PROTECTION OF HUMAN GENETIC INFORMATION: BALANCING INTERESTS IN THE USE OF PERSONAL GENETIC DATA

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Abstract

Genetic technology can be of great benefit to people. However, one of the most dangerous aspects of new technology is the danger of the genetic information becoming available to people who might be involved in making decisions that affect every aspect of our lives, especially employers and health insurance companies. This might lead to a genetic discrimination, and recent surveys indicated that health insurance coverage has been denied to many people due to their genetic status. Mapping of the genome and the advent of genetic testing have triggered a plethora of perplexing ethical conundrums. The most prominent of these involve the interconnected issues of privacy and the ownership of one's genetic information. That information is broadly defined as information about genes, gene products, or one's inherited characteristics, that is, derived from a genetic test or a person's DNA sample. This paper proposes to examine different approaches to genetic information and in doing so, highlight the need for a more unified approach to addressing concerns about the use and potential abuse of genetic information.

I Introduction

THE SCIENTIFIC developments and innovations are contributing a lot nowadays in the process of crime detection and the administration of justice. The courts are heavily depending upon the evidence obtained through scientific methods to find the truth and punish the culprits. At the same time, there is widespread community concern that as developments in human genetics are occurring rapidly, the law will 'fall behind' and not be able to adequately protect the privacy of the individual against inappropriate discriminatory use of their genetic information. On the one hand, there is strong support for better medical diagnosis and treatments, and for assisting with law enforcement; on the other, there is some general fear about uncontrolled or 'mad science', the spectre of eugenics, threats of biological warfare, reports of xenotransplantation (transplant from one species to another), the loss of privacy and the increased possibilities for genetic discrimination.[1]

With the standardisation of scientific technology, a single sample of DNA (found in every cell in the body) will provide information on the present and future

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1 Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information* IP 26 (2001), ALRC, Sydney (2.7).

health of a person and thus, necessarily, that of fellow family members. This latter characteristic of genetic information is worth mentioning. Genetic information not only has historical, eugenic connotations, and can be socially stigmatising, it also involves one's parents, siblings and children. When transported outside the highly confidential confines of the physician-patient relationship, it acquires roles and meanings that can affect the socio-economic survival and the relationships of the individual with his or her family.[2]

With the improvement in computer technology, it has become increasingly easy to store, search and analyse large amount of genetic data and this in itself has promoted an increase in the amount of genetic information that is gathered. The greatest danger of the genetic databank is its potential to engulf a significant part of the population to be a genetic population. In that situation, insurance companies, employers, schools, adoption agencies and many other organisations 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 job, insurance, adoption, health care and other social services and benefits on the basis of information contained in his/her genetic profile, such as genetic disease, heritage or someone else's idea of a "genetic flaw".

Genetic information has the potential to contribute to improvements in the health of individuals, groups and societies. It may enable people to avoid illness through early detection, intervention, and possible gene therapy. It can affect reproduction by providing information that will either encourage or discourage couples in deciding whether to bear children. At the same time, however, for people at risk for a genetic disease, the question of whether to undergo genetic testing is troubling. The possibility of learning that one is not at high risk for a certain disease or disorder must be weighed against the prospect that one might have to learn to live with the opposite result.[3]

The science of genetics has been transformed into a major new industry in western countries, particularly in the US, with public and private investment continuing to skyrocket. Much of this research in the US is funded by the federal government, through the Human Genome Project. The goal of this multi-billion dollar project is to identify and sequence all of the genes that make up the human genome. Much of this research focuses on genetic diagnostics: tests designed to identify genes thought to be associated with various medical conditions. Scores of new genetic tests have been developed in recent years. Genetic tests are rapidly becoming a routine tool for medical diagnosis. The information produced by these

2 Bartha Maria Knoppers, "Who Should Have Access to Genetic Information?" in Justine Burley (ed.), *The Genetic Revolution and Human Rights* 40-41 (Oxford University Press, 1999).

3 D.H. Smith, *et al*, *Early Warning: Cases and Ethical Guidance for Pre-symptomatic Testing in Genetic Diseases* (Bloomington: Indiana University Press, 1998).

tests, while potentially valuable for medical treatment, is increasingly used out of context in ways that are contrary to the interests of the patient. Centre for Genomic Regulation (CRG) has found that an increasing number of healthy individuals have suffered discrimination on the basis of predictive genetic information, a practice known as genetic discrimination.

II Current developments in gene technology

Genes are organised into chromosomes and it is through chromosomes that genetic information is transmitted. A human's chromosomes contain approximately 30,000 genes, and this complete set of genes is known as the human genome.[4] The Human Genome Project is an international effort to map and sequence these genes. This effort is enabling genetic testing, that is, a test of an individual's DNA, which records genetic information in the form of a four letter alphabet. Through a blood test or tissue sample it will be possible to determine aspects of an individual's genetic makeup, which, in conjunction with the human genome map, will allow doctors to determine if an individual has genes that predispose that individual to a certain illness or other debility.

Genetic information is significant in its capacity to provide substantial information about a person's identity and hereditary characteristics from miniscule genetic samples, such as those discarded in our everyday lives, on hair brushes, tooth brushes, cups, and so on, that may be retained and stored for indefinite periods. Genetic information derived from a sample from one individual may also provide information about familial or related ethnic or racial groups. Genes are shared in families, passed from parents to children to grandchildren. This means that a genetic test, which provides information about the genetic status of one person, can also alert others in the family to the fact that they also may have the same mutation. More than other types of testing, a genetic test of a single individual can be viewed as a test of a whole family.

Errors in the genetic code are responsible for an estimated 3,000 to 4,000 hereditary diseases, including Huntington's disease, cystic fibrosis, neurofibromatosis, and Duchene muscular dystrophy. Furthermore, altered genes are now known to play a role in cancer, heart disease, diabetes, and many other common diseases. In these more common and complex disorders, genetic alterations increase a person's risk of developing that disorder. The disease itself results from the interaction of such genetic predispositions and environmental factors, including diet and lifestyle.[5]

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4 Genome refers to the complete set of genetic information in its entirety. The genome is the pattern of deoxyribonucleic acid (DNA) that codes for proteins and physical processes.

5 "Understanding Our Genetic Inheritance" *The U.S. Human Genome Project (The First Five Years: Fiscal Year 1991-1995)*(1990).

Science has developed the capacity to store a million fragments of DNA on a silicon microchip. Each DNA chip is loaded with information about human genes. When a component of a patient's blood is placed on the chip, it reveals specific information about the individual's health and genetic composition, potentially ranging from a carrier state or a future disease, to genetic relationships.[6] The technology can facilitate research, screening, and treatment of genetic conditions, but it may also permit a reduction in privacy through its capacity to inexpensively store and decipher unimaginable quantities of highly sensitive data.[7]

Genetic screening[8] could have great value if used properly to help people take preventive measures to avoid suffering from diseases. The first type of genetic screening used was screening of newborn children for PKU deficiency. This test was made compulsory in the US in 1960's. If the new born is found to have PKU deficiency, they can be put on a special diet, and will not suffer from severe mental retardation.[9]

But the increasing ability to detect the presence of more and more defective genes has re-energised the ongoing debate about the ethics of diagnosing genetic disorder prenatally, after birth, and in adults. As noted above, human race carries 3000-4000 diseases in its genes, and it is important to distinguish between inherited diseases and infectious diseases. Inherited diseases are caused by mutated genes which are inherited by an individual from his or her parents. The identification of genetic disorders, and the potential for developing a therapy, is a powerful force in genetics and medicine. The drawback of this development is that people with genetic flaws, not all of which show up as dysfunctions, may be denied life insurance, health insurance, and access to schooling or to jobs.

