2000] 3 FCR 30, [2000] 2 FLR 512 and *Glaser v UK* [2000] 3 FCR 193.

[44] This point was made in *Marckx v Belgium* 2 Eur. Ct. H.R. (ser A) at 330 (1979-1989), which was followed in *Airey v Ireland* 2 Eur Ct H.R. (ser A) at 305 (1979-1980). These cases are discussed further in Les P Carnegie, "Other International Issues: Privacy and the Press: The Impact of Incorporating the European Convention on Human Rights in the United Kingdom." (1998) 9 Duke J Comp. & Int. L. 311at 334. See also *X and Y v. The Netherlands (1986) 8 E.H.R.R. 235*, where the court said at p276, "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 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."

[45] *Airey v Ireland* 2 Eur Ct. H.R. (ser A) at 305 (1979-1980) at 305.

[46] 2000 3 FCR, 193.

> regulatory framework of adjudicatory and enforcement machinery protecting individual's rights and the implementation, where appropriate, of specific steps.[47]

In another case, which sought to argue that the state had failed in its positive obligations, the court concluded that adequate remedies were already provided for in the common law. In the *Spencer* case[48], which was brought prior to the *Human Rights Act* coming into force, the brother and sister in law of the late Princess of Wales brought an application to the European Commission arguing that the absence of a right of privacy in England, denied them the means of stopping the publication of, or obtaining damages for the publication of an article about their marriage, family and health. They argued that the action for breach of confidence was inadequate in their case and that the absence of a legal remedy was in violation of the positive obligation on the UK contained in Article 8. The Commission took the view that the Spencer's could have brought an action for breach of confidence and that this action would have provided them with damages had they been successful. Although in this case the argument based on Article 8 failed on the facts, if it could be demonstrated that the action for breach of confidence did not provide any means of protection in a particular case, a similar claim could now be made in the domestic courts.

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[47] See the following authorities, *X and Y v. The Netherlands 91 Eur. Ct. H.R. (1985)* and mutatis mutandis *Osman v. the United Kingdom* (1998) 29 EHRR 245. In both the negative and positive contexts, regard must be had to the fair balance which has to be struck between the competing interests of the individual and the community, including other concerned third parties, and the State's margin of appreciation (see *Keegan v. Ireland* 18 EHRR 342.

[48] *Earl Spencer and Countess Spencer v. United Kingdom* (1998) E.H.R.R. 105 discussed in *supra* note 44.

In sum if it becomes apparent that the existing legislation and common law does not provide sufficient protection for the right to respect for genetic privacy, the government could be required to take measures to sufficiently protect this right. The courts will have a major role in defining the limits of the right and its exceptions and in developing the common law in accordance with Convention rights.

These are just some of the ways in which Article 8 may impact upon genetic privacy. Clearly the full extent to which this right will impact upon the rights of individuals in relation to their genetic privacy is still a matter of conjecture as there have as yet been no cases in the UK directly in point. The next section will consider some other ways in which the *Human Rights Act* may impact upon the law.

(e) Rights Between Citizens and State – Vertical Effect

The Act makes it unlawful for a public authority to violate the Convention rights unless an Act of Parliament leaves it no choice.[49] This is described as the Convention rights having vertical affect. A public authority is given a wide meaning[50] in the *Act* and includes local authorities, the police, immigration officers, public prosecutors, National Health Service Trusts, public research institutions, Universities, courts and tribunals, departmental public bodies and any person or body exercising a public function. Even certain quasi-public bodies such as private companies, which carry out a public function, will be public authorities in respect of those functions.

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[49] 6. - (1) It is unlawful for a public authority to act in a way which is incompatible with a Convention right.

Where the holder of a database is a public authority, it will be required to respect the Convention rights including the right to respect for private and family life. It will be unlawful for public authorities such as the police, to access genetic material where that is a breach of Convention rights regardless of who holds the information. Private bodies such as pharmaceutical companies are not public authorities and as a result the Convention will not have vertical effect in the same way. However they will be affected by the Convention rights in other respects.

