Privacy of Genetic Information in Canada: A Brief Examination of the Legal and Ethical Tools That Should Frame Canada's Regulatory Response

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This article investigates the legal and ethical tools that should inform Canada's regulation of the privacy of genetic information. We are the first generation faced with resolving the unique challenges presented by genetic information. Unfortunately, the patchwork of instruments that could regulate genetic information in Canada is insufficient. The prospect of Canadians increasingly generating genetic information without a satisfactory structure for protecting the information is rather alarming. It is therefore important that we commit to reexamining regulations regarding genetic information. Different loci of governance will likely be required. Canada should look to international law and comparative law for inspiration regarding ethical and legal solutions for regulating the privacy of genetic information. The probable regulatory solution for Canada will rest in achieving a middle ground and conceiving of this issue as fundamentally grounded in ethics and human rights.

I. Introduction

Like most issues in medical law, technology defines the basis for an informed ethical and legal discussion[1] regarding privacy of genetic information.[2] In this context, one can consider privacy[3] to be "the right to keep certain information from disclosure to other individuals".[4] Some have recognized the relationship between ethics, law, and genetics for several decades.[5] With new technological breakthroughs, this discourse is currently enjoying a renaissance. Technological progress in genetics will never be static, and any attempt to fully articulate its effects will be fleeting and imprecise. Since scientists recently completed analyzing the entire DNA sequence of the human genetic code, genetic tests have come one step closer to ubiquity. This issue is therefore of ever greater importance.

Before considering how technological developments will affect individuals and human relations, jurists must understand at least the most important consequences of the most significant genetic discoveries.[6] We must be sensitive to the dynamic relationship between genetic technology and economic, scientific, and cultural forces.[7] If we believe that regulatory responses are necessary to curb potential problems of privacy of genetic information, we must continually reflect upon how governance will best respond to new scientific breakthroughs.

Uniqueness of Genetic Information

Those who advocate for privacy of genetic information argue there are several reasons why human genetic data is fundamentally different from traditional health information.[8] First, the information is useful to identify predictive genetic predispositions that would otherwise be undetectable. Secondly, this information may have a significant impact on "the family, including offspring, extending over generations, and in some instances on a whole group".[9] Thirdly, the information may contain a significance not necessarily known or understood at the time of testing. Finally, the information may have cultural significance for persons or groups.[10] These are indeed significant differences (which will be examined below, under "The Public's Role"). Those who oppose privacy of genetic information understate the uniqueness of genetic data.[11]

Evolution of Juridical Debate — The Need for a Fair and Balanced Approach

The nature of the debate regarding privacy of genetic information has shifted considerably from the beginnings of the Human Genome Project.[12] During the early years, jurists identified legal problems and called for a general governmental response. During this stage, jurists simply reacted to the issues that technology pushed.[13] Following this phase, jurists critiqued existing regulations and identified new social, legal, and ethical concerns. Currently, jurists are moving to a stage where they are asking more precise questions.[14] Few argue for no regulation.[15] The degree and nature of regulation is, however, hotly debated.[16] Some remain wary of overextending the hyperbole of the "genetic revolution" and suggest that genetic privacy concerns are overblown.[17]

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The divergence between proponents and detractors is a challenge to finding common ground. While we should celebrate jurists who passionately advocate their vision, we should also realize the consequences of both proponents and critics of genetic privacy in "undermining the benefits [on one hand] and magnifying the social and ethical issues [on the other]".[18] Rancorous rhetoric can chill genetic research by undervaluing the work of scientists, the hopes of industry (by creating unrealistic short-term expectations leading to a fall in investment), and the public's understanding and participation in regulatory debate. This rhetoric deflects discourse to the extremes and damages the possibility of achieving an informed, fair, and balanced discussion on ethics, law, and privacy of genetic information. This has led to calls for a balanced and informed discourse when developing genetic policies and regulations.[19]

Thesis

This article assumes that progress regarding genetic technology is desirable and should continue, or at least that technological innovation should not be hindered.[20] We are the first generation faced with resolving the unique challenges presented by genetic information. Unfortunately, the patchwork of Canadian legislation that could regulate genetic information is insufficient.[21] Relevant legislation and constitutional provisions (such as the *Canadian Charter of Rights and Freedoms*,[22] the *Criminal Code*,[23] laws governing professional confidentiality,[24] and data protection[25]) were mostly drafted before genetic testing was a serious consideration. As such, they are not satisfactory for the broad protection of genetic information. The prospect of Canadians increasingly generating genetic information without a satisfactory structure for protecting the information is rather alarming. It is therefore important that we commit to re-examining regulations regarding genetic information. Once we are satisfied that we are on the right course, we should commit to continuous and incremental improvements to the formal and informal regulatory framework.