There is another argument that if we let the parents chose characters for their children, such as being free from the most common genetically inherited diseases, then this might have a harmful effect on social attitudes toward other people who failed to meet such characteristics. While genetic screening could help people to have children free of the common genetic defects, it would make the life of other

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6 L. O. Gostin, "Health Information Privacy" 80 *Cornell Law Review* 451-528 (1995).

7 *Ibid*

8 Genetic screenings is a systematic search for persons with a specific genotype. These tests that look into the essence of humanity, will allow scientists and physicians the opportunity and ability to alter the human genotype for better or worse. Genetic advancements will bring controversy at every milestone. Genetic screening usually takes place when an individual or group shows risk for a disease or trait. Genetic testing can pinpoint a specific allelic interaction or multiple gene interactions, which may lead to a disorder. The common thread of life is DNA and DNA is the only major requirement for genetic screening. With knowledge of structure and function of DNA scientists can unlock the mysteries of life.

9 D. Macer, *Shaping Genes: Ethics, Law and Science of Using New Genetic Technology in Medicine and Agriculture* (Christchurch, N.Z.: Eubios Ethics Institute, 1990).

people, who did not use the genetic screening and have children who are suffering from a genetic disease more difficult and complicated. This matter could be seen as not an act of fate but the parents' fault for which the parents can be made liable for wrongful birth of a child.[10]

III Confidentiality, personal autonomy and privacy rights in genetic information

One issue that arises is whether a physician or other health professional providing genetic testing services should be permitted without the patient's consent or over their objection to reveal test results (or even the fact that a patient has sought genetic counselling or testing) to third parties. The rule is no different than for medical information in general: confidential information that can be linked to an identifiable patient should be disclosed without the patient's authorisation only when necessary to protect third parties from harm or when disclosure is compelled by law (*e.g.*, reporting HIV test results to public health officials). The question then is: When is disclosure of genetic information permitted in order to protect third parties from harm?

Genetic privacy relates to the complex set of issues surrounding how DNA information about individuals is handled and used. Some genetic privacy issues relate to the acquisition of DNA samples from individuals, other genetic privacy issues relate more to what is done with the DNA information later. One of the challenges with genetic privacy is that genes reveal information about the person they are directly attached to, but they also reveal information about the blood relatives of that person. This means that a person making a decision about, for example, getting a commercial gene test is actually making decisions that can impact other blood relatives. How does privacy work in this kind of situation? In the area of genetics and privacy, there are more questions than answers. The World Privacy Forum has focused on several aspects of genetic privacy, including the use of genetic data in research, pharmacogenomics and personalised medicine, direct-to-consumer marketing, and genetic data in electronic health records and exchanges.

A significant number of critics who maintain that genetic information should remain confidential point to historical abuses: involuntary sterilisation of people with mental retardation around the turn of the century, Nazi abuse and misrepresentation in pursuit of eugenic goals.[11] Fear that knowledge of one's genetic make-up and predisposition will stigmatise the person affected and his/her family, causing diminished or lost employment opportunities and denial of insurance

10 *Ibid.*

11 S.M. Suter, "Whose Genes Are These Anyway? Familial Conflicts over Access to Genetic Information" 91 *Michigan Law Review* 1854-1908 (1993).

coverage as well as an undesirable invasion of privacy are frequently voiced concerns.[12] Moreover, many at-risk individuals may forego genetic testing because they fear denial of future employment opportunities.

The current legal framework of protection against non-consensual collection and use of bodily samples cannot regulate the use of information derived from the collection of "discarded" genetic material, such as saliva from a glass, and so on. To remedy this, some countries are considering amending their privacy law to define 'personal information' to include bodily samples from an individual whose identity is apparent or whose identity may be ascertained from the samples itself. Thus the need to maintain confidentiality is recognised as an ethical obligation inherent in the physician-patient relationship. In legal terms, it may be considered one aspect of the patient's right of privacy.[13]

Disclosure of test data—conflicting views

Genetic information is medical information and as such is entitled to confidentiality. Genetic information is both individual and familial, however, there is a conflict between the duty to protect confidentiality and the duty to warn. There appears to be a duty to inform the patient about potential genetic risks to self and relatives, but other factors may supersede or limit that duty. In certain cases where the results of genetic testing may impact the patient's well-being, or in cases where the patient has experienced a traumatic personal experience (such as the death of a close family member) between the time of testing and the time of disclosure, the physician or counsellor is justified in withholding test results. The decision to withhold information must be based on "specific, articulable information" and the basis of a professional judgment rather than intuition.[14]

The American Society of Human Genetics (ASHG) takes the position that those performing genetic testing for their patients have a "privilege" to disclose genetic risk information directly to relatives of a patient if necessary to mitigate a serious risk of harm to family members. In less critical situations, confidentiality of genetic information should be maintained. That position is consistent with the policy positions of the President's Commission on Ethical Issues in Medicine and Biomedical and Behavioural Research and the Institute of Medicine's Committee on Assessing Genetic Risks, which allow disclosure only when the condition is

12 L.B. Andrews, and A.S. Jaeger, "Confidentiality of Genetic Information in the Workplace" 17 *American Journal of Law and Medicine* 75-108 (1991).

13 M.J. Weiss, "Medical Records On-Line: What Happened to Privacy? A Legal Analysis" *Perspectives on Law and the Public Interest* (1998). *Available at*: www.richmond.edu/~perspec/issued4/biomed.html (accessed on 22nd Mar. 2013).

14 *Supra* note 3.

"serious".[15] Therefore, in extreme cases, physicians may be privileged to violate a patient's privacy if justified by the likely reduction of imminent risk of harm to an identifiable third party. Third parties, such as insurers or employers, who have access to genetic data, may try to use that information to determine whether a prospective employee is predisposed to disability, lack of productivity, or absenteeism.

This misuse of information can be based on data such as test results that are "inconclusive" or "negative" or "positive" results indicating a predisposition or increased risk that may never materialise. Many other additional factors, ranging from diet to stress, contribute to the final outcome. Additionally, screening leads to the creation of an entire class of "unemployable" people. Use of genetic tests by insurers may also lead to a class of "uninsurable" people. These "undesirable" traits can follow people like "scarlet letters", handed down from generation to generation.[16] As genetic information accumulates, people will find themselves stigmatised, sometimes with dire consequences.

Genetic data poses unique privacy issues because it can serve as an identifier and can also convey sensitive personal information. Not only does genetic information provide something like a fingerprint through variations in genetic sequences; it also provides a growing amount of information about genetic diseases and predispositions. In addition to indicating predisposition to disease, "genes do appear to influence behaviour".[17]

A number of countries provide incidental privacy protection for their citizens under the domestic laws. The so-called privacy rights are reflected under international conventions which many jurisdictions recognise, namely article 12 of the Universal Declaration of Human Rights (1948) and article 17 of the International Covenant on Civil and Political Rights (1966) which provides: "....no one shall be subject to arbitrary or unlawful interference with his (or her) privacy." A privacy right of this scope should form the basis of the protection and legal control over the use of personal information in domestic spheres and provide the basis of a comprehensive domestic legal privacy regime.

