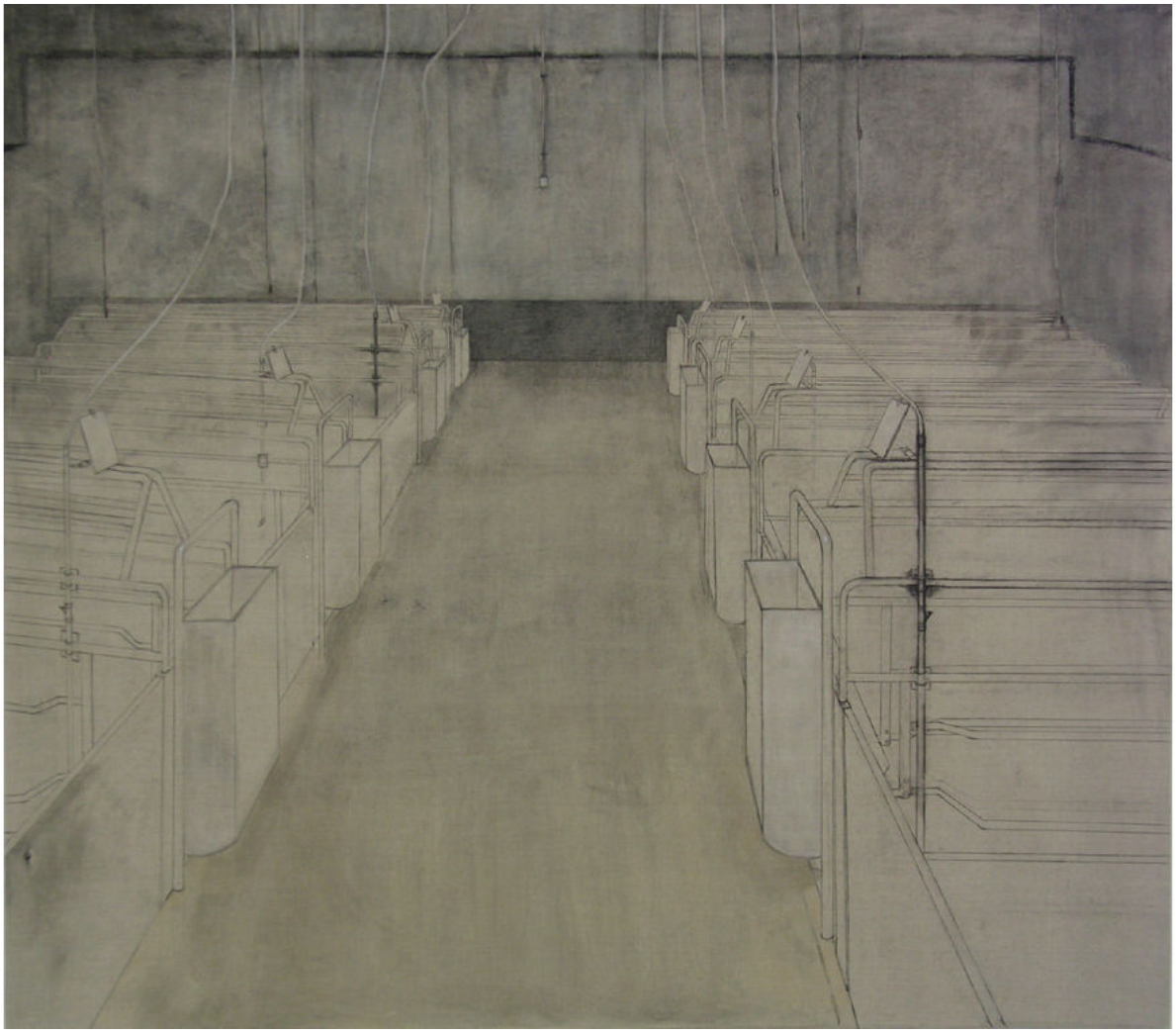
Genetics, Human Rights and the Next Phase of Human Evolution



Observation Room I, 2007 Charcoal and Pastel on Linen, 52” x 60” **by Amie Rangel**

Alberta Civil Liberties Research Centre

Genetics, Human Rights and the Next Phase of Human Evolution

By the
Alberta Civil Liberties Research Centre

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I dedicate this project to Alyssa, my heart.

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Foreword

The Alberta Civil Liberties Research Centre (ACLRC) has a mandate to promote public awareness of civil liberties and human rights issues through research and teaching. This particular report evolved from a proposal for a research project about privacy issues and DNA sampling that an Edmonton lawyer named Joann Blais had originally made to the ACLRC back in 2004.

A multidisciplinary conference addressing the various ethical and legal issues that arise in the field of human genetic research took place at the University of Calgary (U of C) from November 15-17, 2007. The conference, *One Origin, One Race, One Earth: Genetics, Human Rights and the Next Phase of Human Evolution*, was hosted by the ACLRC and the University of Calgary's Department of Medical Genetics. The ACLRC is grateful for the generosity of the following conference sponsors: Alberta Law Foundation, Alberta Lottery Fund, Calgary Health Region, U of C Special Projects Fund, U of C Faculty of Medicine, Genome Alberta, Alberta Heritage Fund for Medical Research, Genzyme, AmGen, MacLeod Dixon LLP, U of C Executive Suite Fund, Brian Seaman, and Brian Edy.

An exhibition of original works of art addressing the theme of human rights and human genetic research took place during the week of the conference at the U of C's Faculty of Fine Arts. An independent jury of art professors from the U of C and the Alberta College of Art and Design (ACAD) had the difficult task of selecting from the various outstanding submissions the one they felt was most representative of the conference theme. The work they selected is the drawing that appears on the cover of this report. The drawing is of a farrowing room at the Swine Research and Technology Centre at the University of Alberta where research in reproduction and sow fertility is conducted. The stark, grey outlines of the stalls suggest an atmosphere of bleakness and despair. I discussed this work with its creator, Amie Rangel, who was at the time enrolled in the Master of Fine Arts programme at the University of Alberta. When I told her that I found the work unsettling and evocative of grainy black and white photographs that I'd seen of Nazi death camps, she said it shares similar qualities through its organization of space, and that if I were feeling unsettled, then she had accomplished what she had intended.0

Many of the issues that were on the conference programme are also discussed in this report. In preparing this report, I gratefully acknowledge the contributions of the following people: Lisa Ellis, Stephen Rimac, Natalie Simpson and Emilia de Somma for their research assistance; Kristyn Stevens for editing and checking footnote references; and Rose Geransar for her steady friendship and leadership in helping to make the *One Origin* conference a reality. I also gratefully acknowledge the contribution of Kendyl Lauzon, a graduate of ACAD, who created the original artwork that accompanies each of the seven main headings of this report. Finally, I accept responsibility for any errors or omissions. I also want to stress that any opinions expressed in this report are mine, and not necessarily those of the ACLRC, its executive-director, or any of my colleagues.

> Nature is neither to be worshipped as if it were some unchanging given, nor is it to be elevated to some untouchable status as if it were fixed and immutable. Since humans have been given stewardship of the created order, the crucial issue is to determine the sort of interference with nature that will advance human welfare, at the same time respecting the dimensions of what it means to be human. This requires a great deal of enlightened ethical discernment, and an awareness of the tentative path along which we are travelling.[1]
>
> Natural selection is the blind watchmaker, blind because it does not see ahead, does not plan consequences, has no purpose in view. Yet the living results of natural selection overwhelmingly impress us with the appearance of design as if by a master watchmaker, impress us with the illusion of design and planning.[2]
>
> Indeed, the respect of human personality is based on the recognition of man's dignity as a worker for evolution, as a collaborator with God. This dignity rests on the new mechanism born with conscience which orients evolution in a spiritual direction, namely, free will. We cannot conceive of a dignity deprived of responsibility, and that which is assumed by man is considerable. Not only his own fate, but the fate of evolution is in his hands. At any moment, he can choose between progression and regression. That is the meaning, as we have seen, of the second chapter of Genesis."[3]

Brian Seaman, Research Associate
January 2010

[1] Gareth Jones, *Clones: The Clowns of Technology?* (Carlisle, U.K.: Paternoster Publishing, 2001), page 131 [Jones].
[2] Richard Dawkins, *The Blind Watchmaker* (New York, N.Y.: W.W. Norton & Co., 1986), page 21 [Dawkins].
[3] Pierre Lecomte du Nouy, *Human Destiny* (Toronto, ON: Longmans, Green and Co., 1947), pages 133-134 [Lecomte du Nouy].

Introduction

Introduction

Ask a random group of a hundred people what they know about DNA or genetics in general and the following could be expected. Many would conjure up images of CSI technicians diligently working to come up with the genetic profile for a suspected killer from a few drops of blood or other human tissue found at a crime scene, enabling the police to eventually make an arrest. There has been such wide attention to DNA and genetic science over the past few decades in news stories, novels, television shows and movies that it's difficult to imagine a media literate person anywhere who has not acquired at least a very basic knowledge of genetics, even if it is not always an accurate one. Therefore, this report has two objectives: i) an explanation of genetic science for a general reader, and ii) a discussion of the ethical and legal issues surrounding human genetic research, with particular focus on donor/patient privacy interests and consent to participate in research projects. In discussing these ethical and legal issues, reference will be made to research ethics protocols, relevant Canadian legislation, and international covenants to which Canada is a party. Throughout the discussion, an underlying theme should become apparent to the reader; i.e. the expansion of genetic knowledge –acquired in accordance with relevant laws and ethical guidelines – does not pose a threat to human rights and freedoms as such. However, the relevant question that needs raising is how this knowledge is to be equitably applied to serve the public good while avoiding the patently false assumption that the answers to many of society's social problems lie in the genes. In the area of human genetic research, law, along with relevant research ethics protocols and international covenants, has established the metes and bounds of how such research is to be conducted. However, because of the unique nature of DNA and the fact that genetics intrinsically concerns itself with the very essence of all organic life, including human, the relevant laws and research protocols need to recognize in a way that is more than symbolic that what we do today in the name of science will have a profound impact on our children and future generations. We also need to be mindful of how knowledge and theories from the field of genetic science have been horribly misapplied in the name of

social engineering in the past – most notably during the first half of the last century – and avoid such warped folly ourselves.

This report is divided into six main sections. Section I briefly sets out the history behind the Human Genome Project, which culminated in the release of the code for the human genome in 2003. There is also a brief discussion of the significance of that development for human health and a call for all persons with a vested interest in ensuring the ethical advance of genetic research to pursue their work with a view to how the fruits of their labour will affect future generations. Section II provides a brief explanation of what DNA is and introduces the reader to the concepts of genetic engineering, genetic discrimination and genetic screening, areas that will be discussed in more detail later in the report. Section III is the source of much of the report's legal discussion, as the reader is introduced to concepts in the field of law and medicine such as: personal autonomy, informed consent to participate in research projects, and genetic testing and a person's right to know the results. Section IV addresses the issue of genetic determinism and discusses the complex relationship between a person's genetic predisposition to a disease or condition and the external factors of environment and personal lifestyle choices. Section V picks up the discussion of genetic determinism from the previous section and introduces the reader to the concept and history of eugenics, which saw its most brutal application in Germany under the Nazis. The forced sterilization programmes of Canada and the United States in the pre-World War II era – although decidedly not on a scale with what occurred in Hitler's Germany and certainly without the mass, state-sanctioned murder of hundreds of thousands of people that occurred in German internment camps and hospitals – are also briefly discussed. Finally, in Section VI, the report's underlying themes are summarized, and the section ends with a recommendation for a *Genetic Charter* that would serve as single source of ethical guidelines for genetic researchers working in the area of human health, physicians, lawyers and citizens generally.

Chapter I

One Origin and One Race

I. One Origin and One Race

Statement of Purpose*: This section introduces the reader to a brief history behind the Human Genome Project. There is also a short discussion of the significance of the Human Genome Project for human health. The section ends on a philosophical note with reference to a French biophysicist and philosopher named Pierre Lecomte du Nuoy who, writing out of the ashes of World War II, hoped for a future where people would accept that we are the authors of our evolution in the moral and spiritual senses of the word. With the decoding of the human genome in 2003, humanity is now at the threshold of possibly shaping our physiological evolution as well. The rhetorical question remains: should we?*

The human genome is humanity's common heritage and future, and genetic science has finally cracked the complex chemical code for deoxyribonucleic acid (DNA) containing the instructions for life. Philosopher and author Francis Fukuyama has described human DNA as follows:

> DNA molecules are the famous twisted, double-stranded sequences of bases that make up each of the forty-six chromosomes contained in the nucleus of every cell in the body. These sequences constitute a digital code that is used to synthesize amino acids, which are then combined to produce the proteins that are the building blocks of all organisms. The human genome consists of some 3 billion pairs of bases, a large percentage of which consists of noncoding, 'silent' DNA. The remainder constitutes genes that contain the actual blueprints for human life.[4]

For dedicated genetic researchers and microbiologists, few things are more beautiful than the chemical matrix of a cell, even the cell structure of bacteria – the lowest of life forms. Genetic scientists had already mapped out the DNA sequences of less complex forms of life such as worms prior to the launch of an ambitious international effort called the Human Genome Project to decode human DNA. The culmination of many years of work involving a huge expenditure of capital and led by teams of scientists from the United States and Great Britain, the project can trace its origins to an earlier interest during the Cold War era by the United States Department of Energy in

[4] Francis Fukuyama, *Our Post-Human Future: Consequences of the Biotechnology Revolution* (New York: Farrar, Strauss and Giroux, 2002), page 73.

researching the effects of radiation on human genes when the prospect of a devastating nuclear exchange with the former Soviet Union seemed inevitable for a large number of people of that time.[5] The Human Genome Project got off the ground in October of 1990 when the U.S. Department of Energy and the National Institutes of Health (NIH) – the NIH is the federal agency responsible for public funding for health research in the United States – initiated the project.[6] The importance of the project to human knowledge and health can not be overstated, as genetic research is showing that many of the diseases and conditions adversely affecting the quality of our lives have their origins in our genes. To cite but a few examples: the gene that causes Huntington's disease has been located on chromosome number four; a cystic fibrosis allele has been located on chromosome number seven; a gene linked to colon cancer has been located at chromosome number two; mutant genes linked to two types of inherited breast cancers have been located on chromosomes seventeen and thirteen; and the genetic origins of childhood leukemia and Duchenne's muscular dystrophy have also been established.[7]

One of the driving premises for this audacious project was the hope of eventually locating the genes responsible for, in whole or in part, the thousands of conditions that adversely affect the quality of life for many people. As geneticists continue to make these discoveries in the DNA chain, how health care services will be delivered in the near future – indeed the very nature of health care – will experience significant and revolutionary change. As George P. Smith II has suggested:

> With more than 12,000 conditions being recognized as having their origins in single gene defects, the ultimate success of the Initiative [the Human Genome

[5] Kevin Davies, *Cracking the Genome: Inside the Race to Unlock Human DNA* (Baltimore, Maryland: The John Hopkins University Press, 2002), page 15 [Davies]. Decoding the human genome has, arguably, been the most ambitious and significant scientific project in history. As one microbiologist has put it: "The goal, which was to complete the sequence determination by 2003, was comparable to putting a man on the moon. The task was finished two years ahead of schedule, and by 2002 the human genome sequence, along with partial and completed sequences from 150 bacteria and eight higher organisms, was publically available." (Karl Drlica, *Understanding DNA and Gene Cloning: A Guide for the Curious*, 4th ed. (Hoboken, NJ: John Wiley & Sons, 2004), page 308 [Drlica]).

[6] Robert N. Proctor, "Genomics and Eugenics: How Fair is the Comparison?'" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 57 [Proctor].

[7] Ted Peters, *Playing God? Genetic Determinism and Human Freedom*, 2nd ed. (New York, N.Y.: Routledge, 2003), pages 5-6 [Peters].

> Project] holds awesome opportunities for improving the health of all world citizens and minimizing their human suffering from disease. [8]

Discoveries and advances in human genetic research are also having a significant impact on how pharmaceutical research is being conducted. Although it may seem incredible to anyone informed by contemporary equality values as enshrined in the *Canadian Charter of Rights and Freedoms*, pharmaceutical research projects historically have not accounted for either ethnic diversity or gender differences. We now know that not only are there gender-based differences in drug absorption rates but we also know, thanks to genetic research, that variances in the genetic markers among different ethnic groups can affect drug absorption rates too. In the United States, where much of the world's pharmaceutical research and product development occurs, formal recognition of the need to account for gender differences and ethnic diversity when conducting publicly-funded health research was not achieved until 1993 when the legislation concerning federal funding for medical research projects was amended to include women and ethnic minorities in clinical research protocols.[9] A U.S. bioethicist named John Robertson, in issuing a challenge for health care administrators and health care policy-makers there, has written a message that has equal resonance in a Canadian context:

> Meeting the health care needs of all citizens, including women and minorities, is a compelling state interest. Because biological and genetic variation in women and minorities may differ significantly from that in white males, requiring their inclusion in funded research is essential if valid information about their health is also to be produced.[10]

As geneticists pursue their research into the genetic markers for a growing number of conditions and how such markers are triggered by environmental or lifestyle factors, the challenge for anyone with an interest in improving human health – be they scientists, ethicists, philosophers, lawyers or interested laypersons – is two-fold:

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[8] George P. Smith II, *Human Rights and Biomedicine* (The Hague, Netherlands: Kluwer Law International, 2000), page 148 [Smith II]. Also see Proctor at page 58, and Davies at page 43.
[9] *NIH Revitalization Act (P.L. 103-43)* (online: National Institutes of Health <http://www.nih.gov/about/almanac/historical/legislative_chronology.htm#1990>).
[10] John A. Robertson, "Constitutional Issues in the Use of Pharmacogenomic Variations Associated With Race," in Mark A. Rothstein, ed., *Pharmacogenomics: Social, Ethical, and Clinical Dimensions* (Hoboken, NJ: John Wiley and Sons, 2003), page 301 [Robertson, 2003].

1) to ensure that laws and ethical guidelines keep pace so as to guide the genetic researchers who hold, in a profound way, the future in their hands; and
2) to allocate the benefits of such research equally and without prejudice.

These are not insignificant challenges, and our ability to rise to them will not only test our current wisdom and values but will define our generation for those who are yet to come. Will future generations look back on us as courageous pioneers who conducted ourselves with a teleological view of seeking that which is best for our species and the planet? Or will future generations look back on us as fools unable or unwilling to rise above our fears and ignorance? One thing can be said for certain. There have been few other developments in the history of science as the decoding of the human genome that have elicited so much excitement, hope and, conversely, disquietude. Ruth Chadwick and Antonio Marturano have described this apparently dichotomous paradox thusly:

> The hopes and fears surrounding genomics are multiple: on the one hand, there have been fears that genomics might be used to increase discrimination and health inequalities; on the other hand, there are promises that genomics will lead to improved and indeed individualized health care and that it will provide new cures for hitherto intractable conditions. There are those who see the potential for genomics to be a global public good, on the one hand; while on the other some commentators have pointed to the potential for, at worst, biopiracy and exploitation of genetic resources of population groups.[11]

Do we progress inspired by intellectual curiosity and informed by values that include a respect for life and a respect for the inherent worth of all members of the human family? How we apply our increasing knowledge of life at its molecular and sub-molecular levels will determine not only the future of our species but will also come to be regarded by our descendents as a defining statement of how we conduct ourselves in the present.

Few thinkers have expressed such profound faith in the future of humanity as eloquently as an early 20th century French biophysicist and philosopher named Pierre Lecomte du Nouy whose most famous work, *Human Destiny*, was written out of the

[11] Ruth Chadwick and Antonio Marturano, "Computing, Genetics, and Policy: Theoretical and Practical Considerations," in Herman T. Tavani, ed., *Ethics, Computing and Genomics* (Sudbury, MA: Jones and Bartlett, 2006), page 75 [Chadwick and Marturano]).

ashes of the worst war to date in history and published just prior to his death in 1947. For du Nouy, human beings were beyond evolving in the physiological or anatomical sense and now had to accept responsibility for evolving on a spiritual and moral plane.[12] In this regard, du Nouy believed that the evolutionary process had brought the human brain to the point where it was incumbent on us to take responsibility for our evolution and aspire to a more transcendent status leaving behind our self-destructive tendencies.[13] Du Nouy also believed that philosophy should not only guide and inform science but that it ought to be, in his words, "the real goal of science."[14]

Unfortunately, the choices that most of us make seem rarely informed by the transcendental idealism and incisive curiosity that characterize a scientist and original thinker like du Nouy. While it is a fact that the methodical process of genetic research ("pure science", as one geneticist has described his work to me) might occur in an antiseptic laboratory, it is also a fact that the policies and decisions behind the funding for health science research, not to mention the legal and ethical protocols that regulate and monitor it, are anything but examples of "pure science." Rather, policies and decisions are informed by and driven by prevailing ideologies and values – ideologies and values that may inspire human advancement or, conversely, reduce us to the vilest of levels. One only needs to watch the evening news to see how ethnic, political and religious disputes continue to define our global village, bubbling to the surface with heinous consequences for life, peace, and human evolutionary development. Distressing as well is our apparent propensity for seeking easy solutions to difficult social problems and the eagerness with which self-seeking political leaders and opinion-shapers of every generation are too quick

[12] "Evolution continues in our time, *no longer on the physiological or anatomical plane but on the spiritual and moral plane*. We are at the dawn of a new phase of evolution and the violent eddies due to this change in the order of things still conceal that fact from the eyes of the majority. The transition from the ancestral animal, still squirming within us, to Man is too recent for us to be able to understand the ensuing conflicts which often seem disconcerting and incomprehensible. We are incapable of realizing it, but we are actually living in the midst of a revolution, a revolution on the scale of evolution. In comparison, the social revolutions we witness, even if they cost hundreds of thousands of human lives, are but tragic children's games and will leave no trace in the future." (Lecomte du Nouy, page 104).

[13] "Nature has finally succeeded in producing its masterpiece in the shape of the human brain. But the great laws of evolution are still active, even though adaptation has lost its importance as far as we are concerned: we are now responsible for the progress of evolution. We are free to destroy ourselves if we misunderstand the meaning and the purpose of our victories; and we are free to forge ahead, to prolong evolution, to cooperate with God if we perceive the meaning of it all, if we realize that it can only be achieved through a wholehearted effort toward moral and spiritual development." (Lecomte du Nouy, page 121).