Different *loci* of governance will likely be required. Understanding how to harness the strengths of different institutions will be a challenge.[26] Canada cannot be inward-looking when working towards a solution. Rather, the federal government must work with provincial governments, professional organizations, other states, and international organizations when crafting a full solution. The government must also solicit public opinion and ensure that the Canadian public is well informed.[27] Most importantly, no solution should cater to the rhetoric of either extreme. By examining this issue from a human rights perspective, the reasons for protection seem clear. In Canada, we have decided that individuals should have the right to self-determination, personal freedom, privacy, equality, and freedom from discrimination.[28] By not protecting the privacy of genetic information, we risk undermining these important principles of the Canadian ethos.

Canada should look to international law and comparative law for inspiration regarding ethical and legal solutions for regulating the privacy of genetic information. The probable regulatory solution for Canada will rest in achieving a middle ground[29] and conceiving of this issue as fundamentally grounded in ethics and human rights.

Outline of the Article

In section II, this article will investigate the relevant social and technological background regarding privacy of genetic information. Section III will examine both ethical and legal frameworks for regulatory reform. Sections IV and V will survey international law and comparative law approaches to regulating genetic information, respectively. The article will then conclude in section VI with suggestions on how Canada should respond to this dilemma. Due to space constraints, I cannot examine case law in this paper. This is not a grave hindrance, however, since it remains a peripheral mode of governance in this area of law and ethics.

II. Social and Technological Background

Since the commencement of the Human Genome Project, technological advances have greatly widened the range of genetic information that can be gathered and quantified. Technological improvements have enhanced both the accuracy and predictive ability of genetic information.[30] In addition to improving the results of genetic tests, developments in computer storage systems have made data more easily available in diverse formats. Data can effortlessly flow through different jurisdictions (across provincial and national borders) and become integrated into other computer databases.[31] Once information is added to a database, it is very difficult to extricate it completely.[32] Computers and electronic data banks of genetic information have enabled new methods of informational analysis. Not only is more genetic information available now than in the past, the information is more useful because of increasingly sophisticated methods of analysis. If genetic information is not well-regulated, then it will be difficult to control the spread of this useful data in order to respect privacy, for example.

The Public's Role

Both the government and the private sector currently handle genetic information. To an increasing extent, however, genetic testing and information is the domain of private industry.[33] Corporations are by institutional design opposed to fully disclosing their data or business strategies (for our interest this includes genetic information).[34] Since corporations are unwilling to provide frank and open accounts regarding their work with genetic technology and its consequences, the general

public has received the story filtered through the mass media. Some literature on privacy of genetic information has developed in an academic context, but like other academic discourses, seems to have had little success in shaping public attitudes. Some scholars therefore charge that rational and effective policies will result only if full and fair disclosure of scientific data is available to a more engaged and informed Canadian public.[35] The media has, nonetheless, revealed many potentially disturbing issues regarding disclosure of genetic information to the public.[36]

Canada, like other developed countries, does not currently have a unified approach to regulating genetic information. Consequentially, diverse problems related to handling sensitive genetic information have arisen in the media regarding genetic information proper,[37] employment,[38] genetic samples used in medical research,[39] discoveries of genetic diseases,[40] crime fighting,[41] and the fight against terrorism.[42] With many potential applications for genetic information, genetics is clearly affecting human relations in many ways. Without full disclosure regarding the potential risks associated with genetic information, it is not surprising that much of the public remains anxious about genetic discrimination and the loss of privacy.[43]

Some uses of genetic information have been more readily accepted both by the public and formal legal regimes. For example, both the public[44] and the law[45] have accepted the use of genetic information for "criminal surveillance of morally reprehensible activities".[46] (This article will not focus on the use of genetic information in the criminal law context since this has recently received extensive treatment by the Supreme Court of Canada.[47] Instead, the *lacunae* in the law will be given more extensive treatment.) Many uses of genetic information, such as proposed data banks of genetic information for specific populations, are not publicly supported.[48]

Genetics and Social Forces

This issue is affected by, and informs, myriad social forces. With the possibility of shaping so profoundly many human interactions, one legal writer observed:

> Today, DNA is not merely the name of the genetic material, it is also the name of a perfume. It is only by taking account of the shifts in meaning, in connotation and in significance that are involved in the transformation of molecular genetics into mass culture that we shall do justice to the public understandings of the new genetics.[49]

Genetic information thus has the capacity to reshape many human relationships, be they at individual or institutional levels. This article accordingly treats genetic information as important not just for its inherent value, but also for its consequential worth. That is, the symbolic and intangible role of genetic data is likely more significant than any physical use of the information.