IV Eugenics and genetic manipulations

The desire to strive towards betterment is an inborn human trait that has transformed man from a long-tailed, tree-swinging primate to a techno-savvy, go-

15 L.J. Deftos, "The Evolving Duty to Disclose the Presence of Genetic Disease to Relatives" 73 *Academic Medicine* 962-68 (1988).

16 A. Cavoukian, and D. Tapscott, *Who Knows? Safeguarding Your Privacy in a Networked World* (New York: McGraw-Hill, 1997).

17 Leroy Hood and Lee Rowen, "Genes, Genomes, and Society" in Mark A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 27 (Yale University Press, 1997).

getter. Although desire has been considered the root cause of all things evil, it has provided man with the impetus to improve. This crave for betterment gave rise to a concept called 'eugenics'. Eugenics involved the promotion of selected hereditary traits and was practiced since the time of Plato.

Recent advances in genetics and reproductive technology have opened the door to a new form of eugenics,[18] termed "modern eugenics," or "human genetic engineering," that is focused on repairing faulty genes associated with disease or other health conditions. Human genetic engineering is the science of manipulating an individual's genetic makeup, or genotype, with the intention of altering his or her observable traits, or phenotype. Human genetic engineering can be divided into two categories—negative engineering, referring to the correction of genetic disorders and deficiencies; and positive engineering, referring to the enhancement of an individual's genetic make-up. Some liberals argue that genetic engineering undermines equality because limited access to high-priced enhancements would confer biological advantages only on those offspring whose well-off parents can afford those technologies, thereby exacerbating the gap between the haves and the have-nots.[19]

Biological advances are making it increasingly possible in medical contexts to take decisions about the kinds of people who are born. For more than forty years, ante-natal testing has made it possible to terminate a pregnancy when the foetus has some detectable serious disability. With *in vitro* fertilisation, there is the possibility of transferring to the womb 'healthy' embryos rather than others.[20] Sex selection to avoid sex-linked disorders is another option available. Safe and reliable gene therapy is not far away. And then there is gene counselling which may affect people's choice of spouse or partner.[21] The power to decide for and against certain human characteristics is terrifying because, as the Nazi case reminds us, in some hands it could be appallingly misused. Because this is terrifying, it is tempting to turn away from thinking about it. Those who oppose ante-natal screening claim it to be eugenic and they give the example of Nazi case in support of their claim. Those who are willing to consider the development of some of these technologies say, and probably think, that nothing eugenic will arise.[22] The existence of genetic screening

18 The term eugenics is derived from the Greek word "eu," meaning good or well, and "genos", meaning offspring.

19 See, for example, R.A. Lindsay, "Enhancements and Justice : Problems in Determining the Requirements of Justice in a Genetically Transformed Society" 15*Kennedy Institute of Ethics Journal* 3-38 (2005); M. Mehlman, "The Law of Above Average: Leveling the New Genetic Enhancement Playing Field" 85 *Iowa Law Review* 517-93 (2000); C. Farrelly, "Genes and Equality" 30 *Journal of Medical Ethics* 587-92 (2004).

20 Embryo transfer largely avoids entanglement with the abortion issue.

21 Jonathan Glover, "Eugenics and Human Rights", in Justine Burley, *supra* note 2 at 103.

22 *Id.* at 104.

programmes for certain serious disorders, with the women or couples being given the option of terminating the pregnancy if genetic disorder is detected, makes a difference to how many people of different kinds are born. Some have seen this as an unacceptable case of eugenics.[23]

If to practice eugenics is to intend the birth of some kind of people rather than other, these parents, in aiming at the birth of a baby without genetic disorder rather than one with the disorder, were making a eugenic choice. One anti-eugenic view can be expressed by saying that one should prefer the slogan 'make people healthy' to 'make healthy people'. Gene therapy largely fits this. But there are complications. One complication as raised by Jonathan Glover is the contribution of genes to a person's identity. Perhaps replacing a gene, which contributes to a disorder, is little threat to the identity of the person. But massive genetic changes could blur the boundary between changing the characteristics of one person and replacing one person by another. The other complication as raised by Glover is about germ-line gene therapy. This means that the genetic change is passed down to future generations. Germ-line gene therapy can be seen as not just curing a disorder in one person but as changing the gene-pool.[24]

V Property rights and patent protection in the human genome

Controversies generated by genetic information as property rights around the world have driven countries to adopt varied approaches to patentability.[25] In Europe, the European Biotechnology Directive[26] states that neither the human body nor any of its elements can be patented at the various stages of its formation and development.[27] Although it permits the patentability of an element "isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene,"[28] it clearly excludes from patentability any inventions that, if commercialised, would be contrary to public policy or morality.[29]

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23 *Id.* at 106.

24 *Id.* at 110.

25 T. Caulfield, & L. Sheremeta, "Biotechnology Patents and Embryonic Stem Cell Research: Emerging Issues" 1 *Journal of International Biotechnology Law* 142(Part II, 2004).

26 Directive 98/44 E.C. of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions. This is a European Union directive in the field of patent law, made under the internal market provisions of the Treaty of Rome. It was intended to harmonise the laws of member states regarding the patents of biotechnological innovations, including patent varieties and human genes.

27 Directive 98/44/E.C,*id* , art. 5 (1).

28 *Id.*, art.5(2).

29 *Id.*, art. 6(1).

At the international stage, the World Trade Organisation (WTO) rules on intellectual property,[30] stipulates what qualifies as a patentable subject matter: Patent shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.[31]

This rule covers all forms of technology, the place of invention and whether products are imported or produced locally.[32] This wide application covers even the field of biotechnology in so far as the material or method passes the article 27(1) test. TRIPs also limit a patent holder's exclusive right to twenty years from the date of filing.[33] The European Group on Ethics in Science and New Technologies was requested by the President of the European Commission to look into the ethical aspects of the patentability of inventions involving human cells. In the group's opinion, the need to avoid excessively broad patents on human cells lines was underlined.[34]

Property rights in the human body are fundamental natural rights. The US Supreme Court in *Union Pacific Railway Co.* v. *Botsford*[35] acknowledged that: "No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others..."[36] Of course, people also have the right to exclude others from their bodies. People should have property rights in their personal genetic information. They should be protected by law as an incorporeal thing against misappropriation and misuse, including discrimination in employment or insurance contexts.

The rationale for ownership right is twofold: ownership will protect the basic human rights of privacy and autonomy and it will enable the data subjects to share in the tangible benefits of the genetic research. Proponents of this viewpoint often cite the principle of genetic exceptionalism, which asserts that genetic information needs a higher level of protection than other kinds of personal information such as financial data. One may argue, however, that the recognition of such ownership rights would lead to inefficiency along with the disutility of genetic discoveries.

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30 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments—Results of the Uruguay Round, Vol. 31, 33 I.L.M. 81.