[14] Lecomte du Nouy, pp. 186-187.

to exploit for political gain or to enhance their status in the public arena. This tendency to seek out easy solutions, along with an apparent inability to admit error until it is too late, has resulted in past courses of action that leave the more sensible among us in bewilderment at the foolishness of choice and barbarity of action of our predecessors. Therefore, it is incumbent on anyone who seeks the positive application of the secret of life at its minutest level to look to the past for lessons as to what will happen when advances in science are misapplied. As noted by Dorothy Nelkin, the risk of a return to some very ugly and well-worn paths is always lurking in the shadows of the human psyche:

> In the rush to incorporate the latest research into institutional decisions, the highly complex and poorly understood relationship between genetics and environment, between nature and nurture, may be grossly oversimplified. And in the urgency to find unambiguous solutions for social problems, important values such as equal opportunity, personal privacy, individual and family autonomy may be compromised or obscured.[15]

One can only hope that the intelligent and sensible among us will come to realize that human evolutionary destiny lies in the moral sense, as we strive to conduct ourselves within a legal and ethical framework that is reflective of a duty of care. Nothing less significant than the future of the human race and the future of all other species on our planet is at stake. As a science writer named Kevin Davies has so eloquently put it:

> Now that we have cracked the genome, we face the ultimate challenge of understanding what the sequence means and what it can teach us. We have the awesome potential – should we so desire – of rewriting the language of God and the responsibility of harnessing the genome to improve the human condition in an equitable and ethical manner. The childhood of the human race is about to come to an end.[16]

[15] Dorothy Nelkin, "Bioethics and Law," in Cosimo M. Mazzoni, ed., *A Legal Framework for Bioethics* (The Hague, Netherlands: Kluwer Law International, 1998), page 129 [Nelkin].
[16] Davies, page 9.

Chapter II

DNA: "The force that through the green fuse drives the flower"

II. DNA: "The force that through the green fuse drives the flower"

Statement of Purpose: *A quote from a 20th century Welsh poet named Dylan Thomas introduces this section to underscore the profundity of the discoveries in the world of genetics over these past couple of decades. The section goes on to provide a brief explanation of what DNA is. The reader is also introduced to the concepts of genetic engineering, genetic discrimination and genetic screening.*

A 20th century poet named Dylan Thomas intuitively sensed the presence of a vital force in all living things and creatures when he wrote a poem many decades ago in which he said: "The force that through the green fuse drives the flower, Drives my green age; that blasts the roots of trees, Is my destroyer."[17] What a poet intuitively senses also has a basis in scientific fact. We now know that DNA is not only the chemical force driving the "green fuse" of a poet's flower. DNA is also the chemical force to the life and growth of each cell in the poet's brain, blood, muscles, skin and other organs. Indeed, if every example of living organic matter – bacteria, plants, fish, birds and mammals including humans – were reduced to their tiniest constituent molecular parts, life could be viewed as nothing more than the sum total of countless complex chemical processes occurring repeatedly in non-random ways, for reasons science has yet to fully understand.[18] Furthermore, these chemical processes occur in accordance with a chemical code so old that, measured in terms of linear time, one may be forgiven for suggesting that DNA itself is eternal even though the individual carriers of it are not. In other words, the tree on your lawn, the squirrel squawking from the safety of a high branch, you, me, and every other person, plant, fish, bird, and animal on this planet constitute nothing more than a dense mass of countless individual cells, each one containing a molecule of DNA.[19] And paradoxical though it may seem, while these

[17] Dylan Thomas, "The Force That Through the Green Fuse Drives the Flower," in Daniel Jones, ed., *The Poems of Dylan Thomas* (New York, NY: New Directions, 1971), page 77 [Thomas].
[18] "Every lifeform on Earth has a different set of instructions, written out in essentially the same language. The reason organisms *are* different is the differences in their nucleic acid instructions." (Carl Sagan, *Cosmos* (New York, NY: Ballantine Books, 1980), page 21 [Sagan]).
[19] "There are tens of billions of known kinds of organic molecules. Yet only about fifty of them are used for the essential activities of life. The same patterns are employed over and over again, conservatively,

molecules of DNA contain the chemical instructions for cell division and growth, they also contain the instructions for the eventual deterioration of cells, and then their death. Lecomte du Nouy, the philosopher-scientist, fully grounded in empiricism and intellect, saw beauty in what many of us would otherwise see as our tragic destiny:

> Thus the birth of an already evolved individual brings about his death at the end of a time varying according to the species. After having transmitted life to one or several other individuals he disappears, he rejoins the inorganic universe from which he had miraculously emerged. And we can say that from an evolutive point of view, the greatest invention of Nature is death.[20]

But the poet, carried away by depth of feeling and the wings of imagination, felt the truth, and more intensely. To paraphrase the words of Dylan Thomas, DNA is also the force that is, in a sense, the *destroyer* of each organism whether that be the simplest single-celled amoeba or a human being – that incredibly complex creature which the creationists among us believe was created by a divine intelligence or evolutionists believe to be the highest, although probably not the final, product of four billion years of evolution.[21]

A. What is DNA?

DNA is the basic chemical instruction code for all life and is therefore the fundamental component of our genes.[22] DNA is a nucleic acid that comprises four chemical compounds known as bases – deoxyadenylate, deoxythymidylate,

---

ingeniously for different functions. And at the very heart of life on Earth – the proteins that control cell chemistry, and the nucleic acids that carry the hereditary instructions – we find these molecules to be essentially identical in all the plans and animals. An oak tree and I are made of the same stuff. If you go far enough back, we have a common ancestor." (Sagan, page 24). See also Joel Davis, *Mapping the Code: The Human Genome Project and the Choices of Modern Science* (New York, NY: John Wiley & Sons, 1990) [Davis], and Dawkins who provides a particularly useful explanation of the theory of evolution for readers who are non-scientists.

[20] Lecomte du Nouy, page 62.

[21] "If we plunged through a pore into the nucleus of the cell, we would find something that resembles an explosion in a spaghetti factory – a disorderly multitude of coils and strands, which are the two kinds of nucleic acids: DNA, which knows what to do, and RNA, which conveys the instructions issued by DNA to the rest of the cell. These are the best that four billion years of evolution could produce, containing the full complement of information on how to make a cell, a tree or a human work. The amount of information in human DNA, if written out in ordinary language, would occupy a hundred thick volumes. What is more, the DNA molecules know how to make, with only very rare exceptions, identical copies of themselves." (Sagan, page 25).

[22] Walter Bodmer and Robin McKie, *The Book of Man: The Human Genome Project and the Quest to Discover Our Genetic Heritage* (New York, NY: Scribner, 1995), page 10 [Bodmer and McKie]. See also Drlica, page 14.

deoxyguanylate, and deoxycytidylate – represented, respectively, by the letters A,T,G, and C. In a strand of DNA, these bases exist in a one-to-one ratio and complement each other in pairs such that A always pairs with T and C always pairs with G.[23] Each of the estimated three billion nucleotides is composed of a base, a sugar and a phosphate.[24] The sugar and the phosphate constitute the two spines on either side of the acid molecule. The bases lie flat like the rungs of a spiraling ladder or the steps of a spiraling staircase. To the naked, untrained eye looking through a powerful microscope, a strand of DNA would not appear to resemble much more than a blob. When people picture what a molecule of DNA looks like they must rely on the visual representation of the molecule's chemical composition – the spiraling ladder – that famous double helix model developed by two scientists named James Watson and Francis Crick and which was first published in a science journal back in 1953 as a simple black-and-white diagram.[25]

When a single spermatozoa succeeds in fertilizing an ova, a cell is thus created that is capable of dividing and growing into the dozens of different types of cells that will themselves eventually divide exponentially and grow into the various organs, hair, blood, bones and tissues of a new human in accordance with the genetic code carried by the DNA.[26] The human body comprises an estimated 10 trillion cells, each of which contains DNA and each of which is the descendant of a single original, or parent, cell, which is the fertilized ova.[27] However the reason for cell division and growth that takes a single cell

[23] Davies, pages 20-25.
[24] "The entire nucleotide sequence for an organism is called a genome. … The amount of information available is so large that new computer technologies are being developed to analyze it. The study of life at the whole-genome level constitutes a new discipline that has been given the name genomics." (Drlica, page 14).
[25] Davies, page 2.
[26] "It sounds incredible, yet that single scrap of DNA is the critical product which is created when egg meets sperm, joining the inheritance of a mother and a father in equal parts. In this way, a single cell – the fertilized egg – is produced, one that has the potential to form a new and unique individual under the guidance of the DNA within its nucleus. The human body is made up of a hundred million cells of many different sorts, and all contain the inherited information that comes from that first, single cell created at fertilization. These instructions carry the biological details necessary for making all the different tissues and organs, and the cells of blood, skin, kidneys, lungs and many others including, of course, the brain. These guidelines make each of us unique – apart, of course, from identical twins. As the embryo and then the child, matures, the DNA script within its cells is read and translated into proteins from which tissue, nerve cells and hormones are constructed. These in turn are transformed into organs, thought processes, memories, and even behaviour patterns, which range from instinctive flinch reactions to complex tendencies that include our elusive musical talents, and the urge to use our left or right hands." (Bodmer and McKie, pages 10-11).
[27] Dawkins, page 177.

formed at conception to a fully developed human being is one that, even with all of the technology and knowledge available to contemporary science, remains a mystery. That chemical processes and cell division occurs in the body is as observable a fact as it is quantifiable. However, why these processes and divisions occur is, given our current level of knowledge and technology, beyond our comprehension. All that can be said with certainty is that each of us, indeed all of life, is the product of chemical processes that occur in ordered, non-random ways to foster cell growth and cell reproduction. In a very real sense, DNA does contain the chemical code for life.[28]

B. Can DNA be altered? Should it?

One day, decades hence, geneticists may be able to alter this chemical code in order to prevent debilitating diseases or conditions from developing, and even to slow the aging process and thus extend the human lifespan to 200 years or more. Indeed, as our knowledge of life at the molecular and sub-molecular levels expands, the prospect of altering genes to remove debilitating conditions or diseases like Huntington's disease from the gene pool will probably prove to be irresistible, most notably for those of us unfortunate enough to be found through genetic screening to be carriers of such latent diseases or conditions in our genes.[29] Genetic engineering, which would entail tweaking or manipulating the genes themselves, may come in four types:

1) somatic cell gene therapy (SCGT) – involves transferring a gene into the cells of a human to correct a genetic defect;
2) germ line gene therapy (GLGT) – involves the insertion of a gene into the reproductive cells of an afflicted patient;

[28] "DNA is the true chemical of life, for it is the essential component from which our genes are made. In it is encoded the genetic language that controls our destinies. And an astonishingly powerful lexicon it is. Just six million millionths of a gram of DNA carries as much information as ten volumes of the *Complete Oxford English Dictionary*." (Bodmer and McKie, page 10). A full discussion of the role that DNA plays in cell division and growth is beyond the scope of this paper. An excellent book that is understandable to a reader with a non-science background is *The Misunderstood Gene* (Cambridge, MA: Harvard University Press, 2001), written by a professor of molecular biology named Michel Morange.

[29] "The concept of gene therapy is so inherently simple that it is hard to believe that it will thwart researchers much longer. Ten or twenty years from now, gene therapy may be a viable option for dozens of genetic diseases. If the technology does become successful, there will be those who advocate using gene therapy to modify genes in the germline – sperm and egg cells – so the errant gene can be prevented from being passed down to future generations. Some scientists would go even further: they harbor dreams of enhancing memory or postponing aging." (Davies, page 224).

3) enhancement genetic engineering (EGE) – involves inserting a gene into a patient's reproductive tissue to ensure that the disorder in the patient's offspring will be corrected and;
4) eugenic engineering – involves the identification of a gene responsible for a desirable physical, intellectual or emotional quality and then enhancing it to make a person stronger, faster or smarter, for example. This type of manipulation is still very much theoretical and would in any event contravene existing ethical guidelines.[30]

However, such a prospect is one that, paradoxically, elicits both a sense of hope and a sense of unease. Hope, because within our current range of knowledge and biotechnological capacity, medical science has already provided us with the ability to prevent needless suffering for conditions that just decades or even a few scant years ago, would have drastically reduced the quality of life for persons afflicted with the conditions or diseases. Unease, because many discerning observers of how health science research is funded understand that, however pure and objective the pursuit of scientific knowledge might wish to appear, its actual practice and future course is influenced by the political ideologies, cultural norms and, sadly, nuanced prejudices of culture, gender, class, and religion that continue to persist even in supposedly transparent democracies. Moreover, given the cultural and social reality of prevailing prejudices based on distinctions between people such as economic standing, ethnicity and religious belief, there is justification for unease that genomics could be improperly used to support or even enhance inequalities in the provision of health care services based on social and cultural constructs.

The extent to which natural processes may be modified or altered should prove to be the greatest challenge facing genetic scientists and researchers in the coming decades. The capacity in the near future to alter a person's genome, if pre-natal genetic testing has shown the presence of a disease-causing mutation, should spur anyone with an interest in equitable access to health care in all its aspects to ensure that rational ethical guidelines are in place, buttressed by law:

[30] Smith II, pages 149-150, *passim*.

> To juxtapose the word genetic with the word technology accounts for both the incredible excitement and the incredible fear that genetic technology generates. Paradoxically, both reactions stem from the same reality – our capacity to experiment with the origins of the human species and of every human person.[31]

Notwithstanding the theoretical possibility of altering genes at the embryonic stage, it is critical to stress that such alteration is neither currently undertaken, nor would it be ethically permissible in any event given the rules and guidelines as set out in current medical research ethics protocols. Altering the chemical composition of cells at the embryonic stage would effect changes in future reproductive cells such that the alterations could be passed on to future generations. The ethical position against such intervention has been reinforced by section 5 (1) (f) of Canada's *Assisted Human Reproduction Act* R.S.C. 2004, c. 2, which says nobody shall knowingly "alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants…."[32] Given our current knowledge and level of biotechnology, engaging in therapeutic intervention of human germ line cells or human embryonic cells, when we can not foresee the consequences, would present an unacceptable risk. However, gene alteration of somatic cells – those cells that are beyond the embryonic phase – may be an accepted form of therapy under certain circumstances, as set out in article 8.5 of Canada's *Tri-Council Policy Statement* concerning medical research on humans:

> Gene alteration (including "gene therapy") that involves human germ line cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval.[33]

C. Genetics, Delivery of Health Care Services and Discrimination Concerns

Distinctions based on social constructs and an allocation of health care resources based on, among other factors, the ability to pay is of acute significance, of course, to citizens of the United States where private medical insurance is the norm as opposed to a country like Canada which has a publicly-funded health care system. The allocation of

[31] Jamieson, page 3.
[32] *Assisted Human Reproduction Act* R.S.C. 2004, c. 2.
[33] "Ethical Conduct for Research Involving Humans," *Tri-Council Policy Statement*, August, 1998, Article [8.5] [*Tri-Council Policy Statement*].

health care services in the United States occurs in a system of private medical insurance driven by profit, and the development of the genetics branch of medicine over the past three decades has occurred both within this environment and indeed has been itself largely driven by it. A commercialized health care system where premium health care that offers the latest in genetic screening tests – for a variety of genetic disorders or conditions – is available only to those who can afford to pay, can only contribute to inequality of access to health care for large numbers of people. Many Americans already feel considerable unease over how health care services – including genetic testing and diagnostic services – are delivered in a system driven by the maximization of profits for huge private insurance companies and Health Management Organizations (HMOs). A 2001 public opinion survey of a representative cross-section of 1800 adult Americans to ascertain their views about genetic testing/genetic research and privacy issues has shown that, although there is general support for genetic testing as a diagnostic tool, unless there are adequate privacy protections in place to prevent the release of resulting data to third parties such as employers or private health insurance companies, those who might otherwise be counted on to support such testing would be very reluctant to participate.[34] The same survey also showed a divergence of views regarding the issue of anonymity for genetic research participants, with persons under 50 years of age expressing the greatest concern for protecting the privacy interests of donors and test subjects. With persons 60 years and older, the question of anonymity became less important. Some commentators have suggested that the reason for this generational difference in views is that those who are still active members of the workforce are vulnerable to genetic discrimination in terms of seeking employment or health insurance coverage so can be expected to be the most demanding of enhanced protection for donor anonymity.[35] There can also be an interesting generational divergence of opinion over the issue of compensation for donations of tissue. In the United Kingdom, the Medical Research Council carried out a survey a few years ago of public opinion toward collecting human tissue for medical research projects. Younger Britons tended to either view compensation for the use of

[34] Mark A. Rothstein and Carlton A. Hornung, "Public Attitudes About Pharmacogenomics," in Mark A. Rothstein, ed., *Pharmacogenomics: Social, Ethical, and Clinical Dimensions* (Hoboken, New Jersey: John Wiley & Sons, 2003) [Rothstein and Hornung].
[35] Rothstein and Homung, page 10.

their tissue as something to which they were entitled as a matter of right, or they were at least willing to consider compensation, particularly when the research was expected to lead to a new pharmaceutical product or innovative therapeutic product that would generate profits for the patent-holder. However, older Britons tended to be more altruistic, regarding the donation of tissue as a gift or as part of their obligation to society.[36]

The prospect of genetic discrimination may also arise even in countries like the United Kingdom or Canada which have publicly funded health care systems. In such countries, where private insurance is also available either through employers or on an individual basis to supplement public health care for matters that the public system does not cover – i.e., dental care, eye care and physician-prescribed pharmaceuticals – there is concern that testing showing a genetic predisposition to a given disease or condition could result in discrimination against an applicant seeking such health care insurance. There may be good reason for such concern. In the United Kingdom, a survey of otherwise healthy individuals who were carrying recessive genes that were linked to genetic disorders showed that more than one such person in ten was either denied insurance or if they were approved for coverage, they were obliged to pay higher premiums than others in their age category or were required to have extensive medical examinations.[37] Commercialization of health care can also lead to a situation where what is considered to be prohibitively costly treatment for many will be accessible only to those of us with the financial means to pay. Commercialization of health care can also result in a society where the marketplace determines how we define disease and disability.[38] This context will be influenced as well by advances in genetic science as pre-

[36] For more on this, see Kenyon Mason and Graham Laurie, "Consent or Property? Dealing With the Body and its Parts in the Shadow of Bristol and Alder Hay," (September, 2001) 64 *Modern Law Review* 710, page 724, [Mason and Laurie].

[37] Edna Einsiedel, "Whose Genes, Whose Safe, How Safe? Publics' and Professionals' views of Biobanks," Report prepared for *The Canadian Biotechnical Advisory Committee*, March 2003, online: <http://www.cbac-cccb.ca>, page 20, [Einsiedel].

[38] "There is little doubt that modern health care is more business-oriented than at any other time in history, with patients increasingly cast as 'consumers' entitled to unencumbered access to services. At the same time, the science of genetics has become closely tied with industry. A huge amount of money has been invested in the development of genetic technologies and products. As such, there is a fear that commercial pressure, coupled with our culture's consumer ethic, will facilitate the geneticization of our society by emphasizing a market-driven definition of normalcy, disease and disability." (Timothy Caulfield,

natal genetic screening and genetic testing for people whose family histories show heritable genetic disorders becomes more prevalent.[39]

However, notwithstanding whatever concerns there may be about how genetic information may be used, genetic testing and research in the medical setting currently enjoys broad public support in Canada. For example, a survey conducted by *PricewaterhouseCoopers* of Canadian attitudes a few years ago about genetic screening has shown that more than 90% of respondents favoured genetic testing for the purposes of identifying persons at risk of developing a genetically-based disease or condition later or to identify those persons at risk of passing on a gene linked to a disease or condition.[40] Moreover, an extensive report about Canadian attitudes toward genetic testing and research was prepared for Health Canada by the market research and public opinion firm *Pollara Research* following a series of detailed opinion surveys and also several focus group sessions. From the data, three main considerations emerged as factors that people might weigh in deciding whether they would undergo screening for genetic conditions that had not yet manifested themselves:

- The purpose of the test – 89 % of participants reported that they would undertake screening because of a family history of a particular condition or disease.
- Whether the test would show, with a significant degree of certainty, that a particular disease or condition would manifest itself later in life. If screening would not show an unambiguous risk factor, then people were less willing to undergo screening.
- Whether there is a cure or treatment currently available. If not, many people saw little benefit to undergoing screening for a condition for which there was no cure. However 95% of those surveyed said they would volunteer for genetic screening if it was part of a diagnostic process that would help health care researchers come up with better therapy for a disease or condition that ran in their family. And 58% said they would undertake genetic screening out of curiosity about their own genetic makeup.[41]

"Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution," (2000) 45 McGill L. J. 437, page 450, [Caulfield]).

[39] "Because choices by individuals may sometimes have adverse effects on others, including the unconceived, public agencies may be moved to discourage or limit some of these options." (Allen Buchanan et al., *From Chance to Choice: Genetics and Justice* (Cambridge, U.K.: Cambridge University Press, 2000), page 305 [Buchanan et al.]).

[40] Christine E. Jamieson, "Genetic Testing for Late Onset Diseases: In-Depth Thematic Analysis of Policy and Jurisdictional Issues" (Ottawa, ON: Health Canada, Working Paper 01-03, September 2001), page 13 [Jamieson].

[41] See "Public Opinion Research Into Genetic Privacy Issues," Final Report, March 2003 (Biotechnology Assistant Deputy Minister Coordinating Committee, Government of Canada, by Pollara Research and Earnscliffe Research and Communications), pages 6-7 ["Public Opinion Research"].

Chapter III

Personal Autonomy and Informed Consent

III. Personal Autonomy and Informed Consent

Statement of Purpose: *This section contains much of this report's legal discussion, as the reader is introduced to concepts in the field of law and medicine such as personal autonomy, informed consent to participate in research projects, genetic testing and a person's right to know (or not know) the results of such testing. Consent issues that arise in instances where capacity is in question, either because of age or infirmity, are discussed, as are some of the challenges that arise in, and are unique to, Aboriginal communities.*

A. Definition of Autonomy

Autonomy, as defined by *Merriam-Webster On-Line*, is a noun that means:

> **1** the quality or state of being self-governing; *especially*: the right of self-government
> **2** self-directing freedom and especially moral independence
> **3** a self-governing state.[42]

Personal autonomy, within the Canadian legal tradition and indeed throughout the English-speaking democracies, has attained a high status at law. Personal autonomy is also a cultural value that an overwhelming majority of persons living in a democratic state would identify as being an important part of being human, even if fewer of them would be able to give a cogent explanation as to the basis for their feeling or belief. The philosophical basis for the concept of the autonomous individual with an inherent right to personal dignity may be traced back through an ideological lineage that arguably finds its most eloquent and influential voice in the writing of an 18th-century German philosopher named Immanuel Kant.[43] Indeed, Kant was a staunch critic of utilitarianism, viewing it as a philosophy that would in practice actually undermine the inherent value and dignity of

[42] Online: Merriam-Webster On-Line <http://www.m-w.com/dictionary/autonomy>.
[43] Leon R. Kass, *Life, Liberty and the Defense of Dignity: The Challenge for Bioethics* (San Francisco, CA: Encounter Books, 2002), page 16 [Kass].

individual persons.[44] However much utilitarianism, or the greatest good for the greatest number, has found expression in the political process of the modern, democratic state in such concepts as "majority rule," it is the Kantian ideal of the rational, autonomous person using reason to make decisions that underlies our notion of individual autonomy in the medical context and which finds its clearest expression in our legal and ethical requirements.[45] With over 90% of Canadians affirming a personal right to decide whether or not to undergo genetic screening – as a public opinion study done for Health Canada has shown – personal autonomy as a value resonates great power for most adults.[46]

B. How is autonomy exercised?

Does autonomy include a right not to know that one carries a genetic predisposition to a certain disease or condition? To pose that question among a group of bioethicists and privacy law advocates is to open the floor to considerable debate and discussion. The official position of the Privacy Commission of Canada on the question of privacy and confidentiality within the genetic context is unambiguous:

> The ethical principle of autonomy suggests that one should have meaningful physical and psychological control over oneself. Any form of mandatory genetic testing and the reporting of results to oneself or to others – even for purposes that may initially seem quite justifiable – violates that principle and threatens the right to privacy. The loss of autonomy and privacy can be the genesis of a life-long psychological prison – the prison of one's perceived genetic 'programming.'"[47]

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[44] For a general discussion of the broad outlines of Kant's philosophy, see *The Internet Encyclopedia of Philosophy* entry for Immanuel Kant, online: The Internet Encyclopedia of Philosophy <http://www.iep.utm.edu/k/kantmeta.htm#H9>, and for a summary of his critique of utilitarianism in particular, see Part 9: "If we allow utilitarian calculations to motivate our actions, we are allowing the valuation of one person's welfare and interests in terms of what good they can be used for. It would be possible, for instance, to justify sacrificing one individual for the benefits of others if the utilitarian calculations promise more benefit. Doing so would be the worst example of treating someone utterly as a means and not as an end in themselves."