Who Should Have Access to Genetic Information?

Genetic information is important to many different people and institutions, some of whom have legitimate ethical and legal claims, and others who do not. Normally, the individual who was genetically tested should know the results.[50] Doctors, who could use the information to help the patient, may have an interest in accessing it. Individuals who are directly linked to the person being tested may have strong and compelling claims for accessing the genetic information. Family members, especially genetic family members, may have a stake in this information. Genetic family members could determine if they should be tested. On the other hand, family members could discover distressing information about relatives (whether intentionally or not).[51] It can be unclear whether relatives should have access to an individual's genetic information without the patient's informed consent. The basic presumption is against allowing access without consent. The question of whether there is, or should be, an ethical or legal duty on an individual to disclose information to genetic family members is important when considering how this information should be regulated in personal contexts.[52]

Many other individuals and institutions, whose ethical and legal rights to the information are spurious, may desire access to the genetic information of patients. Businesses may wish to screen employees to ensure they do not suffer from genetic diseases,[53] and may gather sensitive information about clients.[54] Insurance and loan companies desire this information to determine premiums and types of coverage for clients.[55] Finally, the state may wish to store genetic information for various reasons such as preventing disease, understanding where to invest money in research and care facilities, promoting a healthier population, as an evidentiary tool in criminal law,[56] and in preventing crime.[57] Currently, there is a growing international consensus about how genetic information should be handled; nonetheless, there remain many critics of the preferred approach. Some, such as Arthur Caplan, believe that in the absence of laws against genetic testing there should be a moratorium against it in jurisdictions that do not have sufficient protection against genetic discrimination.[58] Others take a more pragmatic approach. It is clear that both legal and ethical concerns should inform whatever response is created regarding privacy of genetic information. Canvassing who should have access to this information is obviously an enormous topic in terms of both scope and importance, and is presented here merely to underscore how potentially explosive the debate about genetic information could be if we do not resolve privacy issues as they arise.

III. Theoretical Constructions

The following discussion on the relationship between ethics and legal choices is not intended to be exhaustive. Most importantly, it does not engage either the utilitarian or deontological schools of ethics. Instead, it merely highlights the ethical difference between individualism and collectivism.

Ethical Interpretations — Individualistic and Communitarian Ethics

At first blush, the protection of genetic information is perhaps not as controversial an ethical issue as human cloning or genetic testing. Genetic information is, after all, a consequence of genetic testing. Should ethical discussions be limited to the controversial act itself or to the consequences of the act as well? I am not alone in believing that ethics should inform legal approaches to regulating the privacy of genetic information: a full treatment regarding privacy of genetic information is not complete without considering ethics.[59] Staid legal approaches not informed by ethics will undoubtedly leave *lacunae* in regulations. The most recent efforts on this subject in international and comparative law recognize that ethics must contribute to any serious discussion.[60] Recently, both UNESCO's *International Declaration on Human Genetic Information* and American legislation opposing genetic discrimination have underscored a central tenet of medical liability: the importance of good ethics.

Good ethics, it should be noted, depend on good facts.[61] With rapid technological change in this area — as demonstrated in the previous section of this article — there is significant difficulty in harnessing these indeterminate and ever-changing facts into good ethics and eventually good law. Putting aside the issue of factual indeterminacy, I will briefly examine individualistic and communitarian ethics to gain a deeper and more nuanced perspective on possible regulatory approaches.

Modern Canadian society, like that of other secular Western states, is predicated on what some refer to as "intense individualism".[62] This commitment to individualism runs so strong that in many cases it operates to the detraction of community goals. Intense individualism, and the concomitant notions of individual autonomy and self-determination, suggest that the state should equip each individual with the ability to make decisions for themselves without undue restraint.[63] This can elicit a provocative tension between the consequences of individualism and the goals of society. For the benefit of society, a commitment to individual rights should be complemented with an equal commitment to individual responsibility.