(f) Rights Between Private Persons - Horizontal Effect

The fact that the term public authority includes courts and tribunals and that they are required not to act incompatibly with Convention rights[51] will have a major influence on the development of the private law.[52] This is described as horizontal effect of the *Act*. In any case before the court whether concerning a public body or private one, it is arguable that the court could be acting incompatibly if it did not give effect to the Convention rights even if it was determining the rights and duties of private parties.[53] The courts would thereby be obliged to develop the common law in accordance with the Convention. An alternative view which is sometimes argued is that the courts could be at risk of acting incompatibly only in their own sphere in relation to the administration of justice and in relation to the remedies they give to private litigants. This approach could

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[50] Public Authority is defined in *section 6(3).*

[51] *Section 6.*

[52] Oliver points out that there is a lively debate taking place in the law journals between Lord Justice Buxton on the one hand who argues that the Human Rights Act will have little or no effect on private law and Sir William Wade, Murray Hunt and Gavin Phillipson on the other hand who argue for direct or indirect horizontal effect. Dawn Oliver "The Human Rights Act and Public Law/ Private Law Divides" (2000) EHRLR Issue 4

[53] Thomas Raphael makes this point in Thomas Raphael, "The Problem of Horizontal Effect" (2000), *EHRLR* Issue 5 493 at 494.

prevent the court granting remedies against private litigants who violated rights and would limit the horizontal effect of the *Act*.

A second means by which the Convention rights will impact upon substantive private law is in cases where primary legislation cannot be interpreted in accordance with the Convention rights. In such circumstances the courts are required to issue a declaration of incompatibility, signalling to Parliament that such legislation ought to be changed, whilst retaining parliamentary sovereignty.[54] A special fast track procedure is provided for in the act to enable legislation to be amended in such circumstances.[55] As a result the *Human Rights Act* may result in legislation relating to confidentiality and privacy being amended if the existing provisions are deemed to insufficiently protect the right to respect for private and family life.

Convention rights also have to be taken into account in the development of the common law and this also leaves room for significant developments in the common law action of breach of confidence towards protection of privacy. Indeed it has been said that, "Article 8 would give English courts the tools to bridge a specific gap in the existing legislation and common law causes of action."[56]

It should also be noted that the possibility of taking a case to the Court in Strasbourg is still permitted and as a result the interpretation of the Convention will have to adhere to the jurisprudence adopted by that court. In the words of Lord Hope "..the fact remains

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[54] *Section 4 of the Act* provides for this.
[55] The Secretary of State can amend any offending legislation by a statutory instrument.

that the judges of our courts are not free to go their own way. The last word on matters of Community law lies with the Luxembourg court and the last word in matters relating to the Convention rights lies with the court in Strasbourg."[57]

(g) Evolution of the Common Law

The extent to which the courts in the UK will embrace the rights of the Convention remains to be seen. There appear to be conflicting indications of the extent to which the law may change. For example, in a recent case before the Court of Session in Scotland called *Anderson, Doherty and Reid v the Scottish Ministers and the Advocate General of Scotland*[58] which concerned the interpretation of Article 5 of the Convention and the grounds of detention under Mental Health Legislation, the court was conscious of the need to avoid usurping the role of the legislature in interpreting Convention rights. Lord Phillip appeared to endorse a cautious approach of the courts by saying, "In these circumstances, governments must be free, as they must in relation to a multitude of areas of human activity to alter their policies as developments in medical and social thinking dictate ."

This appeared to suggest that a degree of deference would be paid to the state and that Convention rights ought not to stand in the way of evolving policies. On the other hand, a number of cases suggest an enthusiasm for the adoption of a rights jurisprudence in the courts. In the case of *Earl Spencer v the UK*, previously discussed, it was suggested that the common law action for breach of confidence may have developed to provide a

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56 *Supra* note 44 at 339.
57 *Supra* note 26 at 446.

sufficient remedy to protect the right to privacy in cases in which the media publishes revelations passed in confidence."[59] One commentator has argued on the basis of the indication of this case together with the *Human Rights Act* that the action for breach of confidence will inevitably expand and develop.[60]