[45] Kass, note 23: "Whatever persists of a non-utilitarian ethic in contemporary bioethics descends from this moralistic view. The respect for persons so widely celebrated in the canons of ethics governing human experimentation is in fact a descendant of Kant's principle of human autonomy."

[46] "Public Opinion Research", page 8.

[47] "Genetic Testing and Privacy", page 30. An equally strong view has been expressed by an Ottawa lawyer who specializes in civil liberties and privacy issues. According to Eugene Oscapella: "Respect for autonomy can be used to support the argument that individuals should not be forced to acquire genetic information about themselves. In many cases, such information might not harm the individual. In other cases, however, this knowledge could be catastrophic – such as learning, against one's wishes, that one has the gene that causes Huntington disease." (Oscapella, para. 1.3).

A person exercises personal autonomy by becoming fully informed of the facts of a given situation and then makes a decision to take action, freely, without duress or compulsion.[48] Autonomy involves a choice to do or not do something. Therefore, for the principle of autonomy to have any meaningful significance in its application, an autonomous choice must be exercised by an individual on the basis of all relevant information so that, in the context of genetic research or screening for genetic-based diseases or conditions that would mean having information about the disease or condition. Blind ignorance is not, therefore, arguably, a morally valid example of an autonomous choice or action; indeed, a tenable proposition can be advanced that nobody has a right to genetic ignorance.[49] In the case of somebody with a family history of a debilitating genetic condition, to choose not to undergo genetic screening would, arguably, be immoral. What the person chooses to do with that information will involve a value-based decision as it leads one to examine the extent to which an individual right to privacy and confidentiality should determine the outcome. It must be stressed that, in accordance with current law and ethics, if a person did opt for genetic screening and then decided to not share the results with persons ordinarily within their ambit of care – i.e., family members and/or a sexual partner – that person would be exercising a right in keeping with applicable law and ethical protocols. The belief systems of health care professionals reflect a respect for the wish of a person to not know the results of genetic screening though a significant number of them are at least ambivalent about not disclosing a genetic risk to at-risk family members. For example, although a recent survey of 3600 American health care professionals has shown that over 2/3 of them would support a person's wish to not be told the results of genetic screening, on the question of not telling that person's at-risk relatives, 29% believe that the person's relatives should be informed of their genetic risk notwithstanding the patient's express wish not to be informed.[50]

[48] Rhodes, page 18.
[49] "The clearest conclusion is that no one has a moral right to genetic ignorance. The other noteworthy conclusion is that moral responsibility depends on a variety of factors including blood ties, social relationships, the history of an interaction, and particular features of the situation and the individuals involved." (Rhodes, page 25).
[50] Einsiedel, page 32.

Furthermore, in exercising one's right to an autonomous decision about an issue concerning personal health within the context of genetics can one truly make the right decision without considering wider implications? The exercise of personal autonomy ought not to be exercised in a moral vacuum or without regard to how one's deeds will play out in the public forum. Otherwise the exercise of autonomy becomes no more relevant than the selfish rant of somebody throwing a temper tantrum. As Graham Laurie, a U.K. law professor and ethicist has written:

> The impact of personal decisions on a wider community must also be examined, and this is self-evidently the case in the context of genetics, when uses or misuses of genetic information can have repercussions within families or indeed entire communities.[51]

C. Who really *is* my neighbour?

The genetic reality of the relationships among people at the molecular level will have a profound influence on how we view health and it is a view that will have little, if any, relationship to the choices that people tend to make now in their social lives. Any one of us differs from any other person on this planet by less than $1/10^{th}$ of one percent of our DNA.[52] Indeed, I have personal knowledge of hundreds of my close genetic relatives who are scattered around the world and whose familial lines broke off from mine hundreds, and in some cases, thousands of years ago. A sample of my DNA – obtained from a cheek swab of my saliva – is stored in a huge biobank in the United States that is being compiled under the auspices of a *National Geographic Society* human migration and human origins study that has collected saliva samples from hundreds of thousands of males from around the world representing every populational group and sub-group.[53] DNA is extracted from these saliva samples and then genetic sequences are mapped out

[51] Laurie, page 282.

[52] "Among the many findings of the HGP is that all humans are 99.9% identical at the level of DNA. Consequently, any two humans on the planet are likely to vary genetically only once in every one thousand base pairs. This finding reconfirms that the species *Homo sapiens* is relatively young (about 100,000 years old) and that there are no subspecies. Thus there is no scientific basis for racial classifications; race is a purely social construct." (Mark A. Rothstein, "Epilogue: Policy Prescriptions" in Mark A. Rothstein, ed., *Pharmacogenomics: Social, Ethical and Clinical Dimensions* (Hoboken, New Jersey: John Wiley & Sons, 2003), page 329 [Rothstein, "Epilogue"].

[53] A listing of the genetic relatives of each donor (access is protected by a unique alpha-numeric code and a unique password) is maintained on the project's website: http://www.familytreedna.com/Default.aspx?c=1.

as the project's geneticists search for the genetic markers unique to every populational group and sub-group on the planet. The study started out seeking only male DNA donors because only males pass on the Y chromosome to sons so that makes it easier to trace back what is essentially the genetic "family tree" of humanity. However the project has since initiated a mitochondrial geographical project in an attempt to trace back the roots of the maternal line and thus is seeking female DNA donors as well. The markers from each individual sample of DNA are cross-referenced with the markers of hundreds of thousands of other DNA samples, and are collated into groups of people who share the same genetic markers; an enormous undertaking only possible because of the organizational capacity and speed of modern computers. The list of men who have the same twelve identical, unique genetic markers as me (only a close male relative like an uncle or a brother could be a closer match) has grown to number several hundred and these men are scattered around the U.S., Canada, Ireland, the United Kingdom, and northern Europe. Even more relevant for this discussion though is the fact that I share these same unique genetic markers, though lacking by only one or two, with a man in West Africa, a Muslim male living somewhere in central Asia, and three men who are Ashkenazi Jews.

Therefore, it is incumbent on us to take a distinctly more critical view of the importance we attach to relationships defined by family, nation, language, religion, ethnicity or culture and consider instead our relationships on a global scale.[54] If I – an English-speaking Caucasian male who identifies my ethno-cultural heritage as Anglo-Celtic – am a closer genetic relative of a Muslim male I've never met living somewhere in central Asia than I am to a guy from my home community who is also of Anglo-Celtic heritage, what significance does that genetic kinship mean for the question of "who is my neighbour" if one day I am in need of a kidney, a blood transfusion, or human tissue of some other kind? Although I may continue to maintain kinship in an affective sense with the guy next door who shares a beer with me on my patio, the future status of my health will have much more to do with who I am related to on a molecular level. As our

[54] Rosamond Rhodes, "Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge" (1998) 23(1) Journal of Medicine and Philosophy 10, page 11 [Rhodes]. Also see Rhodes at page 21 where she writes: "Blood alone does not tell the story of our moral responsibility to one another. The bonds that have moral weight and give us thick responsibilities to one another typically include a social component."

knowledge of genetics increases and as we learn more and more about how closely related we all are at the molecular level of DNA, this can only have a profound impact on our concept of ethical obligations arising within the context of medical genetic research.

D. Autonomy and Informed Consent

Autonomy, within the medical context, is comprised of four essential components which, collectively, also fall under the principle of informed consent:

1) freedom to choose and to have one's choice respected by others;
2) non-interference by others when an individual makes a choice;
3) capacity to make a choice; and
4) the choice must be based on reliable information.[55]

The requirements for informed consent for publicly funded research projects in Canada are set out in the *Tri-Council Policy Statement* on "Ethical Guidelines for Research Involving Humans." The Statement provides a comprehensive body of ethical guidelines that apply to anyone or any institution seeking funding from any of the three public funding bodies for scientific research: the National Sciences and Engineering Council, the Social Sciences and Humanities Research Council and the Canadian Institute of Health Research. Public funding will not be awarded to any project that does not agree to comply with the ethical guidelines as set out in the Statement. According to the *Tri-Council Policy Statement*, informed consent – given of the subject's own volition or on behalf of the subject by a parent or legal guardian without compulsion or duress – is the basis for all ethical medical research involving humans. Furthermore, such consent may be revoked at any point of the research project.[56] Informed consent is not only relevant at the beginning phase of the research project; rather it is part of a process that runs through to completion of the research subject's participation.[57] Wherever possible, the consent should be given in writing, unless consent in writing is inappropriate for cultural reasons or there are valid reasons for not getting written consent, in which cases the process by

[55] Laurie, page 186.
[56] *Tri-Council Policy Statement*, articles 2.1, 2.2 and 2.4.
[57] *Tri-Council Policy Statement,* page 2.1 states regarding article 2.1: "As used in this Policy, the process of free and informed consent refers to the dialogue, informed sharing and general process through which prospective subjects choose to participate in research involving themselves."

which the researchers sought to obtain consent must be documented in writing.[58] Obtaining consent cannot be regarded as perfunctory and the process must not be rushed; various factors will determine how much time the researcher will have to take to explain the project, including the extent, how invasive is the research, the potential for harm, and the level of maturity of the prospective subject, parent or guardian.[59] Article 2.4 of the *Tri-Council Policy Statement* sets out what information the researchers must provide at the outset to the prospective subject or the subject's parent or guardian in order for an informed decision about whether or not to participate can be made:

> (a) Information that the individual is being invited to participate in a research project;
> (b) A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
> (c) A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
> (d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
> (e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.[60]

International protocols and conventions applicable to human participation in medical research also require informed consent prior to participation in research and also stipulate that consent must be regarded as part of an ongoing process such that the research participant retains the right to withdraw consent and withdraw from the project at any time.[61]

Surveys of the opinions of Canadian health care workers and medical researchers have shown a fairly consistent degree of consensus on understanding what constitutes

[58] *Tri-Council Policy Statement*, article 2.1. Although the article suggests there may be "good reasons for not recording consent in writing," it does not give examples of what might constitute a good reason.
[59] *Tri-Council Policy Statement*, article 2.8.
[60] *Tri-Council Policy Statement*, article 2.4.
[61] Sheremata, para. 4.D.

informed consent and when such consent is required. First of all, informed consent must be a requirement at the outset of a given project, prior to the taking of any human tissue. However, whether such consent can be extended to further research projects or even to secondary follow-up research is where opinion tends to diverge. Opinions range from those at one end of the spectrum who argue that "blanket consent" should be the operative principle, with researchers having access to the stored tissue for all subsequent research projects. At the other end of the spectrum are those who argue that the researchers must obtain informed consent from the donors for every conceivable use for which the tissue might be required. However many health care workers and researchers find themselves in the middle to varying degrees, some suggesting that donors be provided with a list of potential uses or projects at the outset when they are being told about why their tissue is required while others would simply leave the decision-making to the institutions' research ethics boards about whether future consent is required.[62] Lack of consistency regarding policies is something that has long defined the terrain. Back in 1995, the University of Calgary's Office of Medical Bioethics conducted a national survey of the policies applicable to biobanking and research. Detailed questionnaires were sent to genetic researchers, clinical geneticists, research ethics boards and senior administrators at hospitals. What the survey found were many unresolved issues such as:

- To what extent, if at all, should a patient or research participant have control over the use and future use of one's genetic material?
- Should a patient or research participant retain any right to withdraw a DNA sample or to ask for its destruction once the testing is done or the research project completed?
- Should a donor be contacted regarding future research that may be undertaken using the tissue for which initial informed consent had been given or is there some kind of "blanket consent" that is, in effect, ongoing?

[62] Einsiedel, page 39.

- Should a donor have any right to any financial remuneration of some kind from any commercial venture that might be forthcoming based on research that had involved the donor's DNA?[63]

That these issues remain the subject of discussion and debate may be more of an indication of their complexity rather than an unwillingness to address them.

E. When might informed consent not be applicable?

However, within certain defined circumstances, the principle of informed consent may not be applicable. Pathologists, for example, who maintain tissue banks and whose material come from resected tumours or pathological samples do not regard informed consent as a precondition for doing research on such samples.[64] Moreover, there are researchers who argue that human tissue can be used without first obtaining donor consent so long as it the tissue samples are the subject of anonymized testing. An example arising out of the Centers for Disease Control (CDC) in Atlanta is illustrative. Researchers at the CDC in 1994 wanted to use the blood samples of 50,000 people as part of a study into genetic disorders. The samples, along with detailed medical information about the participants, were collected previously as part of a project called the National Health and Nutrition Survey (NHANES). When these prior samples were collected, the participants were not told that their samples might one day be used in genetic research as well. This provoked controversy within genetics and ethics circles over the question of informed consent or, more to the point, the lack of consent to such usage. The matter was eventually resolved when the administrators of the original survey agreed to permit CDC researchers to do anonymized testing on the blood samples provided that the researchers had obtained the approval of the NHANES ethics review board.[65] Support for the position that stored human tissue can be used for future research purposes without consent – provided this use occurs with prior research ethics board approval and provided that donor confidentiality is strictly protected – has come from Australian sources as well,

[63] B.M. Knoppers, T. Caulfield, and T.D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto, ON: Edmond Montgomery Publications Ltd., 1996), page 2 [Knoppers, Caulfield, and Kinsella].
[64] Bartha Marie Knoppers and Claude Laberge, "DNA Banking/Collecting: A Canadian 'Sample' of Consent Forms," in Knoppers, Caulfield and Kinsella, page 45. [Knoppers and Laberge].
[65] Andrews and Nelkin, page 12.

including the Australian National Health and Medical Research Council.[66] In Canada, provided that genetic data within a biobank or database has been anonymized (i.e., it cannot be linked to a particular individual), obtaining informed consent for the use of such data is not necessary.[67] Retrospective research on stored human tissue and associated data may represent an exception to the informed consent principle within Canada as well. In Alberta, for example, sections 48-50 of the provincial *Health Information Act* permits researchers to access personal health data and stored tissue without consent, subject to making a successful application to a research ethics board and subject also to the proposed project having adequate safeguards in place to protect donor and/or patient privacy, where the research ethics board is of the opinion that obtaining such consent is "unreasonable, impractical or not feasible."[68]

Special challenges may arise for obtaining informed consent in some situations. For a large-scale research project, for example, it may be exceedingly difficult to contact all donors and potential donors in a research project where the group is very large or difficult to track because they are spread over a large geographical area. In such cases where obtaining individualized consent is not practical, some guidelines are set out in Article 3.4 of the Tri-Council Policy Statement. In lieu of the researchers having to get the informed consent of each potential participant, the researchers could consult with either representatives of the group or conduct a survey of the opinions of a subset of individuals.[69] However, Greeley asserts that, within the genetics context, some further adjusting to the standard model for medical research may be required:

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[66] Loane Skene, a law professor at the University of Melbourne, writes that: "Guidelines published by the Australian National Health and Medical Research Council in 1999 specifically state that a Human Research Ethics Committee might waive the need for consent to the use of stored human tissue in research in certain circumstances; and also to the use of stored genetic material and genetic information. The ethics committee might take into account the nature of any existing consent that relates to the collection and use of the sample; the difficulty or intrusiveness of obtaining consent; the arrangements to protect privacy; the possible commercial exploitation of the research; and other factors. However, the guidelines apply only to access for research purposes, not for diagnosis or treatment and can be overridden by an Act of Parliament." (Loane Skene, "Ownership of Human Tissue and the Law" (February 2002) 3 Nature Reviews Genetics 145, page 147 [Skene, "Ownership"]).

[67] Trudo Lemmens and Lisa Austin, "Of Volume, Depth and Speed: The Challenges of Genetic Information" in *Protecting Privacy in the Age of Genetic Information* (Canadian Biotechnology Advisory Committeee, August 2004), online: Canadian Biotechnology Advisory Committee <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00477e.html>, page 4.2 [Lemmens and Austin].

[68] *Health Information Act*, R.S.A. 2000, c. H-5.

[69] *Tri-Council Policy Statement*, page 3.6.

> The same set of samples, or data derived from those samples, may be shared with hundreds of laboratories, which might use it for purposes far beyond those expected by the people whose DNA and data are being shared. Although a DNA sample is a finite resource, if blood from an individual has been preserved as a transformed cell line, a set of indefinitely reproducing white blood cells from the patient, a potentially infinite amount of DNA can be derived from that sample. And, of course, once the samples have been transformed into data, electronic file sharing makes them easily and broadly accessible without any limits.[70]

Also, there are ethnic or cultural groups that may have a special concern about how their DNA and the information to be gleaned from that is going to be used. Such groups may want to, expressly and in writing, restrict the taking of DNA and then the subsequent use to which their DNA is to be put. Moreover, donors may wish to put a restriction as to who may access their samples or data or to whom the samples or data can be transferred. [71]

Informed consent is one of the fundamental principles on which medical research ethics for humans are grounded.[72] Informed consent also, arguably, is the application of social contract theory in a medical research setting, where the principle represents a deft reconciliation of personal autonomy with a utilitarian social ethos. Although personal autonomy and dignity may be important if not paramount human values, they ought not serve to demarcate and separate the individual from other people. Indeed, it is in the dynamic relationship of the individual with family, friends and colleagues that the individual is both enriched and in turn becomes an enricher, ideally making a positive contribution to the experience of other people and to society. Within the medical research setting, the individual donor or research participant who voluntarily donates tissue will do so for a number of different reasons which may include altruism, curiosity, personal relationship with somebody who has a genetic disease or condition for which researchers are working on a cure, or a personal concern with one's own state of health. Though there may be an individual benefit, the individual donor also will have contributed to a project that could benefit thousands or even millions of people. One way to look at ethics

[70] Henry T. Greely, "Genome Research and Minorities" in Mark A. Rothstein, ed., *Pharmacogenomics: Social, Ethical and Clinical Dimensions* (Hoboken, New Jersey: John Wiley & Sons, 2003), page 71 [Greely 2003].
[71] Greely 2003, page 71.
[72] Andrews and Nelkin, page 21; Ching, page 704; and Henry T. Greely, "Iceland's Plan for Genomics Research: Facts and Implications" (2000) 40 Jurimetrics 153, page 179 [Greely 2000].

protocols, particularly as they pertain to individual, informed donor consent, is that they recognize the inherent value of personhood and personal autonomy. However, it is also perhaps as important to recognize that a project which has been conducted in strict accordance with ethics protocols, especially as they concern the issue of consent, is one that will enjoy wide public support. Surveys of Canadian public opinion have shown that people generally have an understanding of how important it is to ground medical genetic research on sound ethical principles; moreover, many Canadians see genetics as key to the future of medical research.[73]

F. Iceland's *deCode Genetics* Experiment

As has been discussed above, the chief rationale for informed consent is the protection of personal autonomy. The objectives of informed consent may be defined as follows:

1) to promote individual autonomy;
2) to protect the patient subject's status as a human being worthy of respect;
3) to avoid fraud and duress;
4) to encourage self-scrutiny by the physician-researcher;
5) to promote rational decision making; and
6) to involve the public in important questions about health care policy and research.[74]

On the other hand, a very different model of consent that has generated considerable criticism and debate within international bioethics circles can be found in Iceland, where a company called *deCODE Genetics* initiated an ambitious genetic research project a few years ago that would essentially involve using most of the nation's adult population as research subjects. There, the Health Sector Database (HSD) was created by way of legislation in 1998 that gave deCODE Genetics sole and unique access to the health records of Icelanders as part of the company's mandate to engage in a wide range of research projects into the genetic basis of various diseases and conditions including asthma, obesity, diabetes and schizophrenia.[75] The legislation made Iceland the only

[73] Sheremata, para. 4.F.
[74] Hrobjartur Jonatansson, "Iceland's Health Sector Database: A Significant Head Start in the Search for the Biological Grailor an Irreversible Error?" (2000) 26 Am. J. L. & Med. 31, page 54 [Jonatansson].
[75] The rationale behind the Icelandic Healthcare Database, according to *deCode* executives, is as follows: "We expect that the IHD and other data bases of its kind will provide ideal opportunities to study

country in the world where a private biotechnology company had access to the national health records.[76] In granting a private company what amounts to a monopoly access to the confidential health records of the nation, the act that set up the HSD employed what is known as "presumed consent" i.e., the consent of the citizens to the use of their data in deCODE's genetic research projects was presumed, although the act reserved to a person the right to opt out of the deCODE project should they indicate a desire to do so.[77] This "presumed consent" caught adults, children, and even the health information of deceased persons in its sweep for a broad range of research projects unless objection forms were filed.[78] However, the children of deceased Icelanders were unable to withdraw their parents' records from the database.[79] In the eyes of the company's chief executives, not the least of which is Dr. Kari Stefansson – its President and CEO – consent in the context of medical genetic research should be presumed because the end of such research is better served by a streamlined consent process, and if anyone objected, there is always the option of simply dropping out of the project. In his view, there are only three elements to consent:

1) the donor consents to have tissue and/or fluid taken from the body;
2) the donor consents to have a portion of their genetic code mapped out from that sample; and
3) the donor consents to allow that genetic information to be used in a research project.[80]

The project's administrators placed confidence – too much confidence, critics argued – in the fact that there are four bodies, one appointed by the Minister of Justice and the

interactions among genes and between genes and environment in the pathogens of commercial diseases. The ultimate goal is to discover new methods to diagnose, prevent, and cure common diseases." (Jeffrey R. Gulcher and Kari Stefansson (deCODE Genetics), "The Icelandic Healthcare Database and Informed Consent" (June 15, 2000) 342 (24) New England Journal of Medicine 1827, http://proquest.umi.com.ezproxy.lib.ucalgary.ca/pqdweb?index=24&did=55091021&SrchMode=3&sid=1&Fmt=4&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1239043994&clientId=12303&aid=2 [Gulcher and Stefannson]).

[76] Jonatansson, page 31.