31 TRIPs, art. 27(1).

32 *Ibid*

33 *Id.*, art. 33.

34 European Group on Ethics in Science and New Technologies, Opinion No. 16, May 7, 2002.

35 141 US 250 (1891).

36 *Id.* at 251.

Biomedical research will be hampered if property rights in genes and genetic material are too extensive. One may also contend that other mechanisms such as informed consent and strict confidentiality rules can accomplish the same result as a property right without the liabilities of an exclusive entitlement.

The expansive version of the property argument is that ownership rights should be conferred on genetic source material including the human tissue sample and any information about the genes derived therefrom. There are narrower versions of this argument but in general what is being discussed is the proprietary "rights of sources". The major rationale for providing these rights is the protection of privacy. Obviously, if this information becomes too widely available or falls into the wrong hands, one's privacy rights are put in the gravest peril. While some maintain that genetic information (in the form of test results) is just an additional component of a person's overall medical record, others support the position of "genetic exceptionalism," that is, "genetic information is sufficiently different from other kinds of health-related information that it needs special protection." Hence, if this position has plausibility, it is imperative that genetic information be regulated more stringently than other forms of personal data. Currently, there are no specific laws regulating the dissemination of this information, despite the fact that genetic testing (that is, testing of DNA to ascertain an individual's predisposition to a genetic illness or impairment). Finally, genetic information is unique in that it doesn't just reveal one's present condition but also future probabilities and predispositions to certain ailments. One's DNA is analogous to "diary" of a person's future medical conditions. Therefore, unlike other forms of data, it is subject to broad and subjective interpretation, opening up considerable room for bias and manipulation. If an employer administers a drug test on the employee and the employee either passes or fails that test; there is usually nothing ambiguous about the results. But what if the same employee takes a genetic test and it reveals that he has gene X which causes diabetes depending upon one's overall genetic background?

DNA material including genes, gene fragments (called expressed sequence tags or ESTs), and related products, are considered to be patentable subject matter. The patent law does not cover "the gene as it occurs in nature,"[37] but when a gene has been isolated and purified it is considered to have been modified. This makes it a "new composition of matter" eligible for patent protection. This conclusion seems consistent with the US Congress's apparent intention that the patent statute covers "anything under the sun that is made by man." Three types of patents are possible: structure patents, covering the isolated and purified gene; function patents, covering a new use for the DNA in question (such as a diagnostic test or gene therapy); and process patents which cover a new method of isolating, purifying, or synthesising

37 Utility Examination Guidelines, 2001.

this DNA material. The patentability of genetic material such as DNA sequences is an intricate and complex issue. Supporters of those patents argue that without the incentive of patents the genome will not be adequately exploited by researchers. Opponents such as Hettinger argue against patents out of respect for life, which should not be the subject of patents. The source or raw material for the gene patents is human tissue, and some ethicists claim that patents should not be given for human material.[38]

The validity and scope of patent protection in the human genome is a question demanding a seperate study. But the issue of gene patentability is analogous to the question of ownership of an individual's genetic information and deserves some treatment. A tenable case has been made on utilitarian grounds that property rights in genetic material are unsound since the social costs are disproportionate to the benefits received. Those costs include the inhibition of research and higher prices for therapeutic products and genetic screenings. Society benefits tremendously from the enhancement of human health through biomedical research and loss (such as undeveloped treatments or genetic screening products) is quite substantial. It may be that privacy and autonomy are marginally safer with a property right, but, here it may be suggested that sound privacy legislation based on informed consent can be an effective means of ensuring genetic privacy and autonomy.

Some might still argue that social welfare concerns such as innovation in biotechnology should not decisively trump an ownership right in one's genetic material and information. But there is no evidence that a property right is a necessary condition for protecting the privacy of genetic information or the autonomy of genetic data subjects. It is certainly possible to develop an alternative means for safeguarding genetic privacy. Thus, the enhancement of biomedical research and the protection of privacy are not mutually incompatible goals. The principle of informed consent can go a long way to protect basic human rights without the need for an exclusive entitlement. Thus, if privacy is a necessary condition of one's security and well-being in the modern, computerised society, preserving the confidentiality of genetic information is of paramount importance. The potential for discrimination and stigmatisation is significant and the substantial harm suffered by the careless dissemination of this predictive data is beyond dispute.

An individual's genetic information can best be protected by laws that treat genetic information as a kind of private property and not through a privacy regime. Genetic information can be protected by as personal property in many ways, including as *quasi property*, as *jura in re propria*[39] or what it may be called "*quasi in rem property*".

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38 N. Hettinger, Patenting Life: Biotechnology, Intellectual Property and Environmental Ethics, 22 *Boston College Environmental Affairs Law Review* 267(1995).

39 Black's *Law Dictionary* 1253 (8th Edition, 2004).

One can make a principled argument that genetic information is best protected as *tangi non possunt*—an incorporeal thing—the subject matter of a right...within the sphere of proprietary or valuable rights.[40]

VI Access to genetic information: by whom and under what conditions?

The issue of access is an important one, both for ensuring maximum benefits to the subject and the society. But the question is, who should have access to genetic information, has been hotly debated for over a decade. Yet, the tentative solution appears in favour of governments and industry policy with regard to insurance and employment as well as in professional guidelines concerning communication of medical information to at-risk family. Genetic liberty must at least include the right to control the use of genetic information (including some form of ownership) and the right to exclude others from use and control. Extension of a privacy right in genetic identity or persona is a way to protect an individual's genetic information.[41] However, it sidesteps the reality that to prohibit or control another's use of his identity for commercial gain, or to otherwise harm the individual, is exercising an individual's property right. The Colorado statute protecting genetic information as an individual's unique property does so "(t)o protect individual privacy and to preserve individual autonomy."[42]

Employment and the use of genetic information

As genetic databases become more common worldwide, there has been a concurrent rise in the use of testing by employers. Although there are legitimate uses of genetic testing, such as the prevention of occupational diseases, there is also concern that employers will use these tests to discriminate against current or potential employees. Without legal intervention, information indicating, for example, whether someone is prone to a debilitating illness or even an "undesirable" condition (such as laziness or depression) may be used by employers to discriminate against employees. Employers could hire only those people whose genes indicate, they are resistant to the health hazards of the work place, which is a cheaper alternative to making the work place safe for all.

Since genetic information can predict an individual's medical future, the employer may require an applicant to undertake a predictive genetic test to determine whether the applicant has a genetic variant that increases the likelihood of that person developing symptoms of a genetic disorder due to the particular workplace or that

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40 *Id.* at 1518.

41 See, Janet A. Kobrin, "Confidentiality of Genetic Information", 30 *UCLA Law Review* 1283 (1983).

42 Colorado Revised Statute Ann. 10-3-1104-7 (1) (c).

renders the individual undesirable to the employer. As Orentlicher points out, however, "employers may have some interests in knowing whether an employee has a genetic risk of disease...particularly...when the public's safety is at stake. Society, then, will be faced with a conflict between an individual's right to privacy in his or her genetic composition and the employer's interest in knowing about its workers' health problems."[43]

Bartha Maria Knoppers[44] briefly describes the public concern with the ethical, legal, and social implications of access to genetic information by insurers and employers. The sources of concerns can be traced as:

First, employment and insurance are two of the most tangible ways in which genetic information may be used to the detriment of individuals. Employers and insurers who have genetic information about individuals are able to discriminate on the basis of genetic factors, thereby denying individuals an opportunity to earn a livelihood and provide for the financial security of themselves and their family.[45]

Second, individuals' legitimate concerns about genetic-based discrimination frequently affect their health decision-making. Already, many individuals who are at risk of genetic disorders forgo genetic testing or participation in research because they fear the results will be obtained by their employer or insurer, thereby causing them either to lose or never to gain access to employment or insurance.[46] Employers have an economic interest in the health of their employees.