The Spencer case was also cited in another important case of Venables v News Group Newspapers Ltd[61], whereby the action for breach of confidence was discussed in relation to the right to respect for private and family life and Article 10, freedom of expression. This case concerned the issue of whether an injunction ought to be granted to prevent the press from ever publishing information about two individuals who had murdered a child, James Bulger while they were young children. Butler Sloss said that the injunctions could be ordered and were in accordance with the law of breach of confidence. This decision was not however made on the basis of Article 8 and the Judge said that it was not necessary to consider whether this right would have justified granting the injunctions. The evolution of the common law action for breach of confidence was however, discussed as follows:

> The common law continues to evolve, as it has done for centuries, and it is being given considerable impetus to do so by the implementation of the Convention into our domestic law. I am encouraged in that view by the observations of Brooke L.J. in the Douglas case (above) at paragraph 61:
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> It is well known that this court *in Kaye v. Robertson [1991] F.S.R. 62* said in

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58 16 June 2000, [2000] UKHRR 439.

[59] *Earl Spencer v. United Kingdom* (1998) 25 E.H.R.R. C.D. 105.

[60] D.B. Squires, 'Striking the Balance Between Kissers and Tellers: the Law of Breach of Confidence',(1999) *Ent. L.R.*, 10(8), 240-243.

> uncompromising terms that there was no tort of privacy known to English law. In contrast, both academic commentary and extra- judicial commentary by judges over the last ten years have suggested from time to time that a development of the present frontiers of a breach of confidence action could fill the gap in English law which is filled by privacy law in other developed countries. This commentary was given a boost recently by the decision of the European Commission on Human Rights in *Earl Spencer and Countess Spencer v. United Kingdom* (1998) E.H.R.R. 105, and by the coming into force of the *Human Rights Act 1998.*
>
> Keene L.J. said at paragraph 165:
>
> ... breach of confidence is a developing area of the law, the boundaries of which are not immutable but may change to reflect changes in society, technology and business practice.

In that case the Judge generally acknowledged that the action for breach of confidence was being extended in order to prevent serious physical injury or death of the convicted murderers. It seems likely, following the dicta in the case that there is room for the action to be extended further in future on the basis of Article 8. Indeed, the genetic revolution may well be one of the "changes in technology" that the Judge envisaged and which may require developments in the common law in accordance with the right to respect for private life.

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[61] (Family Division; Butler-Sloss P, 8 January 2001, [2001] 9 BHRC 587.

Yet another case which concerns Article 8 of the Convention and privacy was the case of *Douglas and Others v Hello! Ltd.*[62] One commentator discusses the development of the law of confidentiality apparent from the judgement:

> Justice Sedley, however, elaborates upon the court's stance. He opined that the law no longer needed to construct an artificial relationship of confidentiality between intruder and victim: it could recognise privacy itself as a legal principle drawn from the fundamental value of personal autonomy.[63]

From these few cases it appears likely that there is significant potential in the common law action for breach of confidence to expand to encompass a more all-embracing concept of privacy. The way in which this will impact upon genetic privacy remains to be seen but in any event the adoption of a rights approach in the determination of when privacy can legitimately be infringed is an improvement upon the traditional action for breach of confidence explored previously.

There is some debate however regarding whether adopting the privacy jurisprudence of the European Court of Human Rights into traditional fragmented areas of the common law is the most appropriate or effective means of protecting privacy. Kearns for example, argues that this is not the best approach:

> From the limited evidence so far, it would seem that the judicial preference is to embrace the European law under Art 8 within the already-established most relevant sector of existing disparate English law on privacy. This is arguably

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[62] [2001] WLR 992.

> lamentable because the European law will consequently be divided in an alien way into separate English doctrines of, for example, trespass, nuisance or breach of confidence, rather than being holistically imported as a welcome, clear and logical privacy law system...... [w]ith privacy being a vastly broader area than simply breach of confidence, it is inconceivable that European privacy law can be simply and narrowly adequately accommodated under the breach of confidence head alone.[64]

Notwithstanding these concerns, this does appear to be the approach that has been taken. The action for breach of confidence may end up unrecognisable if it is twisted and stretched to cover all aspects of privacy required to be protected by Article 8. However the common law has shown itself as malleable and adaptable throughout centuries of developments in the law, so it may adapt well to this admittedly fundamental change in jurisprudence.