A devotion to individualism can lead to situational ethics — that is, allowing individuals to judge each situation by itself and reject the inherent wrongness of anything.[64] Situational, or individualistic, ethics offers a unique perspective on the ethical dilemmas posed by genetic privacy. There are central ethical questions regarding genetic privacy that have uncomfortable answers when responded to through individualistic ethics. For example, is it fundamentally and ethically wrong to allow free dissemination of the genetic information of patients? Is it possible to categorically denounce the use of genetic information by corporations regarding employment, or by insurers to set policies for clients? By focusing on individual rights, intense individualists would likely find these activities to be unethical. Intense individualism does not reject the notion that ethics and ideas can be shared by a society. When there is a conflict between the rights of the community and the rights of the individual, however, intense individualists will favour the rights of the individual.

Communitarian ethics, on the other hand, is important in offsetting the possible negative consequences of a strict adherence to intense individualism. Ethical approaches grounded in modernism, such as communitarian ethics, are centered on the notion that certain ideas are inherently good while others are inherently wrong. Those who subscribe to this approach believe that reaching moral relativity through individualistic ethics is potentially very dangerous. Moreover, they believe that there are universal moral human intuitions shared across society. These thoughts on ethics should inform which legal approaches Canada chooses. The next section of the article compares postmodern legal approaches (analogous to individualistic ethics) with modern legal approaches (analogous to communitarian ethics).

Loci of Legal Governance — Informed Through Ethics

One's theoretical commitments inform not only whether a regulatory approach should exist, but also how it should be manifest through different *loci* of governance. When determining which institutions should participate in crafting Canada's regulatory response, there is a tension between modernist and post-modernist approaches to legal reform.[65] Legal modernism (the legal equivalent to communitarian ethics) is based on several central assumptions: first, "the belief in the possibility of a non-ambivalent, non-aporetic ethical code", and secondly, the associated belief in the "value of reason exercised by the individual apart from any relation to other persons".[66] Essentially, it maintains that there are rules and principles that can lead to acceptable solutions (if properly implemented). Modernism assumes that genetic privacy issues can be extricated from the particularities of institutional context and resolved through codes, formal regulations, and principles, provided they are stated clearly and unambiguously. Formal legal regimes, whether national or supranational, are grounded in legal modernist commitments.

Postmodernism, on the other hand, suggests that solutions will be much more difficult to implement. One cornerstone precept is that each jurisdiction or institution faces particularities. Having an over-reaching code (such as the UNESCO declarations examined in section IV) will therefore fail to satisfy these complexities. Perhaps most distressing to modernists is the postmodern suggestion that formal law is not the only option for governance, nor perhaps the most important.[67] There will be pressures (from insurance companies, businesses, etc.) to adapt certain governance structures. These exigencies and relationships must be recognized.

There is significant divergence between the ethical norms of the two theoretical approaches. One's normative commitments will heavily influence what one envisions as the most appropriate role for legal institutions.[68] Most international work on privacy of genetic information is based on a commitment to modernist norms. This work, bathed in the essence of modernism, centres on formal legal approaches to regulating the issue, rather than legitimizing postmodern notions of informal legal responses. Canadians will likely feel more comfortable regulating an issue as important as genetic information through formal legal instruments. Postmodern legal theory is important in reminding us that informal governance mechanisms, such as relationships between genetic family members, should not be totally neglected.

Four Legal Theoretical Approaches[69]

There are four broad legal theoretical approaches that may be helpful in organizing our thoughts about how to best regulate the privacy of genetic information in Canada: constitutional, statutory, administrative, and market-based regulation. The first is a constitutional, human rights approach.[70] One can imagine this approach standing on its own or complementing other regulatory regimes. It may be effective to circumscribe the application of new technologies that might otherwise encourage discriminatory or stigmatizing practices. This approach relies on existing human rights instruments to interpret new technological applications.[71] One advantage is that existing court processes could be used. Moreover, interest groups could be involved in intervener status. There are also significant disadvantages to this process, since court processes are slow, expensive, and cumbersome. If courts refused to expand traditional understandings and doctrine, then this process could prove fruitless for actively protecting genetic privacy in Canada. Canadian courts are typically more active in protecting such rights, however.