Third, the disclosure of genetic information to employers and insurers raises important concerns about the privacy and confidentiality of genetic information, including the psychological and social consequences that flow from these disclosures.[47]

In today's competitive society, employers and insurance companies seek to control costs of every opportunity. Many biologists and social scientists are expressing concerns that these agencies will seek to use the information coming from the Human Genome Project to screen prospective employees and policy holders. Scientists think that tests can be developed to indicate high risk for genetic illnesses, susceptibility to heart disease, alcoholism, and perhaps even personality or behavioural disorders. Positive test results for any of these problems might be used to deny employment or insurance coverage.

Employers, however, may argue that they have an economic interest in the health of their employees. Certainly, when employees are in poor health they are

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43 D. Orentlicher, "Genetic Screening by Employers" 7 *Journal of the American Medical Association* 1005-08 (1990).

44 *Supra* note 2 at 42-43.

45 *Id.* at 42.

46 *Id.* at 42-43.

47 *Id.* at 43.

less productive, have a higher rate of turnover, are more likely to use sick leave, and are more likely to suffer injury and illness on the job. And their illness may adversely affect the morale of co-workers and customers. Genetic information could be used to predict which asymptomatic individuals are likely to develop late-onset monogenetic disorders (*e.g.* myotonic dystrophy) as well as those who are at increased risk of multi-factorial disorders (*e.g.* cancer and cardio-vascular diseases). In some unusual situations, a genetic disorder may predispose individuals to occupational disease (respiratory disorders) when combined with occupational exposures (dusty conditions). In other rare situations, a genetic disorder (*e.g.* Marfan syndrome) may suddenly incapacitate an employee, causing risk of serious injury to the employee, to co-workers, or to the public.[48]

Application of genetic information for insurance policies

In studies of genetic discrimination, however, applications for insurance policies were rejected for reasons that reflect serious misunderstandings of genetic disease.[49] A gene may be present but "silent," or its effect may not become manifest for some time nor pose any increased safety risk. In those situations, persons may be denied insurance policies far ahead of posing any safety risk.[50] In addition, the use of genetic information by an insurer raises the ethical consideration of whether an individual has a right 'not to know' that he or she has a predisposition to a genetic condition, particularly one that is incurable. Beckwith and Alper concur, stating: "It is not surprising that genetic information is used by health and life insurance companies in making underwriting decisions. From the perspective of these companies, genetic information should be used in exactly the same way as all other types of predictive medical information. In fact, insurers argue that not using genetic information is irrational because it results in unfairly high premiums for those without genetic diseases."[51] In some places, there are restrictions on what insurance companies can ask when deciding whether to insure someone or how much to charge for insurance. The Americans with Disabilities Act, 1990 may also serve to protect individuals who are perceived by employers and insurers to have a disability as a result of genetic-test result.

Keeping international guiding principles of both UNESCO's Declaration on the Human Genome and Human Rights and the Council of Europe's Convention on Biomedicine, it is obvious that fundamental to all three areas—insurance,

48 *Id.* at 44.

49 *Ibid.*

50 *Ibid.*

51 J. Beckwith & J.S. Alper, "Reconsidering Genetic Antidiscrimination Legislation" 26 *Journal of Law, Medicine and Ethics* 205-10 (1998).

employment, and a possible duty to warn—is the classification of genetic information, not as distinct or different, but as sensitive. If treated as such, the central consideration, then, is its use for the purposes of the health and well-being of the person and his/her family, through protection, promotion, and prevention. To that end, there is an absolutely urgent need to reinforce and strengthen existing legislation on the confidentiality of medical and research data generally.[52]

Insurance is based on the complementary principles of solidarity and equity in the face of uncertain risks.[53] It is plausible that if insurance companies could use the results of genetic test many people would be denied vital health and life insurance. The goal of business is to make money. Selling insurance to an individual predetermined to have a genetic disorder (whether they have it or not) is not a money making proposition, because of the increased rate the company would pay out for the individuals health needs. The denial of insurance brings out the classical case of discrimination. Discrimination due to genetic composition is the loudest alarm in the genetic screening debate. Genetic discrimination by insurance companies could leave millions of people without protection and cause an increased burden on the already flooded medical assistance programs.

VII Uses and (misuses) of genetic information

At present, a technique is available that allows scientists to test the DNA of an unborn child for the presence of some hereditary disorders. Included among these disorders are muscular dystrophy, cystic fibrosis, Huntington disease, and Down syndrome. Having such knowledge is both a blessing and a burden for parents. It prevents the shock and agony of learning about the condition when the child is born. The advance knowledge can help parents to prepare, both emotionally and financially, for having a disabled child. Some parents may face a decision about whether or not to carry the foetus to term.

One positive aspect in dealing with genetic information is that parents who have genes that may cause mental retardation in their children should be told the medical facts and informed of the risks entailed in child bearing. Most gynaecologists are of the opinion that if parents have a child with Down's syndrome or phenylketonuria (PKU) which is hereditary disease caused by the lack of the enzyme must be told that their chances are one in four of having a second child with this condition.[54]

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52 *Supra* note 2 at 50.

53 P. Harper, Insurance and Genetic Testing, *The Lancet* 224-28 at 225 (Jan 1993).

54 Harry Gottesfeld, *Abnormal Psychology: A Community Mental Health Perspective* 389 (Chicago: Science Research Associates, Inc., 1979).

Genetic information has many positive uses in the legal arena of criminal law, a genetic defect may be raised at trial to prove lack of mental capacity to commit the crime; biological explanations, such as organic brain syndrome, have been considered admissible exculpatory evidence. At sentencing, genetic information can be a mitigating factor in the punishment phase to explain defendant's behavior, resulting in a lesser sentence. At a parole hearing, the government might introduce defendant's genetic predisposition to violence and other anti-social behavior which makes the individual a likely recidivist who should be denied parole.

Genetic information is also different because of how it has been used in the past. History has provided painful lessons in the misuse of information, in the mistreatment of people, and even in the planned destruction of whole groups of people because of beliefs about their genes. Much of this unfortunate history can be traced to the ideas of Francis Galton—an illustrious British scientist, mathematician, and a cousin of Charles Darwin. In 1883, Galton's notion of biologically superior and biologically inferior humans became codified in the term "eugenics". Eugenics was proposed by Galton as the explanation for why some people achieved more in society—economically, socially, or politically. Such individuals, Galton claimed, were superior in hereditary endowment. On the other hand, people from the lower classes were inferior in their biological endowment. Curiously, social or economic factors that could account for these features were disregarded.