5.4 Conclusion

This chapter has highlighted the ways in which Article 8 of the *Human Rights Act* may influence genetic privacy. The *Human Rights Act* enacted in October 2000 has not yet had time to fully make its mark on the UK legal system although it will undoubtedly bring significant and everlasting changes to the law. Although the immediate impact of the *Act* is likely to be seen in terms of challenges to the actions of public authorities and

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[63] See Dr Paul Kearns 'Privacy and the Human Rights Act 1998' (16 March 2001) *New Law Journal* Vol 151 No 6975 p 377.
[64] *Ibid.*

organs of government, gradually the rights jurisprudence will spread and affect all individuals and every area of law.

Regardless of the interpretation which the courts may give to the right to respect for private and family life in the context of genetic information, it is clear that a balancing exercise will have to be performed on the one hand between the rights of the individual to privacy of his or her genetic information and material and the interests of the state in limiting such a right as a result of the exceptions listed and other conflicting rights.

The way in which the courts will strike a balance between the privacy rights of individuals and other parties' interests in knowing such information remains to be seen and will be a complicated task. However, at least the right to privacy will now be taken into consideration in stark contrast to the position prior to the *Human Rights Act* coming into force. It is hoped that the right to respect for private life of the Convention together with the more limited privacy rights encompassed in the *Data Protection Act* will be a foundation from which to construct a meaningful and comprehensive modified right to genetic privacy argued for earlier in this thesis.

The following chapter will draw together the arguments made in this thesis, will make recommendations regarding the approach that the law should take towards regulating genetic databases, and will consider the Report of the House of Lords Select Committee on Science and Technology Enquiry into Genetic Databases.[65]

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[65] *Human Genetic Databases Challenges and Opportunities, 4th Report* (House of Lords Science and Technology Committee, Session 2000-2001).

Chapter Six

20-20 Vision

Individualism, Privacy and the Good of the Community

Did the House of Lords Strike the Right Balance?

6.1 Introduction

Although the title of this chapter, "20:20 Vision" is not original, it is nevertheless apt. The changes in the next twenty years will be far-reaching, significant and sometimes unpredictable. Society needs a clear vision based on principles to inform the regulation of genetic databases in the 21st Century. The first part of this chapter will bring together the strands of argument made throughout the thesis and summarise their implications for genetic databases in the form of recommendations, which are italicised below. The closing part of this thesis will consider the recommendations of the House of Lords Select Committee on Science and Technology, Enquiry into Genetic Databases[1] in the light of arguments made throughout this thesis.

6.2 Recommendations

The thesis has adopted a modified individualistic, libertarian stance. It has argued that the law should embrace a rights approach to protect individuals' interests in privacy in the context of the genetic revolution. It has also attempted to achieve an effective balance between respecting individual rights and taking account of the interests and rights of society and other parties, by arguing for a modified rights approach in particular, because genetic information is not individualistic.

A dialogue ought to take place in society so that the development of the law is determined, after thoughtful and well-informed debate on what approach ought to be taken. It is hoped that the arguments made here will stimulate and contribute to that debate.

The first chapter outlined the context for this thesis. It highlighted the importance of the genetic revolution and discussed the awe-inspiring advances that have been and will be brought about by the Human Genome Project. It explained what genetic information is and why it is personal, sensitive and of interest to many parties. That chapter also defined genetic databases and highlighted why they raised distinct issues for law and ethics. It was argued that the legal and ethical implications of genetic databases for privacy are important because databases are increasing in number and scale and serve an important function in realising the full potential of the genetic revolution.

Left unregulated, they pose a considerable threat to both individual and group privacy. An analysis which clarifies the distinct issues raised by databases and by genetic information is required in determining the approach that ought to be taken to their regulation. The House of Lords Select Committee on Science and Technology enquiry into the challenges and opportunities raised by genetic databases provides a valuable and

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[1] These are included in *Human Genetic Databases, Challenges and Opportunities, 4th Report* (House of

up to date source of evidence about databases currently in existence and those which are planned.