[77] For a good explanation of the HSD and the *deCode* project, see Greely 2000. Greely writes at page 170: "The Icelandic legislation has been much misunderstood. It does not deal with the collection of DNA samples or the creation of a database of specifically genetic material. Nor does this legislation deal with any genealogical databases. Although the Act refers to coordination of this database with genealogical and genetic databases, it regulates only the creation and operation of a database of clinical medical information about Icelanders, derived from their medical records."

[78] Greely 2000, page 178.

[79] Spinello, page 216.

[80] Gulcher and Stefansson.

other three appointed by the Minister of Health, to monitor the research that is done based on the HSD so as to ensure that such research conforms with international ethical standards. These four bodies are: the Data Protection Commission of Iceland (appointed by the Minister of Justice), an interdisciplinary bioethics committee, a National Bioethics Committee, and an operational oversight committee.[81] The project's administrators also seemed to place great value in the fact that, as of April, 2000 in any event, an overwhelming majority of Icelanders supported the deCode project. A Gallup poll taken in April of that year, seventeen months after the HSD legislation took effect, showed that only seven percent of the population had exercised their option to exclude their health records from the database.[82] However, the project is not without its critics, not the least of which was the Icelandic Medical Association itself, which informed the government that patients' rights and interests were being harmed by the HSD and its approach to the principle of informed consent.[83] Indeed, a legal challenge to the portion of the *Health Sector Database Act* concerning the inclusion of the health records of a deceased person in the database succeeded before the Icelandic Supreme Court, whose 2003 decision in *Guomundsdottir v. The State of Iceland* effectively found the doctrine of "presumed consent" to be unconstitutional.[84] Ragnhildur Guomundsdottir was a 15-year-old Icelandic girl who, through her legal guardian, opposed the automatic transfer of her deceased father's health care records into Iceland's national Health Sector Database. Under traditional Icelandic law, the personal rights of individuals lapse upon death. The provision of the Health Sector Database Act dealing with the automatic transfer of a deceased person's health records into the national database to which deCODE had exclusive access as licensee then, was, on its face, in accordance with traditional law. However, legal counsel for Guomundsdottir argued that she had a legitimate personal interest in objecting to the transfer of her father's health records based on a right to personal privacy as guaranteed by Iceland's constitution. From her father's health records, information about hereditary characteristics that would apply to her own health

[81] Gulcher and Stefansson.
[82] Gulcher and Stefansson.
[83] Einsiedel, page 35.
[84] *Ragnhildur Guomundsdottir v. The State of Iceland* (November 27, 2003) No. 151/2003, online: <http://www.mannvernd.is/english/lawsuits/Icelandic_Supreme_Court_Verdict_151_2003.pdf>. [*Ragnhildur Guomundsdottir v. The State of Iceland*].

might be inferred, her counsel argued, thus her right to personal privacy as guaranteed by the Icelandic Constitution. The Supreme Court agreed, finding that even with the encryption of personal identifiers by way of one-way coding such that the licensee's staff would only be working with non-personally identifiable data, there was still the possibility of hereditary information being linked to Guomundsdottir, which would violate her right to privacy.[85] The court therefore struck down the Act as unconstitutional, thus dealing a fatal blow to deCODE's notion of "presumed consent."

G. Genetic testing and the right to know…or not?

Notwithstanding a legal tradition of respect for individual autonomy – a concept that many argue includes the right of an individual to decline to know genetic information about oneself – the notion of a person retaining the right to remain in genetic ignorance does seem flawed. If genetic testing reveals that a person is the carrier of a dominant gene for a debilitating condition or illness such as Huntington's chorea or sickle cell anemia, why should that person be permitted to live in ignorance and run the risk of passing on the gene, along with the inherent risk of developing the condition or disease, to offspring?

McVeigh and Wheeler state that there are special concerns that arise with DNA testing, though, because of the information which a strand of DNA can yield:

> Advancements in genetic screening make each of our bodies vulnerable in a new and quite frightening way. It is even possible that we might have to unearth the old law which stated that a man owned his hair clippings, but we would do so for reasons that the originators of the law would have found impossible to comprehend. By using DNA 'fingerprinting', an untrained individual with the appropriate kit can test a strand of hair for a range of genetic markers, which in turn provide highly sensitive information about an individual's health. In such cases, Locke's theory would provide little help and so we may need to think further on this issue, and quickly.[86]

The historical record of the eugenics policies of the first half of the past century should serve as a warning about the disastrous consequences that non-respect for individual autonomy and informed consent would bring. Unfortunately, serious breaches

[85] *Ragnhildur Guomundsdottir v. The State of Iceland*.
[86] Shaun McVeigh and Sally Wheeler, eds., *Law, Health and Medical Regulation* (Aldershot, U.K.: Dartmouth Publishing Co. Ltd., 1992), p. 50 [McVeigh and Wheeler].

in ethics continue to arise, reminding those stakeholders concerned about maintaining a sound ethical environment of the need for vigilance. One such example is a scandal that arose out of the Diana Princess of Wales Children's Hospital in Birmingham, U.K. in the 1990s when a woman found out that her deceased baby was being buried without her heart and without the mother having given prior consent. Subsequent inquiries into the practices at that hospital and dozens of other hospitals around Britain established that approximately 11,000 hearts had been removed from deceased infants in the name of medical research over the course of many years and all without the consent of parents or legal guardians.[87] An even more invasive example of an ethical breach involving living human tissue arose out of the United States. During the last three decades of the 20th century, there were physicians around the U.S. who were secretly removing eggs from female patients who were in hospital for pelvic surgery, including laparoscopy for infertility exams and hysterectomies. However, Andrews and Nelkin explain that women who did not yet know they were pregnant were of particular interest to researchers wanting to develop new contraceptives:

> In fact, the researchers who were developing contraceptives especially coveted fertilized eggs from women who apparently did not realize they were pregnant. One of the researchers attempting to develop in vitro fertilization jokingly talked about how he 'poached' eggs – piercing patients' ovaries and aspirating eggs when they were undergoing pelvic surgeries or for other reasons.[88]

H. Does a doctor or researcher have to inform you about a financial interest in your body?

What happens when physicians have a pecuniary interest in the cells of a patient's body? Is there a duty to let the patient know when profits are to be made from extracted tissue? A case out of the United States, *Moore v. Regents of the University of California,* is arguably the best example of the ethical problems that arise when the pecuniary interests of a physician blur with the professional duty of care.[89] John Moore was diagnosed with a form of leukemia in 1976 following extensive testing during a stay in

[87] Andrews and Nelkin, page 160.
[88] Andrews and Nelkin, page 14.
[89] *Moore v. The Regents of the University of California*, (1990) 51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479 [*Moore v. The Regents of the University of California*].

hospital at the Medical Center of the University of California at Los Angeles. The testing included draws of blood, bone marrow and other tissue. Moore's physician subsequently advised him that his spleen should be removed in order to slow down the progress of the leukemia otherwise Moore would probably die. Based on this advice, Moore signed the requisite consent form and the surgery went ahead. Over the course of the next seven years, Moore periodically attended the UCLA's medical centre for several more draws of blood, bone marrow and other bodily substances. These visits were pursuant to the instructions of Moore's physician who insisted they were required for Moore's post-operative care and who also insisted that the testing could only be performed at the UCLA medical centre. The evidence at trial would establish that both Moore's physician and a research scientist at UCLA had a financial interest in exploiting Moore's cells for research purposes but this interest was never disclosed to Moore at any time. Indeed, a cell line from Moore's T-lymphocytes was established by Moore's physician in late 1979. In 1984, the Regents for UCLA obtained a patent on this cell line, naming Moore's doctor and the research scientist as the inventors with UCLA named as the assignee of the patent. With UCLA's aid, agreements for the commercial development of the cell line were negotiated with a biotech company that proved to be very lucrative for all concerned. The Supreme Court of California ruled in its 1990 decision that though Moore had no property rights to either his cells or any subsequent profit arising from them, Moore's physician had an ethical obligation to disclose his financial interest in the matter, which he had failed to do, and that Moore consequently had a right to bring forward a claim for any injury suffered as the result of the physician's breach of his ethical obligation.[90]

John Moore's experience is instructive for a number of reasons, not the least of which is that it suggests the critical role that primary care physicians and clinicians play in the milieu of medical research. The medical researcher, more often than not, will have established professional relationships with primary care physicians and will regard them as an important source for potential research participants. As such, the patient's physician will be aware of the demographic requirements of a given research project and will know that the researcher is working on a particular disease or condition. Often it is the

[90] *Ibid*.

physician who will suggest to the patient that he or she give consideration to participating in a given research project. In such an eventuality, where there is a negative result from the research project, both the physician and the researcher could be found responsible to the patient for any loss or injury. The physician's duty therefore is one that includes not just informing the patient of the benefits but of the risks factors too.[91]

Respect for informed consent in the medical research context is not only a fundamental question of respecting the personal dignity and privacy of the patient or potential donor, however much these may be normative values in research involving humans. It is also a question of legitimizing and enhancing a given research project by ensuring that it has broad, public support – support that is best forthcoming when research participants have been fully informed about the nature of the project, why their tissue sample is important, what they are consenting to, and what will happen to their sample after it is taken. The protection of human rights and the advancement of medical research are not incompatible goals – the principle of informed consent is the nexus where these two goals converge.[92] Few people would question the need for medical research when they can see a personal benefit deriving therefrom or a benefit to somebody for whom they love. Many people too, when considering the immense cost involved in medical research and the laborious process of eventually bringing a new product, therapy or pharmaceutical, might even understand why an assertion of personal property rights to their tissue is an untenable position. However there does seem to be a universal need among humans for respect and self-worth – a psychological need that is not met when our bodies are treated as mere farms to be harvested.

[91] Einsiedel writes at page 35 that: "The ethical conduct of medical research is most directly spotlighted in this doctor-patient relationship."

[92] In arguing against the application of personal property rights to bodily tissue, Richard A. Spinello has said: "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." (Richard A. Spinello, "Property Rights in Genetic Information" in Herman T. Tavani, ed. *Ethics, Computing and Genomics* (Sudbury, MA: Jones and Bartlett, 2006), page 226 [Spinello]).

I. Informed Consent and Capacity

Special concerns arise in situations where lack of capacity to make a decision is at issue, whether this lack be in the legal sense where a child is, by definition, unable to give consent or in the case where the person is incapable of giving consent because of a lack of intellectual capacity resulting from an infirmity of some kind. In such cases, the primary caregivers who have a moral and legal obligation to make the decisions for the person must do so carefully. In instances where other persons are stepping into the place of another to make decisions about whether that person should participate in a given research project, Laurie argues that care must be taken to prevent backsliding into paternalism:

> In the hardest of cases – when capacity is neither wholly present nor absent but in serious doubt – courts have to decide between, on the one hand, respecting the degree of autonomy that is present but reduced, and on the other, treating the person in a paternalistic fashion.[93]

In Canada, the issue of parental consent for the participation of children in medical research is determined in accordance with the *Tri-Council Policy Statement* and the determinative factor is that the child's participation can only occur when it can be demonstrated that the child will not be exposed to "…more than minimal risks without the potential for direct benefits." Furthermore, the participation of a child in a populational genetic research project would also typically be subject to approval by a research ethics board.[94] Three provinces – New Brunswick, Quebec and British Columbia – have legislation which sets out the minimal ages at which minors may consent to medical treatment so these acts might also be of relevance in those jurisdictions when the capacity of a young person to understand the consequences of participating in a genetic research project is at issue. In New Brunswick, a person sixteen years of age can consent

[93] Laurie, page 192.
[94] "The TCPS [Tri-Council Policy Statement] anticipates that parents, as authorized representatives of children, may consent to research on behalf of the minor if the research does not expose the minor to more than minimal risks without the potential for direct benefits." (Sheremata, para. 4.D).

to medical treatment.[95] Moreover, even if the person is under sixteen years of age, he or she can still have a say in decisions regarding health care if, in the opinion of a treating physician or dentist, that person is capable of understanding and the treatment is for his or her best interests.[96] In Quebec, a person as young as fourteen can make decisions pertaining to his or her health care, which would arguably include giving an informed consent to participate in medical research projects.[97] However, such consent is provisional, i.e., the consent of a parent or guardian is also required for a person 14-17 years of age inclusive where treatment for a disease or condition presents a risk of serious and permanent negative secondary effects.[98] In British Columbia, a minor may consent to health care provided that: i) he or she understands the nature and consequences, as well as the foreseeable benefits and risks, of the health care, and ii) in the opinion of the health care provider the treatment is in the minor's best interests.[99] Other provinces, such as Ontario and Manitoba,[100] have legislation that requires consent to medical treatment by minors in the care of the state. In addition, some provinces have provided legislation that deals with advance health care directives by minors.[101] Finally, the courts have been carving out, through a number of decisions arising in consent to treatment cases, a special category known as the "mature minor," which suggests that, in instances where a young person is sufficiently mature and has the intellectual capacity to understand the nature and consequences of consenting to treatment, his or her wishes must be respected.[102] In conclusion, it is fair to say that although "mature minors" should be able to provide consent to participate in medical research projects, it is wise for researchers and hospital research ethics boards to also have the minor's parent(s) or guardian sign off on the project's consent form.

When weighing whether to permit a child's participation in a research project, it is incumbent at all times on the primary caregivers to carefully consider the benefits, actual

[95] *Medical Consent of Minors Act*, R.S.N.B. 1976, c. M-61, s. 2.
[96] *Medical Consent of Minors Act*, R.S.N.B. 1976, c. M-61, s. 3(1).
[97] *Code civil du Quebec*, C.C.Q., L.Q., 1991, c. 64, s. 14.
[98] *Code civil du Quebec*, C.C.Q., L.Q., 1991, c. 64, s 17.
[99] *Infants Act*, R.S.B.C. 1996, c. 223, s. 17 (3).
[100] *Child and Family Services Act,* C.C.S.M. c. C80.
[101] See, for example, *Advance Health Care Directives Act*, S.N.L. 1995, c. A-4.1, s. 16.
[102] See *A.C., A.C. and A.C. v. Manitoba (Director of Child and Family Services*), [2009] S.C.C. 30. *Children's Aid Society of Metropolitan Toronto v. K*., (1985), 48 R.F.L. (2d) 164; *Y. (A.), Re* (1993), 111 Nfld. & P.E.I.R. 91; *Walker (Litigation Guardian of) v. Region 2 Hospital Corp*. (1994), [1994] N.B.J.

and potential, that such participation can bring against whatever risk factor may be present, however minimal that may be.[103]

However, several issues arise in the area of testing an asymptomatic child where there is reason to believe the child may be prone to a late onset genetic disease or condition, not the least of which is the situation where a child may carry a gene that will result in a condition or disease years or even decades away and for which there is no effective treatment. Among other problems, the child in this situation would have no say over how the test results will be circulated, which raises the question of how that might impact on the child's career choice later on and whether a future employer who somehow came into possession of such knowledge might discriminate against him or her. Perhaps, as well, the child's own family might discriminate against him or her, in a completely unintentional way by being overly protective or dissuading him or her from pursuing higher education or pursuing a career path, believing they were acting in the child's best interests.[104]

J. Can a decision truly be autonomous?

There is some question, though, about the practical application of the doctrine of individual autonomy, the premise of which is that a fully informed person will make a free choice. Persons from whom consent is being sought are typically in a position of inequality vis-à-vis the party seeking consent, which can, depending on the circumstances, be a physician, researcher, prospective employer or a prospective insurer.[105] In the context of somebody being asked to undergo genetic screening, for example, most people will have no more than the most basic of understandings – if they

[103] M. Lessick and S. Faux, "Implications of Genetic Testing of Children and Adolescents" (1998) 12(3) Holistic Nursing Practice 38. <http://find.galegroup.com.ezproxy.lib.ucalgary.ca/itx/infomark.do?&contentSet=IAC-Documents&type=retrieve&tabID=T002&prodId=AONE&docId=A20467829&source=gale&srcprod=AONE&userGroupName=ucalgary&version=1.0> [Lessick and Faux].

[104] Jamieson, page16.

[105] "Unfortunately, in many contexts and especially in those of employment and insurance, the individual from whom consent is to be obtained is in a substantially weaker position than the party seeking consent. This is also true in the doctor-patient relationship, albeit the motives of the health care professional are different from those of, say, employers or insurers." (Laurie, page 205). Also, see Laurie at page 312 who says: "The imperative to seek and obtain consent from research subjects gives them an illusion of power and control. In reality, it delegates extremely limited control to individuals. The sole power that is afforded is that to withhold consent – that is, to refuse. Moreover, there is no residual power once consent has been given unless further consent is required at some future point."

even have that – of what is meant by terms like genetic predisposition or risk factor. Furthermore, the relationship between a given gene that may be linked to a disease and the external environmental and personal lifestyle factors that trigger that gene is a complex one which, in many cases, is itself the subject of speculation and therefore in need of further research. In facing a decision whether or not to undergo screening, the majority of people will be heavily reliant on their physicians or genetic counselors – where such counselors are available – not only for medical information but also will be expecting such professionals to give their own opinions. Can a person who is terminally ill with cancer, for example, be expected to make a truly independent decision when he or she has only the hope that an experimental drug – the side effects of which are not yet known – might buy them more time, if not send the cancer into remission entirely?[106]

K. Informed Consent and Aboriginal Communities

Another special concern may arise when the cohorts for a genetic research project are members of an Indigenous tribe or population group. It is in this context that one may most readily see the potential for conflicting values arising as the traditional Anglo-European liberal model of individualism comes up against a traditional Indigenous way of collectivism with its sense of duty to the wider community.[107] The ascendancy of the individual within Anglo-European culture is not a position that finds common ground

[106] Mehlman, page 86. See also Sherman Elias and George J. Annas, "Somatic and Germline Gene Therapy" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 144 [Annas and Elias 1992].

[107] A report prepared by the IPHRC addresses this apparent dichotomy between liberal individualism and the collectivist culture of Indigenous communities at page 30: "Individual consent to research in and by itself is a problematic issue for Indigenous Peoples in light of the collective knowledge concept and Indigenous social mores (Beauvais, 1999). Obtaining consent from individuals in Indigenous communities can be problematic for a number of reasons. As Henderson (1996) has observed, "no single individual can ever be aware of all the cultural concerns that may exist in the community" (p. 83). These concerns may revolve around the issue of releasing information that is private and any disclosure of such information is a moral transgression against families and the community… . For Indigenous Peoples, the Western paradigm of individualism that recognizes the right of the individual to give knowledge through 'informed consent' is contradictory to the concept of collective ownership understood by Indigenous People." ("The Ethics of Research Involving Indigenous Peoples," *IPHRC Report to the Interagency Advisory Panel on Research Ethics* (Regina, Saskatchewan: Indigenous Peoples' Health Research Centre, July 2004), [*IPHRC Report*]. Einsiedel also addresses the challenge of reconciling the liberal notion of personal autonomy with the traditional collectivist culture of Aboriginal peoples at page 33: "The question of informed consent is typically discussed in the context of western notions of personal autonomy, but many indigenous groups have social structures which are based on the collective rather than the individual. How will the process and the assumptions behind these processes of informed consent be modified to accommodate these different social and cultural contexts?"

with many of the world's Indigenous cultures and peoples. Many Indigenous peoples regard group consent, for example, as a principle that is at least as equal in value as individual consent, if not more so.[108] Furthermore, the Anglo-European scientific tradition, with its emphasis on the reductionistic pursuit of understanding the natural world through empiricism, is one that fails to account for the deeply spiritual and emotive regard that Aboriginal peoples traditionally held for the natural order and all its creatures, including humans. For many Aboriginal people, genes have an inherently spiritual quality that transcends the individual experience such that they are regarded as but tiny bits of the much bigger whole that is humanity and indeed all the natural world. In offering us the example of the Maori people of New Zealand, Bita Amani and Rosemary J. Coombe write:

> For the Maori – and their beliefs are echoed by many of the indigenous activists, advocates, elders, and traditional healers whose voices are expressed at international conferences and in NGO declarations – a gene embodies the life spirit. It is the spirit of a people that is passed down from the ancestors and is the gift to future generations for which the current generation is vested with responsibility. Genes cannot be personally or individually alienated because they are part of the heritage of families, clans, tribes, and embody the spiritual identity, not of individuals, but of groups and nations.[109]

Moreover, the religious or cultural traditions of many indigenous peoples are incompatible with the notion that life of any kind is capable of being patented.[110] Finally, when one considers the history of Old World conquest and domination of the world's Aboriginal peoples over the last 500 years, the skepticism and even hostility with which many contemporary Aboriginals regard genetic research can be understood.[111] It was

[108] *IPHRC Report*, page 31.
[109] "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (January, 2005) 2 (1) Law and Pol'y 152, page 158. [Amani and Coombe]. Also see *IPHRC Report*, page 24.
[110] Kara H. Ching, "Indigenous Self-Determination in an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm" (1997-98) 66 Fordham L. Rev. 687, page 688 [Ching].
[111] *IHRPC Report*, page 27. Also see Amani and Coombe, who write at page 156: "There was little indication that the diseases to be studied or the treatments likely to be developed from Project research would benefit the indigenous peoples from whom samples would be taken… . Those concerned with issues of social justice quite properly ask why we should expect indigenous peoples to grant us access to their genetic resources in order to advance medical knowledge about the maladies of the privileged when we will not provide even the most basic of existing medicines or infrastructural resources to alleviate their suffering."

against this background of suspicion and concern that the Human Genome Diversity Project (HGDP) was initiated in 1991 with a mandate by its originators to collect DNA samples from some 500 indigenous groups around the world.[112] The HGDP must be distinguished from the Human Genome Project. The HGDP was set up by a geneticist named Luigi Luca Cavalli-Sforza at Stanford University. Is mandate is to collect DNA samples from different population groups around the world in order to create what will essentially be an open-source database for genetic researchers interested in studying the migration patterns of human populations and to identify genes that confer either resistance or susceptibility to disease.[113]

To help alleviate the concerns of Aboriginal scholars and tribal leaders, the North American Regional Committee of the HGDP advocated that genetic researchers should seek to obtain group consent wherever that was feasible. Their "Model Ethical Protocol for Collecting DNA Samples" stated that the HGDP would only collect human tissue samples whenever an individual donor had consented and, wherever possible, the "culturally appropriate authorities" of the ethnic or tribal group that was the cohort target had also consented.[114]Furthermore, to ensure compliance with these research guidelines, the Diversity Project has refused to fund or otherwise support any research project that fails to adhere to the standards as set by the Model Protocol.[115]

Within Canada, there is support for the position that medical research ethics protocols for projects involving the tissue of indigenous persons should account for the wider concerns and interests at the tribal level. A report along these lines prepared by the Indigenous Peoples' Health Research Centre (IPHRC) – an Aboriginal policy think-tank located at the University of Saskatchewan – has recommended that Canada's *Tri-Council Policy Statement* should formally acknowledge the jurisdiction that indigenous people have over their culture, heritage and traditional knowledge particularly as such knowledge applies to traditional medicines derived from plants. The IPHRC has also recommended that indigenous peoples should be consulted regarding proposed research projects involving the use of human tissue coming from indigenous peoples and also that

[112] Ching, page 692.
[113] See online: The Human Genome Diversity Project <http://www.hgalert.org/topics/personalInfo/hgdp.htm>.
[114] Greely 2003, page 69.
[115] Ching, page 693.

tangible benefit to indigenous peoples must derive from such projects.[116] A basis for such consultation and benefit-sharing, though, may arguably already lie within the research ethics protocols found in the *Tri-Council Policy Statement*. The statement recognizes at page 2.6 that the population group from which tissue samples are to be taken may have cultural values that differ from those of the researchers and that where there is such a divergence in values, research ethics boards need to ensure that appropriate measures are in place to address the special concerns of the group.[117] Finally, there does appear to be a recognition within the *Tri-Council Policy Statement* of the need for sharing benefits with the population group involved in a given medical research project. At page 5.1 of the statement, the principle of distributive justice is explicitly set out along with a call for the resulting benefits from the research project to be made available in some tangible way to the Indigenous people who had participated in the project. Furthermore, the principle of distributive justice must be accorded weight by research ethics boards, research institutions and even corporate sponsors:

> Contemporary concerns with justice in research have broadened: are the overall benefits and burdens of research distributed fairly, and have disadvantaged individuals and groups received a fair share of the benefits of research?
> The above two concerns form the basis of the principle of distributive justice: members of society should neither bear an unfair share of the direct burdens of participating in research nor should they be unfairly excluded from the potential benefits of research participation. The concerns raised by the principle reflect broader obligations to respect human dignity and diversity. They should, therefore, receive the formal attention of researchers, REBs, research institutions and sponsors.[118]

Indeed, in the clearest of language, the Tri-Council Policy Statement states that all the stakeholders responsible for funding and implementing a given research project – be they the researchers, institutions or REBs – occupy important roles in ensuring that a

[116] *IHRPC Report*, pages 7-9.
[117] See page 2.6 of the *Tri-Council Policy Statement* which says: "REBs should proceed cautiously in such cases and require stringent protection for the interests of subjects, such as appointing an individual to act in an independent advocacy role. On the other hand, REBs should not assume an unnecessarily protective role which suggests that those who do not share the culture of the researchers, particularly those in foreign countries, are incapable of making rational decisions in their own interests."
[118] *Tri-Council Policy Statement*, page 5.1.

research project is equitably run from start to finish, with benefits flowing to the research participants being a critical part of that process:

> Whether intentional or inadvertent, the exclusion of some from the benefits of research violates the commitment to societal justice. A commitment to distributive justice in research imposes obligations on, and concerted activities by researchers, institutions and REBs. All have important roles to play in ensuring a fairer distribution of the benefits and burdens of research.[119]

With informed consent being a necessary precondition for any medical research project involving humans, research ethics boards and the researchers themselves need to take particular care when obtaining consent from Indigenous populations. Because the process of obtaining consent in these settings will probably involve negotiations with community representatives such as tribal elders, ethical protocols of the REB in question will need to be specifically tailored to address the need, first of all, for such a consultative process and then the final product itself – an ethical protocol that accounts for the concerns and needs of the Indigenous group at issue.[120] Otherwise, the researchers and the potential donors will find themselves in an ethical quandary because the standard ethical protocols of many REBs are drafted in such a way as to reflect a health science research ethos grounded only on liberal individualism. An individualistic approach to informed consent will leave the individual members of the Indigenous group at issue in the difficult situation of perhaps otherwise willing to participate in the project but feeling reluctant about doing so because the project lacks the endorsement of a tribal council or tribal elders.