It is necessary to look hard at what made the eugenics of the Nazis so terrible.[55] The Nazi eugenic policy had three features which mark it off sharply from current medical debates. The Nazis had a blueprint of the most desirable type of person. They believed in social Darwinism and 'racial self-defence'. And they were indifferent to the autonomy or interests of particular individuals.[56] There was the idea that only the best people should be encouraged to procreate. The *Lebensborn* Programme was set up for this. There was a supposedly scientific basis for belief in a distinct 'Aryan' type of person. In practice, the criteria for choosing the 'best' people were very crude and mainly physical. The other part of the Nazi's programme was that some

55 During the Nazi era in Germany, eugenics prompted the sterilisation of several hundred thousand people then helped lead to anti-Semitic programmes of euthanasia and ultimately, of course, to the death camps. The association of eugenics with the Nazis is so strong that many people were surprised at the news several years ago that Sweden had sterilised around 60,000 people (mostly women) between the 1930s and 1970s. The intention was to reduce the number of children born with genetic diseases and disorders. After the turn of the century, eugenics movements—including demands for sterilisation of people considered unfit—had, in fact, blossomed in the United States, Canada, Britain, and Scandinavia, not to mention elsewhere in Europe and in parts of Latin America and Asia. Eugenics was not therefore unique to the Nazis. It could, and did, happen everywhere.

56 Ruth Deech, "Cloning and Public Policy", in Justine Burley, *supra* note 2 at 110.

should be discouraged from having children, or even prevented from doing so.[57] The Nazi ideology was not one of the importances of the individual. There was a conception of the pure race and of the biologically desirable human being. Reproductive freedom and individual lives were to be sacrificed to these abstractions.[58] The eugenic improvement of human nature is a project surrounded by dangers and nightmares.

The history of the eugenics movement has led to the current concern—even fear—that the new forms of DNA testing, whether for the presence of single genes that can bring on severe illnesses or for genes that can provide clues about susceptibility to chronic diseases, could lead to stigmatisation and discrimination. There are concerns that genetic test results could be used to deny insurance, jobs, educational opportunities, and even government services for mutation carriers or their nearest relatives. What is less easy to accept the idea whether it is good for parents to be able to abort foetuses that will certainly suffer from genetic disorders?

Regardless of how worthy our ends may be—and even, indeed, when they strongly include concern for the well-being of those others—we are not allowed to impose paternalistically to impose these upon them. Persons must be treated as what Kant called 'their own masters' or, in a more recent phase, as self-owners.[59] Kant says that happiness should not be our goal but he also says one must respect moral agents. Practices like slavery and Nazi eugenic programmes are only the most dramatic examples of not treating persons as self-owners.[60]

VIII International guidelines on genetic testing

There are a number of international measures which control the use of genetic testing. Crucial to any reforms at the national level is the adoption and integration of the guiding principles of UNESCO's Declaration on Human Genome and Human Rights and the Council of Europe's Convention on Biomedicine. The UNESCO Declaration on the Human Genome and Human Rights[61] provides under article 6

57 In 1923 Lenz, together with his colleagues Erwin Baur and Eugen Fischer, wrote a textbook, *Outline of Human Genetics and Racial Hygiene*, said to have been read by Hitler, and whose ideas find echoes in *Mein Kampf* These ideas influenced the sterilisation law brought in when Hitler came to power in 1933. This made sterilisation compulsory for people with conditions including schizophrenia, manic depression, and alcoholism.

58 *Supra* note 56 at 114.

59 Kant, *Metaphysics of Morals* 63 (Cambridge: Cambridge University Press, 1996). A thorough explication of the concept of self-ownership is to be found in G.A. Cohen, *Self-ownership, Freedom and Equality* (Cambridge: Cambridge University Press, 1995).

60 Hillel Steiner, "Silver Spoons and Golden Genes: Talent Differentials and Distributive Justice" in Justine Burley (ed.), *supra* note 2 at 135.

61 Universal Declaration on the Human Genome and Human Rights: UNESCO, November 1997.

thus:

> No one shall be subjected to discrimination (by which it means unjustified discrimination) based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

And in article 7:

> Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential under the conditions set by law.

Similarly the European Convention on Human Rights and Biomedicine[62] explicitly prohibits any form of discrimination (by which it means unjustified discrimination) on the grounds of genetic heritage (article 11). And in article 10: "everyone has the right to respect for private life in relation to information about his or her health." Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be informed shall be observed. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient. In addition, article 12 provides that, "Tests which are predictive of genetic disease or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes and subject to appropriate genetic counselling." However, it should be noted that this is not an unqualified right, since article 26 of the Convention allows certain restrictions on the exercise of article 12's protective provisions. The UK Government has not at present signed the convention and so its requirements are not currently binding on UK (a member of EU).

There is considerable diversity of approach within the EU, and varying definitions of "genetic testing" and "genetic information" make interpretation complex. In Austria, employers and insurance companies are prohibited by law from collecting, demanding, or using data derived from genetic tests. Danish legislation aims to ensure that health checks focus on actual/present health conditions and that those conditions are relevant to the employee's work. A working group reporting to the Finnish Ministry of Social Affairs and Health has recommended that employers should not be allowed to subject job seekers to genetic testing during recruitment, or to test employees already hired. French bioethics legislation specifically

62 Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Council of Europe, 1997.

prohibits access by any third party, notably employers and insurance companies, to information held in databanks and makes it illegal for them to ask individuals to provide such information. In the Netherlands, the Medical Examination Act of 1997 prohibits employers from applying medical criteria to recruitment unless there is an unambiguous health requirement for the job. There is also diversity outside the EU. Employers in Japan do not require employees to undergo genetic testing, however they may undertake genetic testing when undiagnosed diseases are being investigated as part of in-work health checks.

The European Group on Ethics in Science and New Technologies (EGE) published an opinion in 2003, detailing the ethical aspects of workplace genetic testing.[63] As a general rule, the report recommends that employers consider a potential employee's current health situation and not on attempts to predict future health. Additionally, the report does recognise certain "exceptional cases" where the health and safety of third parties must be protected, and prescribes a set of "stringent conditions" for such screening. Among the conditions set forth in the report is the need for documented validity of the test used, informed consent of the individual, and protection of the confidentiality of the genetic information itself, which should be provided only to an independent health professional and not to the employer.[64] Consistent with Declaration of Helsinki (adopted by the World Medical Assembly in 1964, and amended in October 2000) and the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997), the basic ethical principles that should be followed in genetic research and services are : Autonomy,[65] Privacy,[66] Justice[67] and Equity.[68]

Despite disparity there is considerable unanimity among EU countries on the issue of genetic information. On June 13, 2007, all EU countries agreed to unrestricted access to genetic information, fingerprints, and car registration in all EU police databases.[69] Thus, police in one EU country will be able to enter a suspect's

63 European Group on Ethics in Science and New Technologies, "Ethical Aspects of Genetic Testing in the Workplace," July 28, 2003.

64 *Ibid.*

65 Autonomy: Choice of participation in genetic testing and medical research should be autonomous, voluntary and based on informed consent; persons or groups with diminished autonomy should be given protection.