The second approach is to regulate through legislation. The state would create laws to address the implications of scientific advances through prohibitions, constraints, or moratoria. Relying on statutory mechanisms brings precision, certainty, clarification, and expression of political consensus.[72] However, there is a chance that once legislation is passed, public debate could be replaced with complacency. There is also a risk that numerous statutes from provincial and federal governments could contradict each other; conversely, statutes could be too limited in scope.[73] An adjunct criticism is that any statutory reaction must be responsive to public opinion. Otherwise, it could appear to be imposed in an excessively top-down fashion. Some authors suggest that statutory responses should be reserved for particularly serious issues, and that there is nothing inherently dangerous about genetic information to warrant regulation through legislation.[74]

Legislation does not exist in a vacuum. Rather, legal norms promulgated through legislation are informed through both local and international values. If we believe that legislative action is important in governing the privacy of genetic information, we should look to precedents in both international law and comparative law for inspiration. Sections IV and V of this article canvass international law and comparative law approaches regarding privacy of genetic information, respectively. For example, UNESCO's *International Declaration on Human Genetic Data* outlines principles that should inform the responses by states to the privacy of genetic information. Article 23(a) states that

> [s]tates should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.[75]

A third approach is for the state to empower administrative or regulatory agencies to manage this issue.[76] This could be realized through either external regulatory or quasi-regulatory agencies. These institutions would then concentrate on quality assurance, standardization, and monitoring. They could gradually develop additional codes of conduct to reflect technological advancements. Existing institutions could enlarge their mandate, or new ones could be created. It is possible to create either narrow regulatory agencies for genetic information in particular, or broader and more encompassing agencies for health information in general. There are strong criticisms against over-reliance on regulatory agencies for governance. Empowering regulatory agencies to address complex and sensitive issues may remove the debate from the public sphere moreso than other approaches. It is also unlikely that this approach would be a sufficiently robust governance tool to satisfy the regulatory demands encompassing reforms regarding privacy of genetic and general health information.

Also included in this third approach would be governance through the doctor–patient relationship. A patient must trust their doctor sufficiently to reveal very personal details. Without this trust, doctors cannot gain the requisite information to effectively treat the patient.[77] Some believe that doctors should therefore play an

important role in helping to protect the confidentiality and privacy of a patient's genetic information.[78] Others underscore that doctors do not have an absolute obligation to maintain confidentiality.[79] There is indeterminacy about when this principle will be broken because of competing values and interests. Since doctors are not bound to an absolute obligation of secrecy, these observers are wary of governing genetic privacy and confidentiality through this mechanism alone.[80] Nonetheless, the physician–patient relationship is a cornerstone for medical law in Canada, and must be seriously considered in this discourse.

A fourth approach is the neo-liberal, market-driven approach. Marketplace ethics, the ethical cousin of economic neo-liberalism, assumes that proper professional practices will ultimately be created through the market, with ethical people making ethical decisions.[81] This approach is the most flexible for facilitating scientific research, since it advocates no formal constraints beyond those imposed by aggregated market forces. Of course, some observers question the efficacy of allowing the private sector to set the governance structure regarding data collection and dissemination.[82] This theory recognizes neither the influence of non-disclosure by market actors,[83] nor the significant role of advertisements and marketing in shaping the choices of market actors.

Application of the Four Legal Theories to Canada

There is currently limited debate in Canada, or at least very little public debate, about genetic information and privacy. This raises some serious questions regarding the proper mix of governance tools. In the absence of an interested public, will Parliament act? If Parliament does not fill the regulatory gap, is it acceptable to leave regulation to the market, the courts, or other mechanisms? If not, how should interested parties publicly pressure the federal government to legislate on this issue? These are important questions that will continue to be raised as the discourse becomes more mature.

The challenge of public policy is that it must contain both substantive policy goals and the public's involvement. Neither can be missing. The above exposition was intended to underscore the interrelationship between different modes of governance. The most effective governance approach is likely some mix of all four approaches, since they would inform each other and help to achieve a more nuanced and complete template for regulation. The following section will analyze the further challenge of creating a framework that is as flexible and dynamic as the technology.

Three Prongs to Any Regulatory Response

Regardless of the regulatory response chosen in Canada, be it a single method or an interlocking of responsibilities, three characteristics should exist: consensus, graduality, and provisionality.[84] Consensus — the commitment to gain and maintain the support of diverse interest groups — should be a priority. Any regulatory approach may otherwise be considered a top-down imposition.[85] In a legal sense, health care was traditionally imposed on individuals by the health community in certain public health contexts; this was restructured only recently with the development of the doctrine of informed consent.[86] There is now an expectation for patients to participate in an increasingly important role when determining their health care *ex ante*.

With the doctrine of informed consent determining the relationship between the patient and their health care provider *ex ante*, it seems hypocritical to empower health care administrators and clinicians to solely decide how the genetic information of patients should be protected *ex post*. Patients should also have the opportunity to participate in determining what is done with their health information *ex post*. For consistency, patients' rights should be respected and buttressed with legislation or through the common law. Of course, the amount of power ceded to individuals is at least somewhat determined by the choice of regulatory approach. Some approaches lend themselves to greater patient involvement.