L. Privacy and Confidentiality Concerns

The legal model of autonomy and the medical model of confidentiality need to be reconciled in the context of genetic information. Otherwise, our health care professionals are left on the potential horns of a dilemma. Though both models are premised on the need for the research participant to give informed consent prior to participating in the project, the models, strictly speaking, diverge on the issue of confidentiality with the

[119] *Tri-Council Policy Statement*, page 5.2.
[120] *IPHRC Report*, page 32.

legal model based on patient autonomy and the medical model based on a physician's duty to warn others in certain strictly defined circumstances.[121] In accordance with the strict application of the legal model, the DNA donor whose genome was shown to carry a gene that could cause a debilitating condition would have that information retained in the strictest of confidence. However, in contrast, in accordance with the medical model, a health care professional in a clinical setting is under a professional duty to warn family members of the possibility of a genetic condition in their genetic makeup. Furthermore, for practical purposes in clinical settings, doctors usually see a need to communicate to patients' families what would otherwise be considered as confidential information because family cooperation and support is usually required to assist in helping patients accept the news of a debilitating condition or disease, particularly once that condition or disease reaches the symptomatic stage.[122] In reconciling these two models for purposes of genetic research projects, particularly in the case of large biobanks, clearly defined laws are necessary so as to protect physicians who, acting in accordance with their professional obligation to alert family members of a genetic condition, might otherwise be sued by tissue donors for breach of confidentiality. Furthermore, laws may be necessary to safeguard the genetic information from private medical insurance companies who might otherwise discriminate against the DNA donor in declining to provide coverage because of the risk of that person developing a genetic-based condition or disease.

Concerns about the use to which a person's genetic information might be put are well-founded. After all, it is in the application of genetic information outside of a hospital or university research laboratory that personal privacy issues arise, not in the actual practice of the science itself. And it is here where lawmakers, ethicists, and health service administrators must rise to the challenge of addressing the legitimate privacy expectations of health care system users while ensuring that research scientists and health care professionals are able to pursue their work as freely as possible, subject to whatever ethical guidelines might be appropriate. Indeed, many ethicists and health science

[121] Martin Letendre, "Le Devoir du Medicin de Prevenir les Membres de la Famille d'un Patient Atteint d'une Maladie Genetique" (2004) 49 McGill L.J. 555, page 559 [Letendre].
[122] Roy Gilbar, "Medical Confidentiality Within the Family: The Doctor's Duty Reconsidered" (August, 2004) 18 Int'l J.L. Pol'y & Fam. 195, page 203 [Gilbar].

researchers advocate a regulatory regime specifically tailored to the collection of genetic samples and the retention of such samples and all data derived from them. Three reasons have been given for this:

1. the volume of information that can be gleaned from a single sample of DNA;
2. the increasing speed with which a person's DNA may be tested; and
3. the links between the DNA database and the information databases that contain information derived from the DNA itself.[123]

A regulatory and ethical regime specifically oriented to the collection and storage of human tissue for genetic research purposes is of critical importance as our health care system increasingly adopts a mass populational model for such research projects; a model that is more commonly known as a biobank. Unfortunately, existing legislation in Canada that is aimed at protecting personal information and that is supposed to protect personal privacy does not cover genetic information.[124]

M. Biobanking and Mass Populational Research Projects

A biobank may be referred to generically as a repository of the actual physical specimens themselves, i.e. the DNA, blood or other tissue samples, as the case might be.[125] However the term biobank can also refer to the place where the information that such DNA samples yielded to researchers is stored.[126] Biobanks in Canada tend to be held by laboratories in large hospitals or major universities for the purpose of diagnosing diseases which have some genetic basis or for conducting research into the genetic nature of diseases. From a privacy and personal liberty perspective, access to biobanks

[123] Trudo Lemmons and Lisa Austin, "Of Volume, Depth and Speed: Thc Challenges of Genetic Information" in *Protecting Privacy in the Age of Genetic Information* (Canadian Biotechnology Advisory Committee, Ottawa: August 2004), online: Canadian Biotechnology Advisory Committee <http:cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00477e.html> [Lemmons and Austin]. See section 1 in the Introduction.
[124] For example, the federal *Personal Information Protection and Electronic Documents Act*, R.S.C. 2000, c. 5 and Alberta's *Personal Information Protection Act*, R.S.A. 2003, c. P-6.5 contain no provisions relating to genetic information.
[125] Lorraine Sheremata, "Population Biobanking in Canada: Ethical, Legal and Social Issues" in *Protecting Privacy in the Age of Genetic Information* (Canadian Biotechnology Advisory Committeee, August 2004), online: Canadian Biotechnology Advisory Committee <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00477e.html> [Sheremata].
[126] Sheremata, note 9.

established for the purpose of medical genetic research must be restricted to health care researchers and remain off-limits to third parties such as law enforcement agencies and private health insurers. Indeed, within the Canadian health care community, there is a broad consensus among primary care practitioners that law enforcement agencies and the justice system generally ought not to have access to genetic databases that have been established for medical research purposes.[127] (There is already a national criminal law biobank in Canada containing the DNA samples of persons convicted of serious crimes like murder or sexual assault, and to which various law enforcement agencies around the country submit the samples taken from such persons pursuant to lawful authority.) In the United States, DNA sampling and testing outside of the health research arena is expanding at a dizzying rate for reasons that should raise serious concerns among anyone concerned about individual rights and liberties. Such expansion was occurring even prior to the terrorist attacks of September 11, 2001:

> As a tool for surveillance, DNA tests are appealing. Our society is witnessing a striking tendency to test and bank the tissue of an ever-wider range of people – from soldiers who go into battle to chaplains' assistants, from violent to nonviolent felons, from immigrant families to foreign adoptees. Characteristically, it is not doctors or public health officials who collect tissue samples for identification, but governments, law enforcement agencies, the military, and immigration authorities.[128]

In the United States, biobanks ranging in size from a few hundred DNA or tissue samples to millions of samples are the norm, with types of banks ranging from small operations to the largest of banks – the one maintained by the United States military which routinely collects DNA samples from all military personnel in the event that should they die in combat operations, their DNA samples can be used to help identify the deceased remains.[129]

A mass populational genetic research project would involve taking tissue samples from large numbers of people and then extracting DNA from such tissues to yield data of

[127] Einsiedel, page 37.
[128] Lori Andrews and Dorothy Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York, NY: Crown Publishing, 2001), page 124 [Andrews and Nelkin].
[129] Patricia A. Roche and George J. Annas, "Protecting Genetic Privacy" (May, 2001) 2 Nature Reviews Genetics 392, page 394 [Roche and Annas].

great significance to society in terms not only of adding to our understanding of the complex relationship between genes and non-genetic factors such as diet and environment, but also in terms of contributing invaluable knowledge to health care administrators who are responsible for devising a national health care policy.[130] Such large-scale research projects typically involve taking tissue samples such as blood or saliva, from which DNA is extracted and individual genetic profiles are determined.[131] There are mass populational studies currently underway in several other countries; the United Kingdom, Norway and Estonia, for example. The United Kingdom Biobank began recruiting donors in 2006 and will eventually have bio-samples from 500,000 U.K. citizens between 40-69 years of age as part of that nation's National Health Service's research into the early detection and treatment of a range of serious illnesses, including cancer, heart disease diabetes, arthritis, and various forms of dementia.[132] Norway's HUNT project began in 1984 and since then, 100,000 residents of a county called North Trondelag have donated tissue samples and completed extensive questionnaires about their health and lifestyles. HUNT collaborates with Norwegian and international health research groups conducting research into diseases or conditions such as cancer, diabetes, musculoskeletal disease, mental illness, urinary incontinence, obesity, and cardiovascular disease.[133] The Estonian Genome Project was founded in 2001; its aim is to create a database of the health, genealogical, and genome data from bio-samples representing 10% of Estonia's population. This database will be accessible to Estonian and international health researchers as they continue to better understand the link between

[130] "Disparities in health status constitute a significant global issue, but can genome-based approaches to health and disease help to reduce this problem? Social and other environmental factors are major contributors to health disparities; indeed, some would question whether heritable factors have any significant role. But population differences in allele frequencies for some disease-associated variants could be a contributing factor to certain disparities in health status, so incorporating this information into preventive and/or public-health strategies would be beneficial. Research is needed to understand the relationship between genomics and health disparities by rigorously evaluating the diverse contributions of socioeconomic status, culture, discrimination, health behaviours, diet, environmental exposures and genetics." (Francis S. Collins et al., "A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era" in Herman T. Tavani, ed., *Ethics, Computing and Genomics* (Sudbury, MA: Jones and Bartlett, 2006), page 303 [Collins et al.].
[131] Sheremata.
[132] Online: http://www.ukbiobank.ac.uk/about/what.php
[133] Online: http://www.huntbiosciences.com/

genes and environmental factors in common diseases such as cancer, diabetes, and depression.[134]

In Canada, a mass populational cancer study got underway in June of 2008 with the launch of *The Canadian Partnership for Tomorrow Project*, which involves cancer research organizations and biobanks from five regions: the British Columbia Cancer Agency, the Alberta Cancer Board, Cancer Care Ontario with the Ontario Institute for Cancer Research, Quebec's CARTaGENE project, and Cancer Care Nova Scotia with Dalhousie University coordinating the work for the four Atlantic Canadian provinces. Three hundred thousand randomly selected donors between the ages of 35-69 are being recruited for the project. They will be asked to fill out lifestyle questionnaires, have physical measurements taken (including weight, height and Body Mass Index) and samples of blood, urine and toenail clippings will be taken. The health of these participants will be monitored for up to 30 years through cancer registries, hospitalization records and other health-related databases. The project's mandate is to determine the relationship between genes, lifestyles, and environmental factors in the development of cancer, as genetic researchers seek to identify biomarkers, i.e. those molecules in the blood that can be used to diagnose cancer at its earliest, most treatable stage.[135]

A sound ethical protocol for such a biobank requires that the purpose of the biobank, and to what use the donor's tissue or bodily fluid is to be put, be fully explained to the potential research subject or the person's parent or legal guardian prior to the sample being collected. A potential research subject can only give consent when he or she has been fully informed about the nature of the research to be undertaken and this consent may be withdrawn at any time.[136] The samples themselves are cryogenically preserved and the data obtained from them are stored in a computer database as sequence data which can then be co-related to diverse information such as the donor's age, diet, and various environmental and lifestyle factors.

In terms of research ethics protocols, biobanking procedures ideally should serve the interests of both researchers and donors of tissue samples. The interests of both

[134] Online: http://www.geenivaramu.ee/index.php?lang=eng

[135] http://www.partnershipagainstcancer.ca/tomorrow_project

[136] *Tri-Council Policy Statement,* articles 2.1, 2.2, 2.4, 2.8.

should not be regarded as mutually exclusive; indeed medical genetic research has broad public support within Canada provided that the privacy concerns of donors are adequately addressed. In researching the public opinion of adult Canadians toward genetic research and biotechnology issues, Health Canada has found that fully 73% of those surveyed desire "…a balance between protection of privacy and health research in the biotechnology sector. Only small, but equal, minorities of 12% and 13% chose one over the other."[137] Therefore, in order for research to progress, there has to be a high degree of public confidence that the privacy of donors will be respected. Research into the attitudes of Canadians regarding genetic information has shown that 2/3 of Canadians see genetic information as "most private and confidential" and they do not want other people to have access to this information without their express consent.[138] Canadians report being most concerned about third-party, non-medical personnel – such as police forces or insurance companies – accessing their genetic information.[139] Indeed, 58% of those who participated in a federally-funded survey about their opinions regarding genetic privacy said that access to personal genetic information needs to be more strictly regulated than other health information.[140] As noted by Einsiedel and Sheremata, concerns about access and how the genetic information will be used are especially acute when mass samplings of large groups of people are contemplated as part of ongoing efforts to learn more about the complex relationship between genes and environmental factors in the triggering of diseases:

> Large-scale population genetics research initiatives are aimed at uncovering gene-environment interactions implicated in a variety of complex human diseases. A shift has occurred in medical genetics away from traditional linkage analysis that focuses on specific heritable conditions, impacting relatively small numbers of

[137] "Public Opinion Research", page 12. Interestingly enough, although Canadians assign a high value to the right to privacy, where rights and obligations start to conflict, the absolute right to privacy rights starts to lose its ascendant position. See Sheremeta at paragraph 4.F: "Rather surprisingly, if forced to choose, slightly more people emphasize research than privacy protection…It appears that the more people learn about genetic research and biobanking, the more likely they will conclude that the benefits of the research outweigh the risks involved."
[138] Einsiedel, page 14.
[139] Einsiedel, page 22.
[140] "Public Opinion Research", page 9.

> affected individuals and their families, to population genetic research initiatives that focus on large heterogeneous populations.[141]

There are two stages to DNA biobanking: the preservation of the human tissue samples in a secure storage facility and the retention of personal information about the donors – personal information that would of course include the results of any research done on the samples themselves. What makes genetic data unique from other forms of personal medical data is that genetic data discloses a person's individual phenotype, i.e. their physical and mental characteristics.[142] Furthermore, this information will also reveal the genetic composition of relatives of the donor. Therefore, great care must be taken not only in the storage of this data but also in terms of defining who may access it as well as whether there will be further research undertaken. When a potential donor to a populational research project is given pertinent information during the initial phase of the informed consent process, according to the *Tri-Council Policy Statement* that potential donor (or parent or guardian if the donor lacks capacity because of age or infirmity) should be given a choice between a comprehensive consent form that includes a number of options (e.g. the tissue will be used only in the current study or the tissue will be used only for research related to a particular condition or disease) or a more limited consent form that indicates the researcher will contact the donor regarding future uses of the tissue.[143] Furthermore, given that the right to withdraw from a research project is an integral part of the informed consent process, a special situation arises in the context of biobanking DNA since withdrawal would impact on the biological relatives of the donor as well. In such a case, then, the donor's genetic material might be discarded or destroyed, or the data derived therefrom eliminated, or the DNA and data retained but personal identifiers linking the donor to it destroyed. These various options would have to be discussed with the donor or the donor's authorized representative as well.[144]

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[141] Edna Einsiedel and Lorraine Sheremeta, "Biobanks and the Challenges of Commercialization" in Christoph W. Sensen, ed., *Handbook of Genome Research, Genomics, Proteomics, Metabolomics, Bioinformatics, Ethical and Legal Issues* (Weinheim, Germany: Wiley-VCH, 2005), pages 538-539 [Einsiedel and Sheremeta "Biobanks"].
[142] Maxwell J. Mehlman, *Wondergenes: Genetic Enhancement and the Future of Society* (Bloomington, Indiana: Indiana University Press, 2003), page 23 [Mehlman].
[143] *Tri-Council Policy Statement*, page 8.7.
[144] *Tri-Council Policy Statement*, page 8.7.

Research involving human tissue stored in a biobank must always be undertaken in accordance with clearly defined parameters:

> Research must be approved and monitored by institutional ethics committees and certain standards met to safeguard genetic information and stored tissue. Genetic information may not be used by employers/insurers in making decisions, except for the person's benefit.[145]

Furthermore, since populational genetic research will by its very nature involve not only the individual research participant or tissue donor but also the person's family and cultural group as well, genetic counselors might also play an important role in the informed consent process because a prospective participant or tissue donor needs to know that his or her participation in the study will yield information pertinent to the genetic makeup of relatives and members of his or her cultural group as well.[146] Moreover, for these complex research proposals, there will be significant discussion at the level of the research ethics board (REB) for the institution or hospital that will be the locus of the project.[147] This discussion at the REB level will involve consultation with the project's researchers and administrators about ethical concerns and any special guidelines or protocols that may be required. Such consultation would be imperative in setting up a biobank, which of course would typically involve tissue samples from a large number of people from across a diverse cultural spectrum, with concerns particular to a given culture necessitating accommodation that must be made within the ethics protocol in order for the project to successfully recruit donors from that group and ultimately to secure public confidence. Finally, debriefing and reporting the results of a large research project to the participants will be a critical factor in instilling a sense of trust among the participants and ensuring public support as well. However such debriefing may of necessity, owing to the large number of persons involved in the project, involve debriefing an entire family or even a community as opposed to informing each individual donor, which probably would be impractical in any event.[148]

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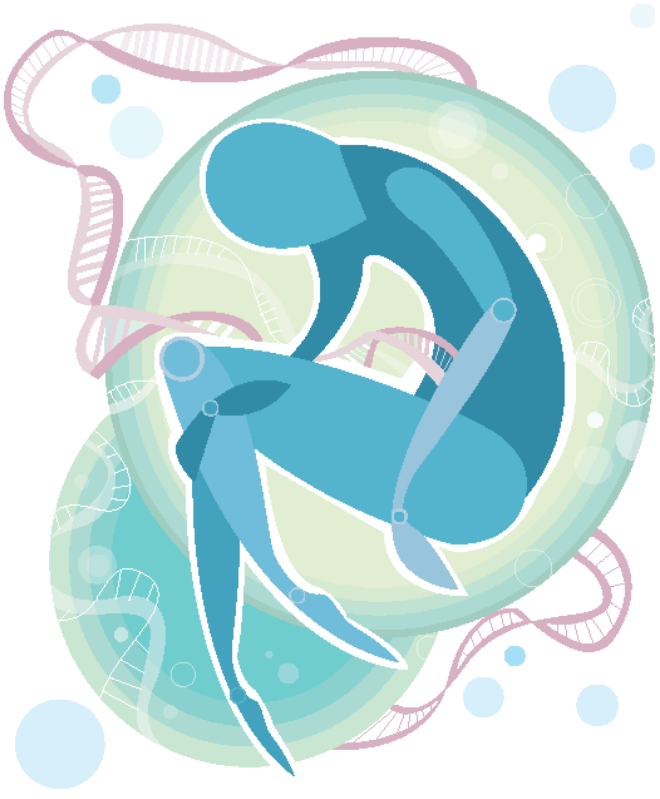
[145] Loane Skene, "Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing" (Spring 1998) 6 Med. L. Rev. 1, page 36 [Skene 1998].
[146] *Tri-Council Policy Statement*, page 8.4.
[147] *Tri-Council Policy Statement*, page 1.9.
[148] *Tri-Council Policy Statement*, page 2.3.

Chapter IV

Genetic Determinism and Discrimination



IV. Genetic Determinism and Discrimination

Statement of Purpose: *This section addresses the issue of genetic determinism and discusses the complex relationship between a person's genetic predisposition to a disease or condition and external, environmental factors or personal lifestyle choices. Though there are some conditions that will develop because of the presence of genes for those conditions, most conditions and diseases result from the complex, still little understood, relationship between the genetic markers for these conditions or diseases and the environmental and lifestyle factors that trigger them into action.*

A. What is genetic determinism?

Genetic determinism – or biological determinism as some prefer to say – is neither a scientific term nor a philosophical theory. Rather, it is the perspective, indeed prejudicial belief, that our entire person – physical traits, intellectual capacity, emotional self and state of health – are the sum total of our genes and therefore immutable. As set out by Smith:

> Biological determinism evolves from the principle of genetic essentialism that posits personal traits – such as mental illness, homosexuality, aggressive personality, exhibitionism, dangerousness, shyness, stress – have a genetic or biological disposition and, indeed, are predictable and determinable at conception; thus the social context in which the traits are manifested is minimized under this principle. In a word, biological determinism recognizes essentially that one's fate is determined by his or her genetic inheritance.[149]

Because genetic or biological determinism carries the message that people are no more than the sum total of their genes, this presents a huge problem for anyone concerned about human rights and civil liberties.[150] Advocates for human rights and civil liberties believe that, by virtue of being human, all persons are entitled to rights such as equality before and under the law, life, liberty, and security of the person. Consequently, these rights are not dependant on a person's ethnic or national origin, gender, or economic or

[149] Smith II, page 150.
[150] Proctor, page 59.

social standing. Indeed, in Canada, we have accorded constitutional protection to affirmative action programmes that have as their purpose the "amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."[151] However, biological determinists would have us believe that our individual situations in the present and in the future can be viewed in isolation of broader social, cultural and economic contexts. In other words, factors such as the socio/economic standing of our parents, racism, sexism, luck or a host of other factors have a minimal, if any, role to play in determining our lot in life. In the biological deterministic perspective, who we are, who we have in our social network, who we date and fall in love with, how we earn a living, has been pre-determined by the complex interplay of the proteins, amino acids and base chemicals at work in our bodies' cells from birth, indeed even from the embryonic stage. Thus, in the eyes of a biological determinist, if you have a criminal record, it is because you have a genetic predisposition to aggression and/or venality; if you are poor, it is because you have a genetic predisposition to laziness and any other negative traits that would inexorably bring you to a life of indigence; if you are rich, it is because of positive traits such as industriousness or shrewdness that are inherently genetic in their origin.