66 Privacy: Identifiable information (clinical, genetic, *etc.*) of individuals or groups is confidential and should be protected. Data privacy is an increasingly important issue in the healthcare industry. All individuals—including patients, employees, consumers or investors—expect protection of their personal data, which can comprise name, work and home address, family information, employment or financial details, or more sensitive health information.

67 Justice: There should be no discrimination against individuals (born or unborn including embryo) or groups. No harm should be done and benefits should be maximised.

68 Equity: There should be equitable access to information, tests and procedures.

69 Ian Traynor, "DNA Database Agreed for Police Across EU" *The Guardian* 13 Jun. 2007.

genetic data into a database and obtain matches for any other EU countries as well. The new system will also feature the sharing of fingerprints and pictures for non-EU citizens seeking visas to enter Europe. The system can store the data for up to 70 million people. It has been hailed as a way to tackle immigration issues and transnational crime.[70]

IX Disclosure of genetic disorder in medical practice

The doctrine of confidentiality in the practice of medicine was promulgated to encourage free and open communication between patient and physician, aid in diagnosis and treatment, and reassure the patient that the information disclosed to the physician or obtained by the physician through diagnosis within the confine of the physician-patient relationship would remain secret. At the same time, physician owes duty to warn relatives and other members of the society if their interests are involved. The main case concerning a practitioner's duty to disclose medical information to third parties is *Tarasoff* v. *Regents of the University of California*.[71] In this case, during treatment of out-patient (Posenjit Poddar), Moore, psychologist at University of California, learned that Poddar intended to kill Tatiana Tarasoff for refuting romantic advances. Moore had warned campus police of Poddar's intentions, and that the police had briefly detained him, but then released him. Two months later Poddar shot and stabbed Tatiana. Plaintiffs (Tatiana's parents) brought a wrongful death claim against the four psychologists for their failure to constrain Poddar and their failure to warn Tatiana. In this case, the trial court dismissed the cause of action, and the appellate court supported the dismissal. An appeal was then taken to the California Supreme Court. The main issue in this case was whether the relationship between a therapist and a patient support the duty on the part of the therapist to exercise reasonable care to protect identified third parties against dangers posed by the patient's illness?

In *Tarasoff*, the Supreme Court of California addressed a complicated area of tort law concerning duty owed. Their analysis required a balancing test between the need to protect privileged communication between a therapist and his patient and the protection of the greater society against potential threats. The court held that a psychologist could be liable for not warning a murder victim that one of the psychologist's patients expressed intent to kill her. The court weighed the confidentiality interests against the public interest in safety from violent assault, and concluded that "the public policy favouring protection of the confidential character of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert dangers to others."

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70 *Ibid.*

71 551 P. 2d 334 (Cal. 1976).

Although under the common law, as a general rule, one person owes no duty to control the conduct of another[72] nor to warn those endangered by such conduct,[73] the courts have carved out an exception to this rule in cases in which the defendant stands in some special relationship to either the person whose conduct needs to be controlled or in a relationship to the foreseeable victim of that conduct.[74] Applying this exception to the present case, the relationship of defendant therapists to either Tatiana or Poddar will suffice to establish a duty of care; as explained in section 315 of the Restatement Second of Torts, a duty of care may arise from either "(a) a special relation ... between the actor and the third person which imposes a duty upon the actor to control the third person's conduct, or (b) a special relation ... between the actor and the other which gives to the other a right of protection."[75] Here, it may be noted, an additional duty may be imposed on the medical geneticist to recall former patients to inform them about newly discovered risks of treatment as well as current and future information about conditions that are or could be inherited.

However, in *Oslon* v. *Children's Home Society of California*,[76] the appellate court found no duty to disclose a genetic condition to relatives. The case involved a woman who had agreed to have her infant son adopted. Thirteen years later she, then married, gave birth to another child who later died of a genetic disease. When she contacted the adoption agency to inquire about the health of the son she had put up for adoption, she was informed that the child was still alive, but also had the genetic condition. She and her husband sued the agency for wrongful death of their son, intentional infliction of emotional distress, and fraud, claiming that the agency had a duty to warn them that her child had a genetic disease. The trial court dismissed the complaint and the appellate court affirmed, holding that there was no special relationship between her and the agency that created a duty to notify her of the risk of having another child.

The special relationship situations generally involve some kind of dependency or reliance.[77] In *Mann* v. *State*,[78] the court recognised the trend toward recognition of a duty to aid and protect in any relationship of dependence or of mutual dependence. One of the requisite factors to a finding of special relationship is detrimental reliance by a person on conduct of another which induced a false sense

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72 *Richards* v. *Stanley* (1954) 43 Cal. 2d 60, 65 [271 P.2d 23]; *Wright* v. *Arcade School Dist.* (1964) 230 Cal. App. 2d 272, 277 [40 Cal. Rptr. 812]; Rest. 2d *Torts* (1965) § 315).

74 Prosser, *Law of Torts* § 56, 341(4th ed. 1971).

74 Restatement Second of Torts, ss. 315-320.

75 *Tarasoff* v. *Regents of the University of California,* 17 Cal. 3d 436 (1976).

76 (1988) 204 Cal. App. 3d 1362.

77 *J. A. Meyers & Co.* v. *Los Angeles County Probation Department,* (1978) 78 Cal. App. 3d 309.

78 (1977) 70 Cal. App. 3d 773.

of security and worsened the position of the person relying on the conduct.[79] In *Pate* v. *Threlkel*,[80] the Supreme Court of Florida recognised the duty to warn patient of transmissibility of genetic disease to child. In *Schroeder* v. *Perkel and Venin*,[81] the New Jersey Supreme Court held that the physicians had a duty to the child as well as an independent duty to the parents to disclose that the child suffered from cystic fibrosis. Failure to diagnose the disease and advise the parents was a breach of the physicians' duty to the parents.

In another case, in *Safer* v. *Estate of Pack*,[82] the Supreme Court of New Jersey held that a physician has a duty to warn individuals known to be at risk of avoidable harm from a genetically transmissible condition. In *Safer*, a woman was diagnosed with colorectal cancer due to familial adenomatous polyposis, an autosomal-dominant condition predisposing to colorectal cancer. She filed a complaint against the estate of Pack, the deceased physician who treated her father for the same condition 30 years earlier, alleging a violation of duty on the part of this physician because he failed to warn her of her own health risks. She argued that if she had known about her risk of having this condition, her cancer could have been detected at an early and curable stage through regular surveillance. In a decision that differed from that of the *Pate* court, the *Safer* court found that the physician's duty to warn may not be satisfied in all cases by informing the patient of the risk to his relatives. The court asserted that the physician must take reasonable steps to guarantee that immediate family members are warned.[83] This ruling defines a duty to warn that extends to family members in the case of hereditary conditions.

One criticism of wrongful life and wrongful birth actions is that these actions seem to be inherently discriminatory towards the disabled.[84] Parents undoubtedly face daunting emotional and financial burdens when they raise a child who has a disability. However, allowing an action for wrongful birth or wrongful life is not the answer. These claims encourage eugenic abortions, by both parents and by medical providers alike. For someone who is actually living life with a disability, recognition of these causes-of-action must seem disrespectful and morally reprehensible, if not utterly revolting. Current legal and professional policies privilege respect for patient autonomy and allow disclosure to third parties without the patient's consent only as a last resort in exceptional situations. One reason is that physicians'

79 *Williams* v. *State of California* (1983) 34 Cal. 3d 18, 28.