It is necessary to clarify the issues raised by genetic databases. In addition, it is helpful to gather and synthesise this sort of evidence on the extent of planned and existing genetic databases in order to ensure an informed discussion of the issues raised. Sufficient public understanding of genetic technologies is a prerequisite to informed debate.[2]

Chapter two examined the meaning and theoretical underpinnings of privacy and its interrelationship with autonomy. It emphasised the inherent value of privacy in safeguarding dignity as going beyond its instrumental value in preventing discrimination or serving other functional purposes. Privacy was conceptualised not only as a right to be let alone, but also as a positive right which allows an individual control over information that relates to him or her. It was also argued that privacy could be thought of as a collective right, on a theoretical level at least, that can belong to groups as well as individuals. The right not to know certain information may become increasingly important as genetic technologies become increasingly sophisticated and may influence the way in which we think about ourselves. Jonas, in discussing human cloning is perceptive in reminding us of the benefits of ignorance!

Lords Select Committee on Science and Technology, Session 2000-2001)

[2] See Jon Turney, 'The Public Understanding of Genetics – Where Next?' (1995) *Eur. J. Gen. M*, Vol 1, no 2, 5-20 at 5. He says "as the Human Genome Project gathers momentum, there is wide agreement that a broad effort to improve public understanding of genetics will be needed to underpin public debate about the applications of new genetics." See also Bartha Maria Knoppers, 'Reflections: The Challenge of Biotechnology'. She argues that there is, "an underlying need for greater transparency and public participation in policy development and that rational and effective policies will only result from additional

> That there can be (and mostly is) too little knowledge has always been realized; that there can be too much of it stands suddenly before us in a blinding light… The ethical command here entering the enlarged stage of our powers is: never to violate the right to that ignorance which is a condition for the possibility of authentic action; or: to respect the right of each human life to find its own way and be a surprise to itself.[3]

This chapter also drew attention to the disparity of views about the importance and meaning of privacy and argued that it was necessary for the law to adopt a rights approach to the regulation of genetic databases in order to adequately protect the interests underlying privacy.

It is necessary to clarify and reach a consensus on what is meant by terms such as individual autonomy, individual privacy, group autonomy, and group privacy in order for the law to reflect those values accurately. In addition, the alternatives and consequences of a rights approach to the regulation of genetic information and databases must be evaluated.

The communitarian approach discussed in chapter three highlights a valid and important principle: collective interests warrant consideration alongside individual rights in developing the law. This outlook strengthens the rights approach, whereas following the

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basic scientific data being made available to a more informed and engaged (Canadian) public."(2000) *J Public Policy* 45 RD McGill 559.

communitarian approach exclusively without safeguarding rights has undesirable consequences. A modified rights approach reconciles the communitarian approach and social nature of genetic information to achieve a powerful and resilient compromise.

In promoting debate on the role of the law in this context, it is important to make explicit the collective, social and other interests that compete with privacy. This entails determining which interests ought to be recognised and the weight which should be given to these. It involves clarifying the rights of community and family and taking careful decisions on the regulation of vested interests, including the commercial interests of private corporations and the economic interests of governments.

In Chapter four, the common law approach was criticised for failing to address rights seriously, creating a vacuum in which the hegemony of the medical profession was able to determine, almost exclusively, the circumstances in which confidentiality was respected. The common law did not recognise the inherent importance of confidentiality and privacy, leaving individuals with little legal protection of confidentiality in practice.

The law requires to take a more proactive approach based on an informed and principled community view in order to ensure that rights are safeguarded and that the medical profession operates within defined parameters.

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[3] Hans Jonas, 'Biological Engineering –A Preview' in Englewood Cliffs, *Philosophical Essays: From Ancient Creed to Technological Man* (NJ: Prentice Hall, 1974) pp141-167 at 163.

Chapter five advocated that this could be achieved through the legal recognition of a right to genetic privacy and presented evidence that the law was taking steps in this direction, by means of the *Data Protection Act 1998* and the incorporation of the *European Convention on Human Rights* into the law by the *Human Rights Act 1998*.[4] A rights approach limits the extent to which an individual's interests can be overridden by other interests without substantial justification. This is likely to safeguard the use of genetic material or information against *inter alia* unacceptable discriminatory or eugenic purposes. In addition, a rights approach has the potential to minimise the influence of the practices of the medical profession on the law, since it ought to be the function of law to set legal standards.