Graduality should be a second important hallmark of regulatory reform. Scientific advances occur so quickly that a static regulatory approach would likely be ineffective. There must therefore be a commitment by governance institutions to re-examine general principles and specific regulation in a slow and continuous fashion. No single attempt to overhaul the regulatory regime would likely be satisfactory in satisfying the nuances of the issue.

Provisionality is a third prong of regulatory reform. The goal of regulatory reform should not be to create permanent regulation. There must instead be a rigorous commitment to constantly re-evaluate and refresh the regulations and mode of governance. Timetables for review should be created beforehand and created *ad hoc*. By requiring a constant recommitment to examining the effectiveness of existing regulation, reviews could be subsumed by political opportunists; this must be avoided. Since the relationship between technology and society will continue to change, we must continually revisit the debate and plan for the consequences of new genetic technology.[87] With theoretical examination in hand, this article will now examine international law and comparative law for regulatory models that could inform Canada's approach.

IV. International Law

Since the early 1990s, there have been numerous attempts in international law to organize thoughts regarding genetic information. Although international responses were slow in addressing the concerns of genetic privacy, the discourse has evolved into a full and

complex legal and ethical dialogue. This is exciting both substantively and normatively. The first three international efforts examined below are background and provide context to UNESCO's recent work. The Canadian federal government should closely examine the most recent UNESCO declarations and ensure that Canada's regulatory regime addresses the concerns articulated within the documents.

The *Bilbao Declaration*

The *Bilbao Declaration* of 1993 stemmed from the International Meeting on the Law and the Human Genome Project.[88] Strictly speaking, this was not a normative text. It was, however, the first international document to address the human genome from a legal standpoint. The document underscored the importance for international agreement and for creating supranational control of genetic information. Five of its conclusions touched directly on genetic information:

> 3. Personal privacy is the exclusive possession of each person and therefore it should be immune to any interference. Informed consent is an essential prerequisite for interference in privacy. Exceptionally, for reasons of general interest, access to such privacy could be allowed, in any case under legal control.
> 4. Out of respect for personal dignity, the human body must not be subject to commercialization. However, controlled availability free of charge will be allowed for therapeutic or scientific purposes. Genetic knowledge belongs to humanity and must be freely communicated.
> 5. Genetic technology applied to personal identification, being capable of supplying more information than that strictly necessary, must be restricted to the indispensable requirements of each specific case.
> 6. The use of genetic data giving rise to any discrimination in the field of labour relations, insurance or any other area, will be rejected.
> 7. It is advisable that international agreements be drawn up and that national laws regulating the application of genetic knowledge should be harmonized. Supranational controls should also be established.[89]

The legal principle of informed consent played a central role in the *Bilbao Declaration*. Informed consent provides a buttress for other sensitive issues that could be compromised through the improper access of genetic information. This principle was later integrated into the leading documents on genetic privacy.[90]

Many argue that the media has heightened what people are expecting from genetic testing.[91] The need for proper consent and counselling is therefore underscored in this document, as well as in more recent Declarations.[92] The right to know is another aspect of informed consent, and has been so for decades.[93] An interesting extension of informed consent includes the "right not to know". This notion, originally created regarding AIDS testing, is considered important for genetic testing as well.[94] There is evidence of significant deficiencies of consent among those genetically tested, despite international and national declarations to the contrary.[95] This is a dangerous trend that cannot continue. As of 1999, only 45% of 245 American Genetic Laboratories required informed consent prior to testing.[96] The *Bilbao Declaration*, despite its limitations, provided a basis for future international law instruments to expand upon regarding genetic privacy.

World Health Organization

A second important international document was the 1994 *Declaration on the Promotion of Patients' Rights in Europe* (*Promotion of Patients' Rights*) of the European Office of the World Health Organization (WHO).[97] This *Promotion of Patients' Rights*, while not explicitly regarding genetic information, underscored the close connection between confidentiality and privacy of health information.[98] The document suggested that the right to privacy is interrelated with secrecy. Both are intended to protect patients from disclosure of data in the medical context (both for therapeutic and non-therapeutic treatment).[99] Secrecy traditionally covered the relationship between the patient and doctor. This *Promotion of Patients' Rights* recognized that the rules governing this relationship were no longer sufficient to regulate personal health data stored in data banks and administered by third parties.