80 661 So. 2d 278 (Florida, 1995).

81 432 A. 2d 834, 841 (N.J. 1981).

82 677 A.2d 1188 (N.J. Sup.Ct. App. Div. 1996), *cert.* denied, 683 A.2d 1163 (N.J. 1996).

83 *Id.* at 1192-93.

84 See Darpana M. Sheth, "Better Off Unborn? An Analysis of Wrongful Birth and Wrongful Life Claims Under the Americans with Disabilities Act" 73 *Tennessee Law Review* 641-42 (2006).

duty to protect patient confidentiality is stronger than their duty to family members with whom they have no patient-physician relationship.

The American Medical Association's Council on Ethical and Judicial Affairs examined the consequences of genetic information for relatives in a report on informed consent for genetic testing, which led to a section on disclosure of familial risk in genetic testing in the association's *Code of Medical Ethics*.[85] The council agreed that physicians have a duty to protect their patient's genetic information, but that they should discuss the implications of genetic information for family members prior to testing and should define circumstances under which patients would be expected to notify their relatives of the risks associated with that information.

The American Society of Human Genetics' policy statement on professional disclosure of familial genetic information emphasises the conflict between the physician's duty of confidentiality to his or her patient and the duty to warn family members.[86] The report concludes that physicians have at the very least the duty to inform patients of potential genetic risks to their relatives. The existence of legal and statutory exceptions to patient confidentiality in other circumstances (*e.g.*, infectious diseases, violent crimes), suggests that physicians may have the right to warn family members when attempts to encourage the patient to do so have failed; the harm is serious, imminent, and likely; the at-risk relative(s) are identifiable; prevention or treatment is available; and a physician in similar circumstances would disclose the information (*i.e.*, disclosing would be considered standard practice).

The American Society of Clinical Oncology Policy Statement on Genetic Testing for Cancer Susceptibility recommends that physicians and counsellors address the importance of communicating genetic test results to family members in the pre-test counselling and informed-consent processes prior to testing.[87] Their position is that the health professionals' obligations to at-risk relatives are fulfilled by communicating the risks for family members to the patient and emphasising the importance of sharing this information so that family members may also benefit from it. After careful consideration of the HIPAA[88] privacy rules, this society explicitly concludes that genetic-risk information does not meet the necessary criteria for disclosing without the patient's consent.

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85 American Medical Association, Council on Ethical and Judicial Affairs Report 9 (A-03), Disclosure of Familial Risk in Genetic Testing (Chicago, IL: American Medical Association, 2007).

86 American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure, Professional Disclosure of Familial Genetic Information 62(2) *American Journal of Human Genetics* 474-83 (1998).

87 American Society of Clinical Oncology, American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility, 21(12) *Journal of Clinical Oncology 2397*-2406 (2003).

88 Health Insurance Portability and Accountability Act, 1996.

X Conclusion

Currently, human rights anti-discrimination legislation does not include 'genetic conditions' in its list of prohibitions. Some would argue that it could be included under the broad category of handicap or disability. While genetic screening has become easier and cheaper, treatment of genetic disease lags behind. Thus, while someone may have the ability to determine if they are at high-risk of disease, many people may choose not to find out due to the inability to take any precautionary measures. The concept of a "right not to know" would apply in these situations, allowing a person to control the knowledge about whether he/she has a certain genetic predisposition.

Legal protection is a double-edged sword.[89] However, genetic-specific legislation could be adopted forbidding the use of genetic information in certain sectors such as employment and insurance. Changes in the human rights law with the addition of 'genetic condition', or the adoption of specific statutes, then, are likely to be problematic in that they could further contribute to public perception of various genetic traits as 'abnormalities'. It is this very perception of abnormality, which has also contributed to the hesitancy of family members to share information amongst them, which is one more area of concern.[90] People must avoid placing unrealistic expectations on legislative solutions as they are by no means a universal panacea. They need to be mindful that there are also some drawbacks to a fixed legislative approach, particularly in an area which is undergoing rapid change. Therefore, flexible mechanisms that are capable of adapting with appropriate speed to on-going developments in genetic science and medicine are needed.

Genetic information may provide some indication of vulnerability, but it is not possible to say whether a specific individual will develop the disease, when the disease might develop, or how severe it may become. For example, the Washington Post reported in 2003 that researchers identified a gene responsible for the development of depression after exposure to extreme stress. People with a variation in the identified gene are more than twice as likely as people with the normal version of the gene to react to a traumatic event by becoming depressed. Nevertheless, 57 percent of people with the mutated gene never became depressed and 17 percent of people without the mutation developed depression in response to similar events.[91] In another instance, say for example, Huntington's disease is an inherited neurological disease that results in death by a person in their late 30s or early 40s, after a period of

89 M.A. Rothstein and B.M. Knoppers, "Legal Aspects of Genetics, Work and Insurance in North America and Europe" 3 *European Journal of Health Law* 161 (1996).

90 *Supra* note 2 at 46.

91 Shankar Vedantam, "Variation in One Gene Linked to Depression" *Washington Post*, 18 July 2003 at A1.

extended deterioration of both mental and physical control.[92] Although there is no treatment for the condition, a reliable test for Huntington's does exist. The inheritability of the disease is straightforward, as demonstrated by the fact that children of a person with Huntington's will have a 50 percent chance of also being affected.

In Russia, scientists are discussing the adoption of genetic passports.[93] They believe the passports would prevent disease because they would allow for early detection of an individual's predisposition to numerous health problems, including cardiovascular disease, neurological disorders, and cancer. The test would also allow parents to gain a "genetic portrait" of their newborn children. A genetic passport would also allow for adoption of personalised medicines.[94]

In some context, international rules are being developed to promote the observance of minimum standards in the protection of human genetic information. As stated above, in 1997 the United Nations Educational, Scientific and Cultural Organisation (UNESCO) adopted the Universal Declaration on the Human Genome and Human Rights. The declaration seeks to establish high-order principle but that is not binding on member states. An instrument of binding instrument is the Council of Europe's Convention on Human Rights and Biomedicine, which seeks to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regards to the application of biology and medicine. One should look to the precedents in both international and comparative law for inspiration regarding ethical and legal solution for regulating the privacy of genetic information.

A key component of concern is the perception that there are no or inadequate controls over the process and outcomes of the development and application of gene technology in the area of employment and insurance. Although it is not possible to endorse a particular regulatory solution in advance for all circumstances, one may recognize the need for a range of flexible solutions including guidelines, codes of practice and better education. The rules protecting genetic information must be clear and known to the medical, scientific, business and law enforcement communities and the public.

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92 National Institute of Neurological Disorders and Stroke, "NINDS Huntington's Disease Information Page," Office of Technology Assessment (OTA): Genetic Monitoring and Screening in the Workplace, OTA-BA-455, 13 (Washington, United States Government Printing Office, October 1990), (As cited in *Conditions of Work Digest, "Workers' Privacy III: Testing in the Workplace,"* 66 (International Labour Office 1993).

93 "Genetic Passport Will Foretell the Future" *Science and Life* 20 Jan. 2006.

94 *Ibid*