The current law must be continually critically evaluated in determining the extent to which it should be amended to effectively regulate genetic databases. The impact and changes made by the Human Rights Act 1998 must be monitored to determine accurately the approach that is being taken by the courts, and how it needs to be changed. The House of Lords Select Committee on Science and Technology Enquiry into genetic databases and the reviews of various aspects of human genetics being undertaken by the

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[4] Space did not permit a comprehensive examination of all aspects of the law that apply to databases of genetic information and material. The common law action for breach of confidence, *Data Protection Act 1998* and the *Human Rights Act 1998* were chosen as some of the primary aspects of law that apply. There is an additional body of law and codes of practice that apply to research regulation which have not been covered. In addition, there is international regulation that applies to the conduct of genetic research and to the obtaining, storage, use and destruction of genetic samples and information. For an examination of this regulation, see Deborah Crosby, *Protection of Genetic Information: An International Comparison*, Commissioned by the Human Genetics Commission online: Human Genetics Commission at <www.hgc.gov.uk> at 110.

Human Genetics Commission[5] *in the UK are important steps in the continual evaluation of the laws and public attitudes. Their function in recommending changes is of paramount importance and they help to ensure that the law keeps apace with the scientific developments of the genetic revolution.*

6.3 Evaluation of the House of Lords Recommendations

It is not possible to make definitive or specific recommendations for legislation on genetic privacy and databases that will resolve all of the issues raised in this thesis. The factors, which this writer regards as important, should be evident from previous chapters. Instead, a brief critical examination of the recommendations of the House of Lords Select Committee on Science and Technology contained in the report, "Human Genetic Databases: Challenges and Opportunities"("the Report"), will be undertaken. This section will look at how the arguments for the importance of privacy in Chapters 2 and 3, the review of the law in Chapters 4 and 5, and the modified rights approach set out in this thesis may be incorporated into the law.

The Report made a number of important recommendations including the approach that the law should take to their regulation.[6] Only those relating to privacy and confidentiality will be considered here.[7] The main recommendation is that the primary means of regulating human genetic databases should continue to be the *Data Protection Act 1998*

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[5] For details see the website of the Human Genetics Commission online at <www.hgc.gov.uk>. Recent commissioned reports include Georgina Voss, *Report to the Human Genetics Commission on Public Attitudes to the Uses of Human Genetic Information* (Human Genetics Commission, Sept 2000), and *Ibid.*
[6] *Supra* note 1.

and that no additional protection is required for personal genetic data. This is subject to one major caveat, whereby the Report recommended the establishment of a Medical Data Panel which would have three main functions.

Firstly, it would consider projects for approval which involve national or supra regional secondary use of health and related data. Any large-scale use of genetic databases would be subject to review and would be accountable to this body made up of both lay and professional members. It appears that this would provide some safeguard against research being undertaken without adequate security measures, to prevent research being undertaken which may cause unnecessary harm or stigmatisation to certain groups and it may increase compliance with the laws that exist.

Secondly, it would set policy for approval of projects involving secondary use of such data at regional and local levels. The implementation of such policy would mean that consistency in approach would be more likely in the review of proposals using such databases. The fact that this body could determine the circumstances in which genetic information could be used for secondary purposes may mean that the practical consequences of facilitating access to information for research, and for public health and other purposes may be taken into account while at the same time protecting the privacy interests of individuals and groups. In many cases, individuals will be happy to entrust an impartial body, which has no commercial interests, with deciding the circumstances in which their information and tissue can be used for purposes other than those for which

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[7] *Ibid.* These are contained in Chapter 7 of the Report entitled "Ethics, Privacy and Consent", and are

they originally consented. This will avoid a situation whereby an individual is asked to consent to unknown research with widely drawn consent forms, which would not in reality enhance self-determination.[8] In addition, it will avoid the expense and difficulty of re-contacting individuals who may have donated the genetic material for other purposes some time ago and who may have moved address or have died. Such contact in itself may be viewed as an intrusion of privacy.[9] At the same time, the unsatisfactory state of affairs where researchers, pharmaceutical companies and others would be given carte blanche to conduct whatever research they consider appropriate would also be prevented.