Data processing, which has always raised problems of confidentiality, came to the fore. Modern computerized data processing systems were open to access by more people than merely the doctor. Third parties were, in fact, interested in personal medical data — especially genetic information. Adjunct questions remained, such as whether parents should have access to the genetic information of their children.[100] The WHO sought to address these concerns through the doctrine of patients' rights. The WHO regarded the right of access to health information, and genetic information in particular, in connection with a patient's right to privacy. Several European countries used this initiative as a catalyst for modernizing their regulations in this area.[101]

Council of Europe

The Council of Europe Human Rights and Biomedicine Convention[102] in 1996 created a more robust document on genetic information.[103] The *Convention on Human Rights and Biomedicine* was special for several reasons. First, its legal nature made this document fundamentally different from previous international agreements on genetic information. Second, it had the potential to be a universal document. Membership was open to all member states of the Council of Europe as well as any other country interested in joining. Despite the possibility of extensive membership, the *Convention* remained essentially regional in nature.[104] The *Convention* was also limited since it was not a legal instrument on the human genome in particular.

UNESCO

With the groundwork laid, UNESCO was prepared to take a leadership position. Since the late 1990s, UNESCO has made the most important contributions regarding genetic privacy. There have been many advantages to UNESCO undertaking this mandate.[105] Unlike previous recommendations adopted by international organizations, UNESCO's declarations — written in a standard legal manner and setting ground norms by which member jurisdictions are expected to abide — have been more universally supported than previous efforts. UNESCO's efforts are based on the language and discourse of human rights, which appeals to the contemporary ethical and legal culture of Canada and many UN members.[106] Most importantly, UNESCO's declarations deal specifically with the human genome and are not stretched beyond its intended subject matter, unlike previous efforts in international law.

Since its creation in 1993, UNESCO's International Bioethics Committee (IBC) has concerned itself with developing declarations regarding confidentiality and privacy of genetic data.[107] In 1997, the IBC drafted the *Universal Declaration on the Human Genome and Human Rights*, which was later endorsed by the UN General Assembly.[108] This demonstration of international agreement became a benchmark for states to draw upon for their legislation, regulations, norms, standards, ethical codes of conduct, and guidelines.[109]

As the boldest international law document of the 1990s regarding genetic information, the *Universal Declaration on the Human Genome* was important for several reasons. It strongly articulated the "inherent dignity and diversity" underlying the human genome.[110] "In a symbolic sense," the *Universal Declaration on the Human Genome* states, the human genome "is the heritage of humanity". This fundamental proposition and commitment to human rights should underlie Canada's regulatory response as well.[111] Codifying previous work on the topic, the *Universal Declaration on the Human Genome* stated that informed consent — including the right not to know — is another fundamental proposition in this area of the law and ethics.[112]

One weakness is that the *Universal Declaration on the Human Genome*, despite setting numerous ground norms, allows member countries substantial latitude to regulate around loose language. There are some instances where the *Universal Declaration on the Human Genome*'s open language is constrained by appealing to member states to work within the rule of law.[113] For the most part, there are few mandatory responsibilities for UN member countries. This is a standard for intentional legal agreements and is not unique to this document. It should be noted that the *Universal Declaration on the Human Genome* aims to provide more than simply norms for national regulations. It recognizes the significant international aspects facing a sophisticated regulatory response to genetic information, and therefore underscores international solidarity and co-operation.[114]

Most recently, the IBC prepared a *Draft Declaration on Human Genetic Data*.[115] This *Draft Declaration* became the basis for the *International Declaration on Human Genetic Data*,[116] ratified by the General Conference of UNESCO on October 16, 2003. This groundbreaking *Declaration* is the most full and sophisticated treatment in international law regarding privacy of genetic information. It rationally recognizes that "the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications and for the use of such data for non-medical purposes".[117] It therefore calls for a pragmatic approach to regulating genetic information ensuring respect for human rights, fundamental freedoms, and human dignity. The *Declaration* underscores that the regulatory response of national governments will be very complex, as they must consider and balance many policy goals:

> [T]he principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research, and privacy and security of person, which must underlie the collection, processing, use and storage of human genetic data.[118]

Interestingly, this UNESCO *Declaration* is informed not just by the law, but by ethics as well. Article 24 suggests "[s]tates should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data."[119] Moreover, article 6(a) mandates that "[i]t is ethically imperative that human genetic data ... be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures".[120] States should therefore attempt to make these ethical and legal decisions with the involvement of society,[121] whether represented by the public, non-governmental organizations, academics, or other groups with training and interest in ethics. One way to ensure this occurs is for states to establish "independent, multidisciplinary and pluralist ethics committees."[122] UNESCO's appeal to an ethical approach is not mere lip service; it seems to be sincere that ethics should inform legal regulatory responses. Informed consent is featured even more prominently in the newest UNESCO *Declaration*. Instead of being described as a legal necessity, informed consent is expressed as an ethical imperative as well.[123] UNESCO recognizes that ethics is central to understanding how to regulate genetic information. Canada should similarly commit to ethically inspired regulation.