Unfortunately, the concept of genetic or biological determinism can easily and erroneously be conflated in the minds of laypeople with the acceptable medical diagnostic idea that the presence of a given defective gene in a person's genome indicates that person is at risk of developing a particular type of disease such as cancer or a progressively debilitating condition such as Huntington's disease. Within the health sciences field, depending on the type of disease or condition, there can be widely varying opinions as to how much weight should be accorded a genetic risk factor as opposed to looking at environmental triggers for the condition such as type of occupation, where one lives, or lifestyle factors such as the consumption of alcohol or tobacco. At one extreme of the debate would be those who would regard external environmental factors and personal lifestyle choices as merely secondary influences on a person's health with the

[151] Section 15(2), *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act*, 1982, being Schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11.

genes themselves being accorded much greater weight as triggers themselves for disease as opposed to being triggered themselves by outside environmental factors. Because decisions about which types of medical or pharmaceutical research should receive funding are dependant on a complex process involving the public, health care professionals and administrators, bureaucrats and politicians, public education is critical so that lay decision-makers are aware of what genetic inheritance means and what is meant by genetic risk factor.[152] After all, the source for biological determinism may be nothing more than what seems to be a natural human propensity to prefer to seek out quick and easy solutions to complex social problems; hence, in the case of human health, a desire for a genetic fix for the debilitating diseases and conditions that now exact their immense toll in terms of causing individual human suffering and straining the resources of the health care system.

The danger inherent to our continuing exploration of the complexity of life at its molecular and even sub-molecular levels is that we reduce our appreciation for life to the minutest parts – a clockwork of proteins, amino acids, base pairs. Granted, though on one level, all life, including human, can be objectively and intellectually understood as a wondrously complex process of chemical reactions occurring in a non-random fashion, even on this level we are as yet unable to fully understand how these chemical reactions occur, let alone ***why*** they occur. For that question both simple and profound – the *why* behind it all – even the most brilliant empiricist among us can only run face into what may always prove to be an unanswerable question:

> As mundane as it is, the human genome is essentially one huge parts list. A Boeing 747 contains about 100,000 parts but, as Eric Lander points out, 'having a parts list doesn't tell you how to put it together.' The sequence of the human genome will eventually reveal the identity of the tens of thousands of key components of the human genome and provide an enormous advance in the practice of medicine. However, identifying all the genes will not, in and of themselves, explain how the human mind and body work.[153]

However wrongful may be the belief that humans are irrevocably and immutably shaped in accordance with our genetic code; i.e., that personality traits such as

[152] Jamieson, page 7.
[153] Davies, page 14.

aggressiveness or shyness are less the product of conditioning than they are of some chemically intrinsic "wiring" in the code of our genes, it remains an alluring one.

Though it is true that approximately half of the genes we inherit from our parents are believed to be responsible for brain development, thus indicating that the capacity to think and make decisions does have a genetic component, this genetic predisposition to intelligence cannot be considered in isolation of external factors.[154] Ironically enough, the empiricist who is universally credited with laying the groundwork for modern genetic science, a 19th century German monk named Gregor Mendel, was himself a poignant reminder that genetic endowment requires other key factors like luck and social environment to allow a brilliant mind to grow and flourish. Mendel was born into a poor peasant family and would probably have been relegated to toiling the fields as an indentured servant like his father but for the attentive eye of a local priest who recognized the young Mendel's precocious intellect and got him into a monastery where he received a rigorous education that would not otherwise have been available to a child from a family of limited means.[155] The psychological and physical reality of a person is infinitely more complex than the notion that genes are working together like some immutable binary code to produce a pre-ordained outcome.[156] Furthermore, to reduce human behaviour to genetic factors is to do a disservice to science, since the behaviour of a given person is the product of a complex interplay of many factors – nutrition, social and cultural influences, and environmental factors as well. As Maxwell Mehlman states:

> Identifying genes associated with behavioral traits is difficult because the traits are likely to be complex, meaning they are caused by the interaction of multiple genes and between genes and the environment, and because the traits themselves

[154] Bodmer and McKie, page 131.
[155] Bodmer and McKie, pages 12-14.
[156] "Genetic determinism betrays, above all, a failure to understand that genes are always only contributing causes. Whether a given trait will be present depends not just on the gene or genes in question, but also on the environment, including the environment of the organism's body at a particular state in the organism's development." (A. Buchanan et al., *From Chance to Choice: Genetics and Justice* (Cambridge, U.K.: Cambridge University Press, 2000), page 23 [Buchanan].) Also see Matt Ridley, *Nature via Nurture: Genes, Experience, and What Makes Us Human* (New York, NY: Harper Collins Publisher, 2003) [Ridley], who writes at page 4: "Genes are designed to take their cues from nurture. To appreciate what has happened, you will have to abandon cherished notions and open your mind. You will have to enter a world where your genes are not puppet masters pulling the strings of your behavior but puppets at the mercy of your behavior; a world where instinct is not the opposite of learning, where environmental influences are sometimes less reversible than genetic ones, and where nature is designed for nurture."

> are not well-defined and cannot be identified consistently by different observers.[157]

Indeed, although considerable progress has been made by genetic researchers over these past several years in locating single genes that are direct causal factors for conditions such as cystic fibrosis, sickle-cell anemia, Huntington's disease, and Tay-Sachs disease, there are many other diseases and conditions for which there is no easy explanation as to causation because of a complex interaction between many different genes and environmental factors. Francis Fukuyama explains:

> Other diseases are caused by multiple genes that interact in complex ways: some genes control the expression (that is, the activation) of other genes, some interact with the environment in complex ways, some produce two or more effects, and some produce effects that will not be visible until late in the organism's life cycle.[158]

B. Baby, I'm Not Bad; I'm Just Coded That Way

The fallacy of laying all responsibility for behaviour in a person's genomic makeup is nowhere more evident than looking to the example of the so-called "XYY male" – the genetically-based criminal profile of the 1960s and 1970s. A genetic study of 197 male inmates of a maximum security mental institution in Scotland in the mid-1960s established what the study's lead scientists believed to be a large percentage of XYY inmates. Seven of the inmates carried an extra Y male chromosome and were subsequently described in a scientific journal article about the study as being of below normal intelligence and exhibiting dangerous or criminal tendencies. The article's authors speculated that the proportion of institutionalized males carrying the extra male chromosome could be twenty times greater than males within the non-institutional population. However no comparable studies of the general population were undertaken; nor were any studies done on XYY males who had not run afoul of the law and who were

[157] Maxwell J. Mehlman, *Wondergenes: Genetic Enhancement and the Future of Society* (Bloomington, Indiana: Indiana University Press, 2003), page 44 [Mehlman]. Also see Proctor, who writes at pages 80-81 that: "Even for diseases that are clearly heritable, genes may vary widely in their manner of expression. Five percent of men who have heart attacks before the age of sixty carry a gene that prevents the liver from filtering out harmful cholesterol. Not all of those men with the gene, however, suffer early heart disease – only about half do. Diet or some other factor can apparently ameliorate the negative effects of the disease."
[158] Fukuyama, page 74.

productive members of society.[159] Notwithstanding the limitations of the study, once the popular and mass media picked up the story, the die was cast for exaggerated claims and wild speculation that had a profound impact on the popular imagination of that era. Ted Peters notes the consequences as follows:

> Like leaflets dropped from an airplane, irretrievable and unrevisable news spread that XYY babies were doomed to grow up as social problems. DNA had determined their destiny. 'Congenital Criminals' was the title of a *Newsweek* story. The drama increased when newspapers in 1968 announced that Richard Speck, the notorious murderer of eight student nurses in Chicago, was XYY. The report was false. Speck was XY. But it was too late to modify the public image: if XYY, then violent.
>
> These men became known as 'super males.' A certain common-sense logic led to this. The Y chromosome is a sex-determining chromosome. Women have two Xs. Men have an X and a Y. By and large men tend to be more aggressive than women. Could this be due to the presence of the Y chromosome? Perhaps. Now, suppose we add an extra Y. Would this add an increment of aggressiveness? Do XYY men have a double dose of masculinity? Such has been the reasoning. Is it accurate? [160]

Throughout the late 1960s and into the 1970s, various maternity hospitals in England, the United States, Canada, and Denmark screened newborn babies in order to identify those carrying the XYY genotype. This mass screening was done in spite of the fact that only one male in a thousand is born with an extra male gene and the reason for the extra gene has nothing to do with the genetic laws of inheritance. Instead, what happens in some instances is that two Y chromosomes spontaneously get stuck together in the sperm and if this sperm fertilizes an egg bearing an X chromosome, an XYY embryo is the result. Thus, one must question to what purpose such screening was undertaken. Was this a harbinger of the application of genetic determinism?[161] David

[159] Ted Peters, *Playing God? Genetic Determinism and Human Freedom,* 2nd ed. (New York, NY: Routledge, 2003), page 69 [Peters].
[160] Peters, page 70.
[161] Peters, at page 70, writes that: "Some scientists proposed that genetic testing be done prenatally. Since no remedy for this malady existed, an implied purpose of the proposal was to support selective abortion. Informing parents that their future baby boy would carry the trisomy would give them the option of terminating the pregnancy." Also see Proctor, at page 72: "Concerns about screening have been voiced at least since the XYY scare in the 1960s, when it was 'discovered' that males with an extra Y chromosome tended to show criminal behavior. Calls to screen infants for the criminal gene were met by protests that

Suzuki and Peter Knudtson believe that there is an important lesson to be learned from this earlier experience with the XYY trisomy:

> If there is a single overriding lesson to be learned from the XYY debate, it goes far beyond the questions of the true clinical status, still largely unresolved, of XYY males, or even the unforeseen impact of XYY research on the lives of vulnerable human beings. Instead, this lesson must concern the incredible eagerness with which scientists and non-scientists alike have historically grasped at quick, socially convenient definitions of genetic disability or disease.[162]

C. Genetics and the Brain

Walter Boomer and Robin McKie state that the geneticist's quest to help unlock the mysteries of how the human brain works is at least as challenging as the astrophysicist's quest to discover the origin of the universe, perhaps even more so:

> The mapping and sequencing of all our genes – and up to half our total complement are thought to be involved in controlling brain function — will therefore be critical to this task. Indeed we should expect to learn not just about the sources of psychological impairment, but also about basic human individuality – the power to appreciate musical pitch, artistic ability, mathematical prowess and all the other variable manifestations of human brilliance. After all, it was mental ability that turned Homo Sapiens from a struggling bit player into ruler of our planet. Understanding how our brains helped us achieve that conquest should lead to a true philosophical appreciation of what it means to be human.[163]

With so many debilitating psychological disorders and neurological conditions causing so much distress for large numbers of people – with all the concomitant cost in terms of damaged lives, suffering to persons within the afflicted person's personal circle, and attendant social problems – there should be little wonder that such a large portion of our health care resources is devoted to alleviating the effects of conditions such as depression, schizophrenia and senile dementia.[164] Discovering the genetic factors behind even some of these debilitating conditions will ultimately go a long way toward not only

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this would stigmatize persons, even though there was only ambiguous evidence that the anomaly led to criminality (some suggested that the higher rage of convictions could come from lower intelligence."

[162] David Suzuki and Peter Knudtson, *Genethics: The Clash Between the New Genetics and Human Values* (Cambridge, MA: Harvard University Press, 1989), page 156 [Suzuki and Knudtson].

[163] Bodmer and McKie, page 126.

[164] Bodmer and McKie, page 126.

ameliorating the suffering of those afflicted but will also should help to ensure a more stable social order.

D. Genetic Determinism is Not Grounded on Good Science

It is a fact that the human genome is comprised of 50,000 or so individual genes which drive our development from conception to death and which determine such characteristics as eye colour, size, and intellectual potential.[165] However these genes are in fact themselves influenced by factors as diverse as whether a person smokes or not, whether a person eats properly, whether a person works in a chemically-toxic environment, and other personal lifestyle or external environmental factors. There may be a tendency to place too much stock in the immutability of DNA and hence its role in determining a person's future health prospects. The challenge for science is how to properly announce breakthroughs in genetic science as yet another gene or gene marker is discovered that researchers think has at least an influence on whether the person will develop a particular disease or condition. However, driven by the need to attract funding for further research and cognizant of the demands from politicians, policy-makers, the news media and citizens for results, there may be a tacit recognition among at least some members of the health science research community – particularly those working in the private sector where there is always a demand for a return on investments – of the need to be more definitive in their announcements of a new discovery or promising development, even to the point of "overselling" the discovery.[166] Unfortunately, perhaps, the hype which generally attends the release of news about promising developments in medical research is to be expected when one considers the social reality of the media-saturated culture we live in.[167] With discoveries of disease-causing genes or genetic predispositions

[165] Bodmer and McKie, page 5.

[166] "But history and hindsight have taught that 'foolproof' scientific techniques are often oversold. This will almost certainly hold true for aspects of genetic testing. Figuring out which combinations of the three billion base pairs of nucleotides (and factoring in environmental influences) will give rise to certain traits or disorders will leave enormous room for unjustified speculation. Inevitably, this will lead to error as scientists try to determine the extent to which human beings are determined by their genes." (*Genetic Testing and Privacy* (Ottawa, Ontario: The Privacy Commissioner of Canada, 1992), page 65).

[167] "Unfortunately, this kind of dumbed-down dog-and-pony show in the press tends to erode scientific standards for the rigorous dissemination of data and review of new research that traditionally lend public credibility to important scientific and medical advances. It also illustrates the distortions that take place when a highly politicized area of scientific research – namely, fetal tissue research – is declared off limits

to various diseases and conditions being regularly reported in scientific journals, once the mainstream media learns of such developments, they can be overstated when reported in a consumption-driven culture by news media motivated by the need to attract readers or viewers. Francis S. Collins, a U.S. geneticist who played a leading role in decoding the human genome, has written about the critical need to place genetic science in its proper context:

> As genetic predispositions to everything from cancer or diabetes to novelty-seeking behavior or homosexuality are being reported almost daily in the scientific literature (and regrettably often overstated in the popular press), a new and dangerous brand of genetic determinism is subtly invading our culture. Carried to its extreme, this 'Genes R Us' mentality would deny the value of social interventions to maximize individual potential, destabilize many of our institutions (perhaps especially the criminal justice system), and even deny the existence of free will.[168]

In other words, the concept that is genetic determinism probably owes its origin more to popular media culture than to medical science. As always, the challenge remains that of how to maintain perspective and discernment in a world driven by consumerism and a hunger for information. Having said that, genes do influence or drive our behaviour, in some way at least, though this influence is far from being fully understood. However, as Kevin Davies explains, that influence should neither be denied nor over-emphasized:

> The notion that genes can influence human behavior and personality is a powerfully seductive proposition. In the past five years or so, there has been a steady rise in evidence that many human behavioral traits are at least partially influenced by variations in our DNA, with several provocative studies suggesting that complex behavior can be shaped by alterations in a single gene. The most vivid example came a few years ago, when the behavior of a highly antisocial Dutch family in which men had regularly committed rape and arson, was attributed to a mutation in the gene for a neurotransmitter called monoamine oxidase. The mutation is extremely rare, but its significance has been supported by studies of mice lacking the corresponding gene.[169]

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to government scientists and driven instead solely by unregulated market forces." (Editorial, "Taking stock of spin science" (December 1998) 16 Nature Biotechnology, page 1291 ["Taking stock of spin science"]).

[168] Francis S. Collins, forward to Peters, page x, [Collins].

[169] Davies, page 232.

E. Natural Clones and Genetic Predispositions

Identical twins carry identical genomes because they originate from the same fertilized ovum. Bodmer and McKie state that extensive research into the similarities of interests, lifestyles and personalities of identical twins has shown that, although we are certainly shaped by our individual genetic makeup, we are not pre-destined to follow certain paths because such paths have been pre-determined by our genes:

> Twin research indicates we are influenced by our genes, but are certainly not prisoners of them. In fact, it is more a matter of identical hard-wiring. The eerie coincidences uncovered by these studies stem from the duplicate sensory systems of genetically identical individuals. Each selects a similar world in response to their inherited cues.[170]

The presence of a mutation in a person's genome is an important indicator of risk that the person will develop a disease linked to that mutated gene some time in the future, but it is no more nor less than that – an indicator of risk, one of many factors that need to be considered in assessing a person's future health prospects.[171] Essentially, those of us concerned with the advance of knowledge need to recognize that just as we ought not to place all our faith and funding resources into genetic research in the mistaken belief that the prevention and cure of all disease lies in our genes, neither ought we to minimize the importance of genetic factors. After all, genetic-based disorders are common, with thousands of recognized single gene mutations afflicting an estimated one percent of the population and with over half of these mutations responsible for serious diseases or conditions. A mutation is a mistake that occurs in a gene during cellular replication. A mutation can be harmless or deleterious. A mutation is harmless when it does not involve any change to protein production or when it happens along that portion of a strand of

[170] Bodmer and McKie, page 134.

[171] "Many factors determine the development of complex disorders. The presence of mutant genes is a good indicator of risk but no more than that. Disordered genes interrelate with personal life-style and daily living conditions, including the working environment. Genetic tests cannot account adequately for these 'external' factors, which can be as important as or even more important than inborn characteristics. Even in single-gene susceptibilities such as hypercholesterolemia, moreover, personal efforts in connection with diet and life-style can have mitigating effects. People can seriously reduce the risk of developing disease when informed of their genetic constitutions." (Trudy Lemans and Pupa Bahaman, "Genetics in Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis" in Bertha Maria Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Crownsville, QC: Les Editions Yvonne Blois Inc., 1998), page 137 [Lemans and Bahaman]).

DNA that does not contain the chemical "code" for protein production. On the other hand, if the mistake results in part of the gene losing its function or if extra DNA is added, the body responds by producing modified or defective protein or even none at all and if that protein is intrinsic to biological functioning, a disease results.[172] However, it should be pointed out that mutations do not usually occur unless there has been exposure to external factors such as chemical agents, ultraviolet light or radiation.[173] There are also several multi-factorial genetic disorders in which more than one mutated gene is at work, and this requires testing of large groups of people and extensive testing of different DNA regions.[174]

A study undertaken in Britain a few years ago showed how extensive genetic disorders were among that country's children; given similarities in the demographic and ethnic make-ups of our two countries, it is reasonable to speculate whether a similar incidence might be found among Canada's young people. In referring to a 1991 study called *Ethical Issues in Clinical Genetics* commissioned by the pediatric research unit at Guy's Hospital in London, a law professor named Loane Skene wrote:

> Genetic disorders affect about three per cent of newborn infants; they represent one-third of the mortality in children under 15 years of age and half of the paediatric hospital admissions for the same age group.[175]

F. Is it the genes, environmental factors…or both?

In weighing the evidence and opinions regarding genetic risk as opposed to environmental factors, it behooves health care policy-makers and decision-makers to learn from the past mistakes of previous eras. Hard science may occur in a lab under controlled conditions in accordance with tried and tested methodology and when scientists' findings come under intense scrutiny in national and international peer review processes. However the decisions to fund some research projects but not others, and the levels of funding that may be allocated to some research projects as opposed to others, and the laws and policies that develop based on the latest scientific orthodoxy, are hardly

[172] Sonia M. Suter, "Whose Genes are These Anyway? Familial Conflicts Over Access to Genetic Information" (June 1993) 91 Mich. L. Rev. 1854, page 1857 [Suter 2004].
[173] Drlica, pages 46-49, *passim*.
[174] Suter 2004, page 1863.
[175] Skene 1998, page 2.

made in an antiseptic lab devoid of any considerations for the prevailing political ideology, underlying values be they religious or secular in origin, and even underlying cultural assumptions, including, sadly, preconceived notions about the value of a given project in light of tacit ideas or prejudices rooted in such characteristics as gender or ethnicity.

The relationship between environmental factors, personal lifestyle choices, and genetics is complex and one that does not easily lend itself to certainty in predicting the probability that a given person carrying a defective gene will eventually develop the disease or condition linked to the gene. The limitation inherent to genetics, so far anyway, is that while the science can explain how cells divide, it has yet to explain why cellular division and growth occurs. As discussed by Evelyn Shuster, this makes for a high degree of uncertainty in making certain genetic predictions:

> The paradox is perhaps that the molecules of genes operate through a series of instructions that can be spelled out, but emerge in a way that cannot be fully explained. We may be able to retrospectively determine, from a variety of different approaches, what could have predisposed an individual to behavioral traits and diseases. But no model can enable us to predict how the genes will respond to challenges, interact with the milieu, and restructure themselves to ensure their survival.[176]

There is a misconception among many people that genetic testing yields results that carry the weight of incontrovertible truth; for example, because a person's genome may carry a gene that has been linked to a particular type of cancer, then the person is sure to develop that cancer at some point in the future. However, as has been explained by Andrews and Nelkin, that is not necessarily the case at all:

> But the evidence produced by most genetic tests is only inferential and must be interpreted. And interpretation varies with statistical definitions of what is normal. Also interpretation often assumes causation where there is actually only correlation. In the present state of genetic testing, the error rates – false positives, false negatives – are high. Even reliable tests cannot predict when or how a disease will strike. In many cases, the manifestation of symptoms, their severity,

[176] Evelyn Shuster, "Determinism and Reductionism: A Greater Threat Because of the Human Genome Project?" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 123 [Shuster].