This body would have the expertise to consider the collective rights of groups within society and society, as a whole when determining whether certain uses of information ought to be permitted. In fact, prior to this suggestion some commentators had called for the establishment of a review body such as this in order to ensure that adequate expertise be available to review research protocols.[10] They argued that the Data Protection Commission which has a statutory responsibility for the security of data, tended to rely on codes of practice and to respond to complaints rather than to take a proactive role in the

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summarised in Chapter one of the report. "Summary and Recommendations."

[8] Knoppers makes the point that consent forms are prospective and limited in their ability to enhance self-determination since they may be committed to years in advance of the research being undertaken by which time the person's views may have substantially changed. Bartha Maria Knoppers, "Consent and Confidentiality", in Knoppers, Laberge and Hirtle eds, *Human DNA: Law and Policy*, (Kluwer Law Int, 1997) at p7; See also the review of consent forms currently used in Canada in M J Verhoef, R M Lewkonia, T D Kinsella, 'Ethical Implications of Current Practices in Human DNA Banking in Canada', in Knoppers, Caulfield, Kinsella eds, *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 5-16.

[9] "To recontact former patients or to contact family members of a dead person would be more intrusive of privacy than using anonymised samples without an explicit written consent. *Ibid* at p69.

[10] Jane Kaye and Paul Martin, "Safeguards for research using large scale DNA Collections",(2000) *BMJ* ; 321: 1146-1149.

oversight and investigation of data control. The same commentators recommended a statutory national office for the inspection of genetic databases. It is not clear whether the Medical Data Panel if created would have such powers. However, compulsory licensing of genetic databases would be able to prevent the non-consensual, storage or analysis of genetic material. This is an important function since "DNA can be collected by just about anyone and analysed without the knowledge of the person from whom it is taken."[11]

The Report recommended that the third function of the Medical Data Panel would be to "advise the Government and the Data Protection Commissioner on the interpretation of the *Data Protection Act* in its application to medical data - and, if necessary in the light of medical advances, changing public attitudes or other changing circumstances, to advise on possible amendments to the legislative framework."[12]

The creation of a Medical Data Panel appears to be an excellent suggestion that ought to be implemented and given adequate powers and resources. However, it is essential that individuals who do not want to entrust this body with the power to make decisions about secondary uses of their information should continue to be able to retain the right to opt out of such a scheme except in exceptional cases when the legislature decides that the interests of the individual should be overridden by important community interests. In such cases "legal consent may be found in the legislatures approval and protection of the

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[11] Richard S Fedder, "To Know or Not To Know, Legal Perspectives on Genetic Privacy and Disclosure of an Individual's Genetic Profile" (September 2000) *Journal of Legal Medicine* 21: 557-592 at 581.
[12] *Supra* note 1 at para 7.58.

public's and patients interests assured by the executive branch of government."[13] The Dutch have a similar scheme which allows for the use of anonymous tissue obtained during treatment unless the patient has opted out.[14] In addition, individuals ought to retain the right to withdraw from the scheme at a later date if this is practicable.[15] The Medical Data Panel should be given the responsibility to consider when withdrawal is reasonably practicable. The informed consent process for the taking of a sample of genetic material which will be stored ought to involve a consideration of the issues raised by storing genetic material,[16] and whether the individual is happy for the Medical Data Panel to regulate the secondary uses of such information. For retrospective samples consent could be presumed unless individuals opt out.

A committee such as that described would be able to set policy which would be more flexible than legislation of any sort. It would be able to amend its policies and practices in accordance with advances in the science of genetics and other unforeseen circumstances. It is also beneficial that laws would be kept under review and could be changed if the current provisions proved to be failing to respect privacy rights of those involved. A body with expertise in this area and with lay representation would likely have relevant experience in developing policy with regard to secondary uses of data whereas the Data Protection Commission currently lacks the necessary expertise. The

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[13] Bernard M Dickens, "Choices, Control Access: The Canadian Position" in Knoppers, Laberge and Hirtle eds, *Human DNA: Law and Policy*, (Kluwer Law Int, 1997) p71.

[14] See Kathleen Cranley Glass "Challenging the Paradigm: Stored Tissue Samples and Access to Genetic Information", in Knoppers, Laberge and Hirtle eds, *Human DNA: Law and Policy, (*Kluwer Law Int, 1997).