> and the moment of their onset rest on random events or intervening factors such as diet and lifestyle.[177]

Given the fact that the presence of a gene linked to a particular disease or condition is no guarantee that a person will actually develop that disease or condition, the question is therefore begged: to what purpose should wide-scale genetic testing of new-born infants be undertaken? Suzuki and Knudtson write that:

> Since none of us can hope to claim genetic "perfection" – in the face of an unpredictably changing environment, it is, after all, an absurd notion --how can we pretend to expect it in a newborn child? At least until such time as a genetic abnormality has been indisputably shown to place severe limits on a child's future health, happiness or capacity to learn, it seems most wise to tolerate such imperfection, along with all of the rest. The XYY genotype has not been shown to place such limits on a child's future. Therefore, it cannot be said to have passed this simple ethical test.[178]

Slipping into genetic or biological determinism would have enormous and serious repercussions for individual rights and for the rational development of health care polices. One obvious area that comes to mind is how people arrive at funding decisions for the delivery of various health care services.[179] As Eugene Oscapella has argued, scientific methodology and the future course of medical research would be adversely affected as well:

> One of the dangers of biological determinism, then, is that the root cause for the onset of disease is shifted from the environment (toxic exposures) to the individual (genetic defects). The scientific search shifts from a search for mutagens in the environment to biological defects in the individual.[180]

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[177] Andrews and Nelkin, page 96. Also see Paul M. Schwartz, "Privacy and the Economics of Personal Health Care Information" (1997) 76 Tex. L. Rev. 1, [Schwartz], who writes at pages 20-21: "The role of other factors in determining medical costs is and will continue to be critical. For example, personal behavior tendencies, including eating habits and whether one smokes cigarettes, play a far more important role in deaths caused by cancer than all genetic factors."

[178] Suzuki and Knudtson, page 159.

[179] "Governments will inevitably be drawn to programs that prevent the birth of children with expensive genetic 'disabilities'." (Eugene Oscapella, "Genetic, Privacy and Discrimination," in *Protecting Privacy in the Age of Genetic Information* (Canadian Biotechnology Advisory Committee, August 2004), online: Canadian Biotechnology Advisory Committee <http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00477e.html>, in the area of the report titled "Specific Areas of Concern",[Oscapella])

[180] Proctor, page 80.

Chapter V

Genetic Screening, Personal Choice, and Avoiding the Eugenics of the Past

V. Genetic Screening, Personal Choice, and Avoiding the Eugenics of the Past

Statement of Purpose: *Keeping in mind the discussion of genetic determinism from the previous section, the reader is introduced to the discredited concept of Eugenics. Eugenics was a late 19th century theory that social problems such as poverty or addictions such as alcoholism could be, in essence, purged from humanity through the mass, forced sterilizations of people considered to be "social undesirables" or "moral degenerates." The theory gained popularity throughout much of the industrialized world in the first two decades of the last century, eventually seeing its most brutal application in Nazi Germany. Prior to World War II, though, even democratic countries like Canada and the United States had forced sterilization programmes in place that had the backing of the laws of the day. This section should serve as a warning of where the misguided thinking that genes inevitably govern behaviour can lead.*

A. Genetic Screening

Genetic screening can play an important role as a diagnostic tool. Properly counseled by genetic counselors who can weigh the results and advise a patient of their risk factors, the patient can make whatever changes in lifestyle may be necessary in order to minimize, if not negate altogether, the risk of developing the disease or condition at issue. However, in deciding whether to fund extensive genetic screening, health care administrators need to understand that, in practical terms, little can be gained – and indeed much harm can result – if the focal point of our health care profession changes to prevention of disease through genetic testing and research rather than recognizing the immense role that lifestyle and environmental factors play in determining a person's future health. Of what benefit is it to discover a gene linked to lung cancer, for example, if a person carrying such a gene smokes a pack of cigarettes each day? Indeed, it is in the battle against cancer that we have perhaps the best example of the inherent problem with according too much weight to genetic predisposition. As Robert Proctor notes:

> The most serious objection to predisposition studies, though, is that they can detract attention from the epidemiological fact that cancer is a disease whose incidence varies according to occupation, diet, socioeconomic status, and personal habits such as smoking. Genetics can do little to explain such patterns. Rates of lung and breast cancer, for example – two of the three deadliest cancers – have both risen dramatically in recent years; genetic propensities can have little to do with such increases. Lung cancer rates for U.S. males rose from 5 per 100,000 in 1985 – a fifteen-fold increase. Lung cancer rates for women rose some 420 percent over the last thirty years, and breast cancer rates have also grown.[181]

Screening for genetic disorders may be done in the womb or after birth. Typically, the genetic screening occurs in the early pre-natal stage because the amniotic fluid contains cells with the full genome of the developing fetus. By way of a test called amniocentesis, which is typically done about four months following conception, a physician inserts a needle into the woman's amniotic sac and draws out a sample of fluid.[182] The predictive capacity of genetic testing of new-born infants or prenatal genetic screening really depends on the particular condition for which a given genetic mutation is linked, in varying degrees of probability, as a causative factor in the eventual development of the disease or condition. When a positive prenatal genetic test reveals the presence of a mutated gene that is linked to the potential development of a late-onset disease years or even decades into the future of the child's life, Jamieson notes that difficult issues arise for which there are no easy answers:

> The goal of prenatal diagnosis is to have a 'normal' child. When prenatal diagnosis delivers a negative result, meaning the fetus is 'free' of genetic disorders, prospective parents choose to have the child. When faced with positive results, parents in most Western countries have the option to abort the fetus. Prenatal genetic testing for late onset diseases pushes the 'normal' criteria beyond immediate genetic disorders to future disorders. The social and cultural issues surrounding this issue are immense.[183]

Unfortunately, in spite of the discovery of many genes that are causative factors – at least partially if not always wholly – for a given disease or condition, effective

[181] Proctor, page 77.
[182] Proctor, page 232.
[183] Jamieson, page 17.

therapies are only available for a handful of such genetically-based diseases.[184] Furthermore, what really muddies the picture is the fact that many of these diseases, like Huntington's disease or sickle-cell anemia, for examples, will not manifest themselves for decades. Forearmed with such knowledge, what are potential parents to do?

The oft-touted objection to genetic research or genetic screening is that we are tampering with nature or, if the criticism is coming from somebody of a religious bent, that we are "playing God." However medical science has always been "playing God" as it has sought to gain not only a better understanding of how our bodies function but how to improve the quality of our lives through therapeutic interventions. What is today's standard therapeutic intervention to alleviate suffering, eradicate a debilitating disease or enable a person to lead a productive life, was the subject of some past medical research project or the dream of some health care professional. What is critical as health science researchers continue to explore the human genome right down to its molecular level is that ethics and a concern for sharing of the benefits of such research steer such research rather than the twisted values or arrogance of another age. Gufstafson opines that as knowledge and medical technology progress, what will be considered as standard medical practice will shift but so will our tacit assumptions or overt definitions of what is considered to be 'normal':

> In one sense, every genetic therapy is justified on the ground that it either relieves an impediment to proper natural functioning, as in preventive somatic cell therapy and possibly in some future germ-line therapies, or improves some aspect of the natural that is especially valued in enhancement therapy and radical eugenics. Put a bit differently, what is normal in our biological processes, and what is judged to be abnormal and thus worthy of correction by preventive genetic therapy? What is judged to be normal such that it is worthy of such higher valuation that it warrants enhancement or radical eugenics?[185]

[184] Proctor, who writes at page 67: "For the overwhelming majority of genetic diseases there is no effective treatment. Sickle cell anemia, the gene for which was identified in the 1960s, still has no effective cure. The same is true for Huntington disease, polyposis (a precursor of colon cancers), adult polycystic kidney disease (a progressive kidney disorder), and most of the various cancers for which a genetic predisposition has been found. For these, as for chromosomal anomalies like trisomy 21 (Down syndrome), prevention – through prenatal diagnosis and abortion – remains the only 'therapy'. "

[185] James M. Gustafson, "Genetic Therapy: Ethical and Religious Reflections" (1992) 8 J. Contemp. Health L. & Pol'y 183, page 197 [Gustafson].

Given that there are many genetically-based diseases for which no effective remedy exists at present, an argument may be made that it is ethically wrong to test for such conditions because, as noted by Drlica:

> …unfavorable results of genetic testing of a newborn can place a stigma on the child. Moreover, no child can give informed consent for genetic tests, and there are serious ethical problems associated with exposing non-consenting subjects to the possibility of being linked to incurable diseases.[186]

However, to not screen for diseases or conditions for which there are remedies through therapeutic intervention would be unethical and, in light of current knowledge and technology, would probably constitute medical malpractice. For example, there has been mandatory screening of new-born babies in North America since the early 1970s for a serious genetic disorder called phenylketonuria (PKU) that occurs when the body is unable to absorb an amino acid called phenylalanine that is critical for cell growth. This occurs when an enzyme that breaks down the phenylalanine is deficient. Without therapeutic intervention, which involves putting a new-born infant with PKU on a protein-rich diet, phenylalanine would build up and affect the baby's neurocognitive development, causing mental retardation.[187] Another screening test is the carrier test for the genetic mutation that causes 75 percent of the cases of cystic fibrosis, and which can screen out about half of the "at risk" couples.[188]

There are many parents who would, when presented with the knowledge that their baby would eventually suffer from a deleterious disease or condition that would mean a serious impingement on the child's quality of life, opt to terminate the pregnancy. Although this may be nothing more than the exercise of informed individual choice, how much the choice is indeed truly the product of the exercise of free, individual will by a parent, acting in accordance with her own moral compass and pursuant to the information and advice of her attending physician, remains debatable for Neil Messer:

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[186] Drlica, page 292.
[187] Online: Med Help International <http://www.medhelp.org/lib/pku.htm>.
[188] John A. Robertson, "The Potential Impact of the Human Genome Project on Procreative Liberty" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 217 [Robertson 1992].

> This is borne out by the experience of pre-natal testing for Down's [sic] syndrome, a well-established procedure in clinical genetics. It is standard clinical practice that the parents-to-be rather than clinical staff make the decision whether to have a pre-natal test, and if it proves positive, whether the pregnancy should be terminated. Yet what appears to be an individual, autonomous decision of parents takes place in a wider medical and social context. Parents only have these decisions to make because researchers and clinicians have developed techniques for pre-natal diagnosis and because the law allows the termination of pregnancies on medical grounds.[189]

On the other hand, since the molecular diagnosis of diseases that have their origins –at least in part – in our genes does carry great promise for overall health, if there is a growing demand among the public for wide-scale genetic screening for genetic conditions, and if decisions to terminate pregnancies are made by informed persons, then, according to John Avise, so be it:

> A different eugenics approach, if humanity should choose to employ it, could emerge from new biotechnologies that permit the molecular diagnoses of genetic diseases. Molecular diagnosis is the application of DNA-level assays to reveal the presence or absence of a specific heritable disorder in an individual, and molecular screening is the extension of genetic diagnosis to large numbers of genes or people. If data from genetic screening were employed on a massive scale to influence or direct people's reproductive decisions, in principle the human gene pool would be altered appreciably.[190]

It is one thing for a health care system to offer the option of abortion if prenatal screening were to reveal the high probability of the presence of a gene that will cause a debilitating condition such as Tay-Sachs disease, Duchenne muscular dystrophy, or Huntington's disease. However, opting to abort if an ultrasound were to reveal a foetus of a gender other than that which the parents wish is another matter; an option to which most genetic counselors would strongly object on ethical grounds. As Joel Davis has said:

> Most genetic counselors would strongly object to having their services used for sex selection. When American couples practice sex selection, it is often to avoid passing on sex-linked genetic diseases, such as certain forms of muscular

[189] Neil G. Messer, "The Human Genome Project, Health and the 'Tyranny of Normality'" in Celia Deane-Drummond, ed., *Brave New World? Theology, Ethics and the Human Genome* (London, U.K.: T & T Clark Ltd., 2003), page 108 [Messer].
[190] John C. Avise, *The Hope, Hype, and Reality of Genetic Engineering* (New York, NY: Oxford University Press, 2004), page 170 [Avise].

> dystrophy. Genetic counselors and obstetricians make a resolute distinction between selection to avoid genetic diseases, and selection for particular genetic characteristics such as sex or eye color.[191]

Unfortunately, in many Asian countries, what is otherwise an important prenatal diagnostic tool, is being misused to screen out, in effect, female fetuses which are then aborted, in societies where deeply entrenched cultural preferences for sons are the norm. This is hardly desirous from the perspective of gender equality and probably does not bode well for social order as well. Fukuyama writes that:

> One has to look no further than contemporary Asia, where a combination of cheap sonograms and easy access to abortion has led to a dramatic shifting of sex ratios. In Korea, for example, 122 boys were born in the early 1990s for every 100 girls, compared with a normal ratio of 105 to 100. The ratio in the People's Republic of China is only somewhat lower, at 117 boys for every 100 girls, and there are parts of northern India where ratios are even more skewed.[192]

As Anne Buchanan has stressed, the challenge for contemporary medicine, working in conjunction with law-makers, lawyers and bioethicists, is to improve human health while avoiding the perilous eugenic slope of the past:

> The core notion of genetics, that people's lives will probably go better if they have genes conducive to health and other advantageous traits, has lost little of its appeal. Eugenics, in this very limited sense, shines a beacon even as it casts a shadow. Granted, when our society last undertook to improve our genes, the result was mayhem. The task for humanity now is to accomplish what eluded the eugenicists entirely, to square the pursuit of genetic health and enhancement with the requirements of justice.[193]

B. The Eugenic Nightmare

The horrific medical "experiments" of German and Japanese health care professionals during the Second World War are well-known and are well-documented. [194]

[191] Davis, page 264.
[192] Fukuyama, page 80.
[193] Buchanan et al., page 56.
[194] Marie Fox, "Research Bodies: Feminist Perspectives on Clinical Research" in Sally Sheldon and Michael Thomson, eds., *Feminist Perspectives on Health Care Law* (London, U.K.: Cavendish Publishing Ltd., 1998) [Fox].

Less well-known, though, are the eugenics policies of democratic countries, including Canada, during the pre-Second World War period. Indeed, Mehlman states that at least part of the inspiration for the pre-war eugenics programme of the Nazi regime in Germany was drawn from American eugenics policies:

> Far from being the brainchild of the Nazis, Hitler's eugenics program, which included compulsory sterilization, was heavily influenced by the eugenics movement in the United States. Hitler had read about the Virginia sterilization law at issue in *Buck v. Bell* when he was writing *Mein Kampf* in prison in 1924. The German sterilization law, the first law that Hitler enacted when he came to power in 1933, was modeled on a prototype drafted by Harry Laughlin at Cold Spring Harbor. Laughlin was held in such high regard by the Nazis that they gave him an honorary degree from the University of Heidelberg in 1934.[195]

The roots for the notions that human health can be improved, and behaviour modified through collective control of reproduction, may be traced back 23 centuries to the writings of Plato who advocated in *Republic* the selective breeding of the most intelligent members of society so as to create a superior, ruling "guardian class." However the modern manifestation of the theory of eugenics owes its more recent origins to the 19th century and the ideas of two men in particular – Charles Darwin and Sir Francis Galton. Darwin, most famously known for his 1859 book *On the Origin of Species* in which he set out his theory of evolution by natural selection of the fittest of any given species, was also a proponent of improving humanity through selective breeding. Sir Francis Galton, Darwin's cousin, propagated the idea that people owe it to future generations to apply our talents and abilities in the best way possible.[196] Furthermore, Galton has been credited with having first used the term "eugenics."[197] These earlier ideas were adopted by the eugenicists of the 20th century in a movement that originated in England but spread throughout much of the developed world, including the United States where it had the enthusiastic backing of corporate America, and where it finally found its most heinous manifestation in the horrific legacy of National

[195] Mehlman, page 47.
[196] Smith II, pages 114-115.
[197] Buchanan et al., page 30.

Socialism in Germany, whose eugenicists drew on the American experience with eugenics for inspiration.[198]

The cruel medical "experiments" and mass murder that occurred during the Nazi era in Germany have been well-documented and are permanently etched into the collective consciousness of all decent-minded people. Less well-known are the eugenics movements that operated in democratic countries such as Canada, England and the United States during the first half of the 20th century. These movements, although not marked by the death camps of National Socialism, were characterized nonetheless by paternalistic arrogance, class prejudice, and racism, and were supported by key public figures and politicians of the day from all perspectives along the political spectrum. In Canada, for example, eugenics programmes even had the public support of the man credited as being the father of our public health care system, Tommy Douglas, who would go on to, among other accomplishments, found Canada's first democratic socialist party, the Cooperative Commonwealth Federation.[199] The various eugenics programmes throughout the democratic world, including the pre-Nazi Weimar German republic, may not have involved state-sanctioned murder on a mass scale but they certainly failed, in their enforced sterilizations of hundreds of thousands of people, to properly weigh the public good against values of individual liberty and autonomy.[200] Although, for example, the public discourse of the American eugenics movement stressed the positive aspects of

[198] Buchanan et al., who writes at page 28: "It is largely remembered for its shoddy science, the blatant race and class biases of many of its leading advocates, and its cruel program of segregation and, later, sterilization of hundreds of thousands of vulnerable people who were judge to have substandard genes. Even worse, eugenics, in the form of 'racial hygiene,' formed part of the core of Nazi doctrine. Hitler endorsed it in Mein Kampf, and once in power expanded both eugenic research and, borrowing from U.S. models, a program of sterilization that became the first step toward the murder of handicapped 'Aryans' and ultimately millions of victims of the Holocaust."

[199] Buchanan et al., at pages 30-37, provide an excellent summary of the prevailing eugenics ethos throughout the democratic countries of the pre-World War II era.

[200] Buchanan et al. at page 30: "The history of the eugenics movement prior to the Nazi period is instructive as well. While its record of mayhem was overshadowed by that of the Nazis, we can find, even given the most charitable understanding of its leaders' motives, a failure to deal adequately with the tension between social good and individual liberties, rights, and interests, which has long been the moral problem at the heart of the enterprise of public health." Also see Julie Clague, who writes in "Beyond Beneficence: The Emergence of Genomorality and the Common Good" in Celia Deane-Drummond, ed., *Brave New World? Theology, Ethics and the Human Genome* (London, U.K.: T & T Clark Ltd., 2003), at page 194 [Clague]: "The sorry history of the eugenic aim of social engineering illustrates the dangers of conceiving of beneficence apart from personal autonomy. Many research subjects have been abused by medical personnel in the supposed interests of research, and there is a well-documented history of physician involvement in the mal-treatment of detainees."

improving public health, King notes that the aim in practice was to sterilize persons who were deemed to be genetically unfit to reproduce:

> Although genetic discourse displayed a positive orientation by advocating reproduction for the biologically and socially fit, in the United States the focus was primarily on preventing the transmission of deleterious genes. As a result, eugenic discourse became entangled with race, mental disability, and other presumed determinants of parental unfitness. Consequently, eugenic policies resulted in the development of institutions to care for the biologically and socially unfit and restrictive immigration policies. The best-known consequence of these policies was the coerced sterilizations of massive numbers of immigrants, the poor, and institutionalized persons. These state-sanctioned sterilizations were upheld by the Supreme Court in *Buck v. Bell*, a 1927 case that, while seriously undermined, has never been overruled.[201]

There is no better example of the prevailing thinking in pre-World War II America regarding eugenics as a social policy than *Buck v. Bell*.[202] At issue in the case was the constitutionality of a Virginia law that authorized the sterilization of mentally disabled persons housed in state mental institutions, or, to use the language of the day, the "feeble-minded". Carrie Buck was an 18-year-old patient at the "State Colony for Epileptics and Feeble Minded" and was the subject of an application by the institution for an order to sterilize her. The application was approved by the institution's Board of Directors and it wound its way up through the various levels of appeal, consistently upheld by the courts, until it finally landed at the final level of appeal, the Supreme Court of the United States. Buck's lawyers argued that the sterilization law should be struck down as it violated Buck's constitutional rights, pursuant to the 14th Amendment, to due process under the law and equal protection under the law. However, in an 8-1 decision, the court infamously found that a person's bodily integrity was secondary to the wider interest of society in bettering the "gene pool" and upheld the order for enforced sterilization. Writing for the majority, Justice Oliver Wendell Holmes, Jr. said:

> We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call on those who already sap the strength of the State for these lesser sacrifices, often not felt to be

[201] Patricia A. King, "The Past as Prologue: Race, Class, and Gene Discrimination" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 98.
[202] *Buck v. Bell*, 274 U.S. 200 (1927) [*Buck v. Bell*].

> such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind.[203]

Canada had its own experience with eugenics during the early 20th century too, and, as in the United States or Europe, legally-sanctioned sterilizations that disregarded personal autonomy and dignity were conducted in the name of improving the human gene pool. In Alberta, for example, from 1928 to 1971, there were 4725 cases proposed for sterilization and of those, 2822 were actually approved. Sterilizations were approved if the patients presented what one historian writing about the period has termed "risk of hereditary taint."[204] The history of eugenics in Alberta and other Canadian provinces came under judicial scrutiny in the mid-1990s with the case of Leilani Muir, who successfully sued the Province of Alberta decades after she was classified as a "mentally deficient," confined to a provincial home, and sterilized without her consent.[205]

In short, in accordance with the laws and health care policies of countries throughout Europe and North America during much of the first half of the last century, the eugenics movement generally can be said to have represented the misapplication of genetic knowledge extant at that time, particularly with regard to heredity. Therefore, the theoretical foundation, or premise, for the eugenics movement may be summed up as: 1) the human gene pool needed to be improved and 2) social conditions marked by poverty, abuse of alcohol or other drugs, or criminal behavior had an immutable genetic basis so the genes behind these conditions could be passed on from generation to generation.[206]

The collection and storing of genetic data should raise concerns in the minds of civil libertarians; the adequacy of privacy safeguards being one of them. However, concerns about the impact of such data on individual rights such as privacy may be overshadowed by the challenges posed by the deterministic tendency of people to want to ascribe all human behaviours to a genetic basis only. The history of the last century is

[203] *Buck v. Bell*, page 585.
[204] Angus McLaren, *Our Own Master Race: Eugenics in Canada, 1885-1945* (McClelland & Stewart Inc., 1990), page 159 [McLaren].
[205] *Muir v. The Queen in Right of Alberta*, (1996) 132 D.L.R. (4th) 695.
[206] Buchanan et al., page 40.

replete with examples of where such thinking can lead, if we are not careful.[207] We have the distressing record of the eugenics programmes of the pre-World War II era to draw on as a lesson into how the misappropriation of science by politicians, religious leaders and social reformers can lead society to a point where heinous things are done to those among us who are most vulnerable – all in the name of making improvements the human species. Unfortunately, even in this contemporary age, there are many people who continue to conduct their lives in accordance with narrow, even bigoted, views. It is in such a social and cultural environment that science, with its emphasis on empiricism and rationality as the means toward knowledge, must find its way forward, with ethics and law acting as both guides and the drawers of boundaries.

Unfortunately, as knowledge of the genetic basis for many diseases and conditions that cause suffering continues to advance, there is an inherent risk of such knowledge being wrongfully applied to address social problems. Advances in genetic knowledge also raise other, equally troubling, issues. Take genetic profiling, for example. Racial profiling is an empirical reality in a social and political culture that often seems motivated by fear: just ask any visible Muslim or person of colour who has flown with a commercial airline since September 11, 2001. Given what appears to be a tendency by people to over-generalize about the application of the latest advances in genetic knowledge, a tendency informed, if not driven entirely by, a profit-driven popular media always on the hunt for the next breaking story, there should be legitimate concern about the prospect for genetic profiling as well – a profiling that would have access to science in the application of policies in employment and health insurance which can discriminate against a new class of disadvantaged persons: the genetically unfit.