[15] The Scheme for the Iceland Health Sector Database was heavily criticised for not allowing individuals to withdraw from the scheme in that they could decide not to have future information stored in the database but could not withdraw their information from it because that was not seen to be practical.

Human Fertilisation and Embryology Authority[17] has had relative success in the area of controlling and storage of gametes. A similar model would appear to be a sensible way forward.

With regard to the Report's recommendation that the *Data Protection Act 1998* should continue to be the primary means of protecting personal data, the discussion of the *Act* in chapter five has already highlighted its weaknesses. These will not be repeated in full. Suffice it to say that the major weakness of the *Act* is the number and breadth of exceptions to the Data Protection Principles and the fact that the *Act* only applies to identifiable data. There is no regulation of anonymous data at all. Further, the *Act* does not apply to databases of human genetic material, although such material once analysed in order to produce such information would be covered by the *Act*. As a result, such genetic material, when stored in a database could be transferred, stored, processed and used for different purposes without the *Act* having an impact at all. In addition, it has been argued that genetic information raises particular issues for privacy and therefore a distinct approach to the regulation of genetic databases is required.[18]

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[16] See some of the issues to be addressed in, Gold, Label, Mearns, Dworkin, Hadro, Burns, "Model Consent Forms for DNA Linkage Analysis and Storage", (1993) *Am. J. of Med. Genetics* 47, 1223-1224.

[17] The Human Fertilisation and Embryology Authority is a statutory body established by the *Human Fertilisation and Embryology Act 1990* to regulate, license and collect data on fertility treatments. It regulates the collection, storage and destruction of gametes. The website is <www.hfea.gov.uk>.

[18] This point was also made by the Human Genetics Commission in its response to the Report *supra* note 1 in *Comments to Inform the Government Response to the House of Lords Report on Genetic Databases* (Human Genetics Commission, 2001). Available online: Human Genetics Commission at <hgc.gov.uk/business_publications_response_databases.htm>.

6.4 Conclusion

The call for the legal adoption of a modified rights approach to genetic privacy is an important but only elementary step towards coming to a determination of how to regulate genetic information and material. As one commentator has put it, "... the devil is in the detail, and the problem distils into this: how can an adequate, acceptable and enforceable regime be established which will give due recognition to worthy claims in appropriate measure, while at the same time remaining true to the fundamental values which underpin that system?" [19]

The process of determining where the balance between these interests ought to lie will be for the legislature to debate and determine.[20] However it is hoped that the analysis in this thesis has helped to clarify the arguments for the adoption of one approach. It is also hoped that the arguments contained herein will have persuaded some readers that the law ought to take a proactive approach by actively considering the matters raised by the genetic revolution and by monitoring developments as they occur.

Although it may seem pessimistic to end on a note of caution, it ought to be remembered that although this thesis has concentrated on regulating developments in genetics, another possible response which is open to the law is deciding that the pursuit of knowledge in the field of genetics is just not worth it.

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[19] See Graeme T Laurie, "Genetics and Patients' Rights: Where are the Limits?" (2000) *Med. Law Int.* Vol 5 pp25-44 at 30.

There may be too great a price to pay in terms of our privacy being eroded, and changes to our self-understanding. As Murray says:

> There is a tendency in bioethics, as in other fields, to focus on the immediate practical dilemmas posed by their developments. It may be that the most important challenges posed by the human genome project will not be the pragmatic concerns discussed thus far, but will have to do with the way we understand ourselves, our nature and significance, and our connections, with our ancestors and descendants.[21]

To be sure, developments in genetics are likely, in a similar way to computer technology, to change the way we live every aspect of our lives. We should not focus on the incremental details at the expense of losing sight of the whole picture.

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[20] However, Peter S Harper makes certain sensible recommendations in, Peter S Harper "Research Samples from Families with Genetic Diseases: A Proposed Code of Conduct"(1993) *BMJ*, 306, 1391-94.

[21] Thomas H Murray, 'Ethical Issues in Human Genome Research', (Jan 1991)*The FASEB Journal*, Vol 5 55-60 at 59.

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