C. Reproductive Freedom and Personal Choice

The difficulty inherent to any discussion about genetic screening that would provide information about risk factors for a given genetic disease or condition is that such screening is often conflated with the eugenics movement of the first half of the last

[207] Proctor, page 82: "The biological determinism that underlay the 1930s eugenics movement, however, has by no means disappeared. Genetics remains very much a 'science of human inequality' insofar as the more we look for differences, the more likely we are to find them. In the face of unequal powers and unequal access, there is a great danger of exaggerating the extent to which human behavior is rooted in the genes."

century. Given that even today one can find scholars alluding to improving the "quality of a populational genetic pool" even if it means an infringement of individual civil liberties, as Smith notes, there is certainly ongoing justification for circumspection when we are offering genetic screening and choices to women:

> Although genetic screening involves a minor intrusion into an individual's body and may involve a 'search' … the search is not unreasonable and prohibited if executed properly and justified by a legitimate state interest. Similarly, if mere screening and counseling interfere with the right to procreate such interference may be justified by a compelling state interest which must be preserved. The state's interest in improving the quality of a populational genetic pool in order to minimize suffering, to reduce the number of economically dependent persons, and possibly, to save mankind from extinction arguably justifies the infringement of individual's (sic) civil liberties.[208]

However, can it not be argued that fully informed adults might otherwise be expected to act in accordance with their consciences or values, and make decisions about whether to proceed with a given pregnancy as a matter of individual choice? If so, then the state can play an important role in facilitating such choice through providing adequate levels of funding to health care so that pre-natal genetic screening for debilitating conditions is widely available, genetic counselors are on hand to explain the test results and to offer options to expectant mothers, and to ensure that decisions about whether to proceed with the pregnancy or to abort are made in accordance with relevant ethical guidelines and applicable law. As Buchanan *et al* explain:

> The state can respect the right of individuals to reproduce without any concern for the genetic consequences of their acts for future generations, but it may also seek to encourage responsible choices. It can provide information that would likely be factored into these decisions, and it can provide the means (including genetic tests and assisted reproduction) to make possible reproductive acts that are likely to result in the transmission of the most desirable genes. The state can also seek to foster a climate of opinion in which these issues will be seriously considered and in which public attention is directed to the distant consequences of present-day reproductive choices.[209]

[208] Smith II, page 117.
[209] Buchanan et al., page 336.

However, there are some commentators who see an inherent danger to the policy position that reproductive decisions are solely matters for prospective parents – informed by knowledge of their risk factor for bringing into the world a child with an inheritable genetic disease or condition – to make. Although it seems unlikely, in light of Canada's contemporary rights-based political and social culture that the non-consensual sterilizations of the past could ever re-emerge in the name of improving the human gene pool, as Graeme Laurie has put it:

> …less obvious but no less invidious policies designed to eliminate the unhealthy or undesirable from society may emerge in a piecemeal fashion under the guise of choice and reproductive freedom. Facilitating reproductive decision-making by offering choice, when the only choice available is between carrying a foetus that has been labeled less than normal and the termination of the pregnancy, is for many a choice that cannot be exercised free of undue influence. Indeed, the prospect of the wholesale introduction of state screening programmes for incurable or immutable conditions betrays an attempt to bring societal influence to bear on a woman's right to choose.[210]

Contemporary ethical guardians, informed by values of equality and personal autonomy and mindful of the excesses of the past, are, arguably, the best safeguards against an insidious return to eugenics in reality, if not in name. Surely, as argued by Anne Buchanan, discerning adults are able to appreciate the distinction between a prospective parent making a reproductive decision based on the best available information about all relevant factors – including genetic risk – and a state-sanctioned programme of eugenics the aim of which is to enhance the human gene pool but at the expense of fundamental values like personal autonomy and procreative freedom:

> Back-door eugenics threatens individual liberties and well-being in a manner reminiscent of state eugenics programs, even if this outcome is the unintended effect of private decisions made on grounds of self-interest. The state must intervene as needed to protect the vulnerable from stigmatization and exclusion, as social justice requires, even though these interventions necessarily abridge the benefits that markets can provide to many.[211]

[210] Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge, UK: Cambridge University Press, 2002), page 199 [Laurie].
[211] Buchanan et al., page 342.

Reproductive freedom is an important human value, and therefore, access to genetic testing is an important source of information for prospective parents in order to make informed decisions.[212] Given the current level of genetic knowledge and the predictive nature of genetic screening, prospective parents are making choices based on the information provided to them by physicians and genetic counselors. However the history of the eugenics movement of the past century continues to cast a long shadow and Buchanan asserts we need to be ever mindful of it:

> Still, the notion of eugenics as involving an intrusive state intent on overriding very private reproductive decisions persists because mainstream eugenics often indeed did favor such policies. Without the power of the state, the eugenics movement would not cast so dark a shadow.[213]

In any event, arguably, legislation that promoted eugenics concepts would invite challenges to its constitutionality based on the *Charter of Rights and Freedoms*, probably pursuant to section 7 and section 15 which, respectively, concern a citizen's right to personal security and right to equality under the law. Constitutionally entrenched rights to individual liberty, equality and personal security, coupled with the free dissemination of information about advances in health care to an informed public, will arguably be our greatest assurances against any return to state-sanctioned eugenic policies.[214] Certainly a return to state involvement in what should be a fundamentally private matter is something that no person concerned with individual freedom can even countenance.[215]

Reproductive freedom of choice is a fundamental human right and one that the state should refrain from interfering with or otherwise influencing by means of either law

[212] Buchanan et al., at page 315: "An additional reason for access to extensive genetic services is the role they play in supporting reproductive self-determination. …A potential parent will be in a position to make optimal reproductive decisions only if given a full account of any significant genetic risks, together with counseling on strategies and alternatives. Prospective parents who are afforded expert, extensive, and patient genetic counseling, where indicated, are in a much better position to make decisions that are best for themselves, other family members, and the well-being of any children they bring into the world."
[213] Buchanan et al., page 333.
[214] Buchanan et al., page 342.
[215] See John A. Robertson, "The Potential Impact of the Human Genome Project on Procreative Liberty" in George J. Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992) [Robertson 1992], at page 223: "Coercive governmental intrusion in private, reproductive matters is a frightening infringement of personal, marital, and reproductive freedom. It recalls the eugenic policies of the Nazis and the American sterilization laws of the 1920s that were so widely abused."

or the discretionary exercise of its public spending authority. Arguably, when prospective parents are properly informed about genetic risks, most will make reproductive choices that reflect an unwillingness to bring into the world a child with a risk of developing a debilitating illness or condition.[216] What ought to be of paramount concern to advocates of the normative values of personal choice and individual liberty is that people be fully informed of the risk factors and that genetic knowledge be widely available to prospective parents.[217] In terms of where the medical profession in Canada sees genetic research advances and the issue of human reproduction, there is a clear endorsement for the advance of knowledge that is not at the expense of human rights and freedoms. According to the *Tri-Council Policy Statement* that applies to all publicly-funded health sciences research initiatives undertaken in Canada:

> The aim of genetic research should be to advance knowledge or to alleviate disease, not to 'improve' or 'enhance' a population by cosmetic manipulation. Further, the aim should be to better understand genetic disease, the genetic contribution to health and disease, the human genome, and to help individuals and families with genetic conditions. Accordingly, care should be taken to avoid isolating specific populations so that the group feels stigmatized by the genetic disorder or targeted for 'improvement.'
>
> The rights and freedoms attached to personal relationships, reproduction, and the support of those with handicapping conditions should also be maintained. The freedom of couples who are at risk to plan and carry potentially affected pregnancies, and the support of children and adults with handicapping conditions, should not be compromised.[218]

Some ethicists and philosophers have expressed the view that as growing numbers of conditions or diseases come to be associated with, at least in part, defective genes, and as advances in genetic screening and technology continue, then eugenics in practice – if not in name – will come about as the natural effect of large numbers of individuals

[216] Buchanan et al., page 325.
[217] Robertson 1992, at page 224: "In the final analysis, the new genetics cannot escape our strong normative commitment to procreative liberty. Because genetic knowledge is relevant to the reproductive choices of many persons, it should be available to the widest extent possible. By the same token, it should also remain a matter of personal choice. Individuals, not government, should decide how to use genetic knowledge in reproduction."
[218] *Tri-Council Policy Statement,* page 8.6.

exercising reproductive choices based on genetic testing. Neil Messer believes that a bleak vision of some "brave new world" is invariably invoked:

> It would be possible to use a medical model of health-as-normality to legitimate our fear of diversity and of those who are different from us. This becomes all the more important in the light of the fact that molecular genetics offers a powerful set of tools with which a society could implement 'quality control' of children and eliminate 'abnormalities' from the population.[219]

Granted, given the example of biological determinism run amok during the first four decades of the last century, if a government-funded, health care system were to decide that diseases or conditions having a genetic origin should be the target of positive eugenic intervention, there is historical justification in regarding such a development with suspicion. If, on the other hand, prospective parents, when informed of their high genetic risk of bringing into the world a baby who will never grow to maturity but instead will suffer a debilitating disease that will take his or her life at some point during "the toddler years," decide not to proceed with pregnancy, haven't they made a responsible choice? Furthermore, if these individual choices, whether motivated by a concern to avoid harm to progeny or a self-interested wish to avoid a life-altering situation that would involve both an onerous personal burden and expensive health care costs, cumulatively result in a decline over the years in the incidence of a given disease or condition, then society as a whole benefits from the cumulative result of all these informed decisions.[220] One of the best examples of the cumulative effect of at-risk individuals either deciding to forego pregnancy or to terminate pregnancy if need be is the experience of the Eastern European Jewish community – the Ashkenazi. For various reasons, including social and cultural

[219] Neil G. Messer, "The Human Genome Project, Health and the Tyranny of Normality" in Celia Deane-Drummond, ed., *Brave New World? Theology, Ethics and the Human Genome* (London, U.K.: T. & T. Clark Ltd., 2003), page 99 [Messer]. The result, suggests Fukuyama, at page 87: "The kinder, gentler eugenics that is just over the horizon will then be a matter of individual choice on the part of parents, and not something that a coercive state forces on its citizens."

[220] Proctor, at page 70: "On the matter of therapy for the individual versus population therapy, one can easily imagine that the effect of genetic testing (and therapy) is likely to be populational, even if the motive is individual. The incidence of both Tay-Sachs disease and beta-thalassemia, for example, has already dropped in response to genetic testing among the ethnic populations known to be at risk. Since testing for Tay-Sachs began in the 1970s the number of babies born with the disease as declined to only about one-tenth of previous levels. One can surely expect similar results for other diseases: populational shifts will eventually result from individual decisions."

isolation, Jews whose more recent ancestral origins can be traced to Eastern Europe had a historical tendency to carry the gene responsible for a debilitating neurodegenerative disorder known as Tay-Sachs disease. Although a baby with Tay-Sachs disease appears healthy and develops normally during the first six months of life, things go wrong shortly after as a defective gene in the baby's genome allows for the excessive build-up of an otherwise necessary fatty acid called ganglioside in the nerve cells of the baby's brain. The fatty acid builds up, choking the cells. As the cells relentlessly deteriorate, the baby's muscles atrophy to the point where the baby is unable to swallow. Blindness and deafness occur before the baby dies, usually at around three or four years old. Screening for Tay-Sachs began in the 1970s and since then, the number of babies born with this disease has dropped precipitously to approximately ten percent of previous levels. With regard to the choices prospective parents may make to not have children at all or to terminate high-risk pregnancies, are they the harbingers of "eugenics by stealth" or are they merely examples of informed people making responsible choices? It hardly seems reasonable to attribute to such decisions the language of the eugenics movements of another era.

Another example of how the cumulative effect of many individual choices can affect the incidence of a genetic-based condition in the population as a whole is society's experience with screening for Down syndrome. There are two basic approaches for testing for mutations in a person's genome: 1) a biochemical analysis of substances in the body; for example, the amniotic fluid or 2) directly examining chromosomal DNA in the cells to detect defects.[221] A pregnant woman's amniotic fluid is routinely screened, for example, to see whether it contains an extra copy of genetic material on the 21st chromosome – a condition commonly known as Down syndrome. A review in 1999 of elective abortion rates throughout the 1980s and 1990s for a handful of developed countries, including the United States, France and the United Kingdom, showed that in approximately 90% of cases where pre-natal testing of amniotic fluid showed the presence of the extra genetic material on the 21st chromosome that would indicate a baby would be born with Down syndrome, the women opted to abort their pregnancies.[222] One

[221] Suzuki and Knudtson, page 164.
[222] Caroline Mansfield et al., "Termination Rates After Prenatal Diagnosis of Down Syndrome, Spina Bifida, Anencephaly, and Turner and Klinefelter Syndromes: A Systematic Literature Review" (1999) 19(9) Prenatal Diagnosis 808, page 810 [Mansfield et al.].

may reasonably expect, therefore, that as health science researchers working in the genetic field continue to find the genes that are linked to diseases or debilitating medical conditions that prospective parents will push for genetic screening for these genes and, in growing numbers of cases elect to terminate pregnancies.[223]

However, of more pressing concern should be what kinds of genetic screening are to receive public funding because, as a report of the *Privacy Commissioner of Canada* has pointed out:

> On a more subtle level, governments can practice eugenics by funding certain health services. For example, a government that, through its health insurance, funds pre-conception or pre-natal screening for certain genetic disorders and not others, may be seen as indirectly supporting eugenics by promoting discriminatory decisions by pregnant women and prospective parents.[224]

Then there is the ethical issue of screening for the presence of a disease-causing gene when there is, given current levels of technology, no means of curing the disease. If, pursuant to genetic counseling, prospective parents decide to terminate their pregnancy, and if such a decision is made within a context where the prevailing political and social ethos is such that funding in support of a person suffering from a particular disease or condition is under review or is being scaled back, then the public's perception of disability will be affected. Some ethicists, such as Trudo Lemmens and Poupak Bahamin, have sounded a warning:

> The lack of cures for most genetic diseases presents ethical problems. It has been argued that the pressure for screening (leading to contraception or abortion) is a subtle form of eugenics. The provision of screening and counseling services in connection with particular diseases presupposes a value judgment: contraception or abortion are legitimate alternatives to the birth of children with genetic diseases.[225]

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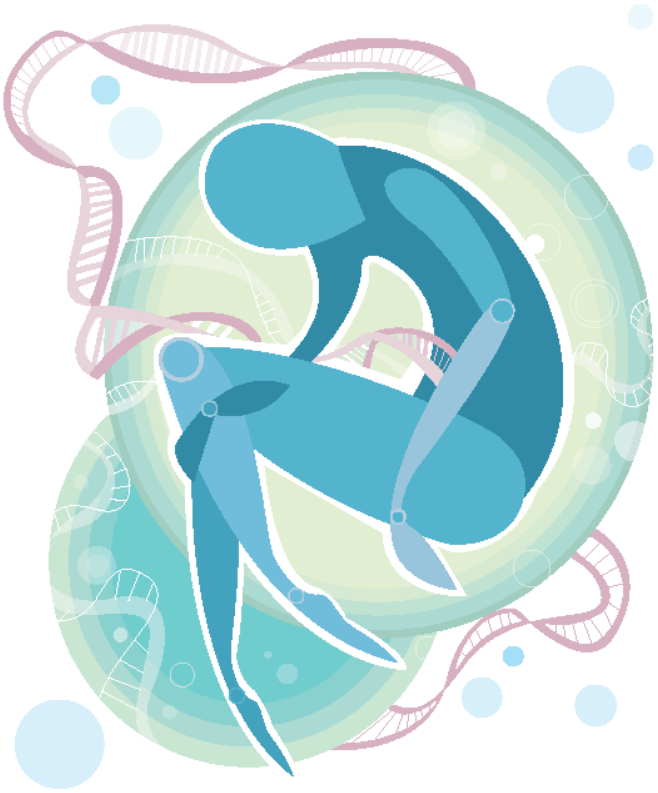
[223] "Each newly discovered disease-causing gene will stimulate a new testing procedure and add one more reason to abort. We can expect abortion to become more prevalent as more and more of the suspected five thousand genetic diseases are located on the DNA map." (Peters, page 107).

[224] "Genetic Testing and Privacy," (Ottawa, ON: The Privacy Commissioner of Canada, 1992), page 37 ["Genetic Testing and Privacy"].

[225] Trudo Lemmens and Poupak Bahamin, "Genetics in Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis" in Bartha Maria Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Cowansville, QC: Les Editions Yvon Blais Inc., 1998), page 145 [Lemmens and Bahamin].

Chapter VI

Conclusion: do we need a Genetic Charter?



VI. Conclusion: do we need a *Genetic Charter*?

Purpose of Section: *The report's underlying themes are revisited and summarized. The section ends with a recommendation for a Genetic Charter to serve as a single source of ethical guidelines for genetic researchers, physicians, lawyers and citizens generally.*

Our body of knowledge about the origin and mystery of life at the molecular and sub-molecular levels is constantly expanding, thanks to the research efforts of geneticists and molecular biologists. The challenge for policy-makers, bioethicists, legislators and health care administrators remains to reconcile interests that can sometimes conflict between the needs of society and the personal liberty and dignity of the individual. This always complex and delicate task cannot occur removed from a broad public engagement. Such an engagement must occur with a transparency predicated on values of equality and freedom that apply to all people, irrespective of economic standing, gender, sexual orientation cultural background, political or religious belief, or physical or mental infirmity or condition. Otherwise, we have the historical reality of the eugenics programmes of another age as stark reminders of where we could find ourselves one day if we are not vigilant to the risk of deciding that some persons have less intrinsic worth than others because we deem them unworthy of a fit within the boundaries of some kind of arbitrarily demarcated norm.[226]

Various scholars who have written extensively in the area of medical ethics have raised some intriguing questions that have relevant application to our discussion.[227] As a matter of basic fairness and equality, should citizens expect access to genetic testing to help make informed decisions about health in general and reproduction in particular? Will Canadians have an equal right to genetic testing regardless of where they live and regardless of the expense to the public health care system? Is it conceivable, for example, that one day a provincial government could decide to de-list from public health care coverage a disease or a condition for anyone who tested positive for a particular

[226] "The search for a balance between public health and personal liberty and other interests will always figure prominently in the ethics of public health. It is notable that eugenicists often portrayed their movements as a campaign for public health. Programs and personnel were often common to both." (Buchanan, page 52).
[227] Buchanan et al., chapter 8, *passim*.

gene or genes that made them susceptible to such a disease or condition? If our public health care system adopted more private health care options and became a mixed public/private system, would persons of lower income levels be able to afford access to genetic screening? Health care in the United States is essentially private in nature and so is of course subject to the demands of the marketplace, with the need to maximize profits for Health Maintenance Organizations often conflicting with professional ethical canons and the Hippocratic Oath, if not driving the provision of health care services altogether. A growing number of American scholars have been raising concern that, as in other fields of activity in the health care sector, medical genetic research and the provision of therapies resulting from advances largely financed by private industry will leave behind persons unable to afford the latest best test that money can buy.[228]

In regulating the progression of medical genetic research, both the blunt particularities of law and the broad guidelines of ethics have their roles to play. Indeed, ethical guidelines may have the greater role to play in the long run because their dynamic and organic nature renders them more responsive to novel situations.[229] Law, which is inherently conservative and therefore slow to respond to exigencies and novel situations, may play an important role in demarcating the outer boundaries of what is and what is not permissible in genetic research, but it is hardly the only tool, and, arguably, not always the best tool either. Canada, with its evolving body of jurisprudence and a legal tradition that protects and enhances human rights and freedoms, can be a world leader in terms of

[228] "In this regard, for example, access to the products of the Human Genome Project will follow the patterns of access to other medical tests and treatments in the United States. This will mean that unless some form of universal health care access is established in our country in the future, the potential exists to exacerbate economic class differences by making the products of the Human Genome Project available to those who can pay for them and denying them to the uninsured and the underinsured." George J. Annas and Sherman Elias, "The Major Social Policy Issues Raised by the Human Genome Project" in George J.Annas and Sherman Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York, NY: Oxford University Press, 1992), page 15 [Elias and Annas 1992]

[229] Some legal writers view law as the determinant social means by which to not only control the direction of science but even to somehow maintain pace even half a step ahead of science. See Smith II, who writes: "In order to meet these new challenges, law and sciences must march together as full partners and not – as in the past – with law behind the scientific cadence… . It is thus vitally incumbent upon the law to develop a contemporary agenda for social change and changing socio-political needs instead of responding simply to or reacting to change itself – especially so here with the Age of The New Biology." For another perspective, see Skene "Ownership": "Problems are being resolves as they arise. The community has generally been well served by ethical guidelines that regulate medical research and this type of regulation is more flexible than formal law. It can be altered relatively easily as knowledge advances and attitudes change. It is not necessary to resort to the legislative process." Page 164.

ensuring the ethical progression of medical genetic research in accordance with laws and ethical standards that not only define this country but also support the betterment of human health.

When reading the different sources of law and ethical codes, domestic and international, relevant to medical genetic research in Canada, one is tempted to say "there oughta be a law," and only one law. This is not simply the complaint of a researcher wishing for an easier way to prepare a report; although, admittedly, there is a bit of that. However, there is a much more pressing need for a single document or Charter if you will, to address the diverse legal and ethical issues that arise in the context of medical genetic research and the inevitable application of research findings in the development of new technologies and therapies, including the emerging field of pharmacogenomics. There is a wider public interest at stake that would be well-served by a comprehensive, understandable statement of the relevant principles and laws. Advances in genetic science, coupled with the Internet's cybermarket offering of genetic testing available to anyone willing to pay for tests or services that fall outside of the regulatory supervision of Canada's health and privacy laws, means that, increasingly, critical health care information and even services for Canadians are flying under the regulatory radar. As in other health care related matters, the prevalence of genetic testing that is available through the private sector (a search on the Internet will unearth hundreds of different labs and companies that will test your DNA for a range of fees) means that irrespective of legislation, Canadians are free to shop around for tests that run the gamut from testing for paternity to testing for traces of different kinds of drugs to testing for the presence of genes that are linked to debilitating diseases or conditions.

Thus, what is needed is a comprehensive *Genetic Charter* to set out the principles that should inform medical genetic research and the inevitable applications of findings in new drug therapies and technologies. In drafting this *Charter*, reference can be made to relevant sources of Canadian law that protect and enhance the dignity and rights of the individual (the *Canadian Charter of Rights and Freedoms* itself, human rights codes, and privacy legislation) as well as relevant international conventions and protocols. Such a *Charter* would, while recognizing the important values of patient/donor autonomy and patient/donor privacy, also recognize the importance of a physician's duty

to warn/inform persons within the patient's ambit of care of inheritable diseases or conditions. However, such a *Charter* should also be prospective, in that it should represent an enduring statement of who we are as humans and also constitute a standard for our children and for future generations.[230]

[230] Such a Charter would have models in the international community. For examples, see the UNESCO's *Universal Declaration on the Human Genome and Human Rights* (November 11, 1997) and UNESCO's *International Declaration on Human Genetic Data* (October 16, 2003).

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