Like the *Universal Declaration on the Human Genome*, the *Declaration* is sometimes limited in how effectively it is drafted. The *Declaration*'s final introductory article regarding non-discrimination and non-stigmatization uses non-binding language to assert that states should make

> every effort ... to ensure that human genetic data ... are not used for purposes that discriminate in any way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.[124]

This is an important aspect of regulation with which all states will grapple; yet, this article is not precise enough to be very effective in mandating states to limit discriminatory practices. Of course, when working on the international level, it is difficult to be precise. In some cases, moreover, precision detracts from the goal of setting a broad normative framework that can be used worldwide.

Other aspects of the *Declaration* are very thorough and provide explicit guidance as to how states should consider legislative responses. The remainder of the *Declaration* covers principles on how to regulate collection of information,[125] processing of information,[126] using genetic information,[127] and storing the information.[128] When determining how to structure its regulatory response, Canada should seriously consider the substantive contents of the UNESCO *Declaration*.

The *Declaration* will likely not be the final instrument passed by UNESCO on this topic. Article 26 empowers the IBC and the Intergovernmental Bioethics Committee (IGBC) to continue to contribute and disseminate information on privacy of genetic information. Both committees will therefore continue to examine how to improve the international principles imbued in UNESCO's declarations. While Canadian academics and regulators should examine the existing UNESCO declarations for inspiration and direction, they should also be aware that UNESCO will continue to respond to new exigencies related to genetic information.

V. Comparative Law

This article does not allow for a full analysis of comparative law. Many jurisdictions have had highly complex initiatives that cannot adequately be captured here. I will therefore be limited to a few thoughts on what Canada can learn from how several states have organized their policy and regulations regarding genetic privacy. What follows is an account of particularly interesting approaches from several jurisdictions.

The United Kingdom

In 1991, the Nuffield Foundation in the United Kingdom established the Nuffield Council of Bioethics as a response to the dearth of government-sponsored organizations for overseeing developments in biomedicine and biotechnology.[129] The Council is designed to identify and define ethical questions raised by recent advances in biological and medical research, and to respond to and anticipate public concern. This organization, although independent from the government, has become the *de facto* national bioethics advisory body. It works closely with official government institutions, such as the Human Genetics Commission, to define appropriate national public policy directions. In 1993, this organization published *Genetic Screening: Ethical Issues*.[130] The Nuffield Council demonstrates several important principles. First, not all policy directives must be government initiated. If there is a gap in governance, between what the government is willing to design and what is required, alternatives are possible. Secondly, Canada should observe the Nuffield Council's leadership on designing public policy that is not merely responsive, but anticipates future circumstances regarding genetic privacy.

Switzerland

The Swiss Federation's reformed constitution has been in force since January 1, 2000. Following its reform, article 119(2)f reads:

> A person's genetic material may only be analyzed, registered or disclosed with the consent of that person, or if a statute so provides.[131]

This is a poignant example of the explicit constitutionalization of the right to genetic privacy. Constitutional reform in Canada is not an attractive option, so it is unlikely that this regulatory alternative will be chosen. However, it does provide a nice example of a different constitutional approach than litigating one's Charter rights.

United States of America

There is a significant amount of American literature and legislation on this issue. Unfortunately, there is insufficient room in this article to fully explore the nuances of American discourse and developments. This brief discussion will focus solely on the most recent American legislative proposals. In the United States, confidentiality of medical records has historically been addressed through a patchwork of state statutes, which are limited to particular professions or institutions. Recent attempts by the federal government to address the issue of confidentiality and privacy of medical data (or at least electronic medical data) in a comprehensive way have proved very controversial.[132] The American federal government has been more successful in implementing regulations regarding discrimination based on sensitive health information, including genetic data.

On October 14, 2003, the United States Senate unanimously passed the *Genetic Information Nondiscrimination Act*.[133] This Bill, supported by the American public and interest groups on behalf of those with genetic predispositions to certain illnesses or harmful conditions,[134] returns to the House of Representatives before it can be sent to the White House to be approved by the President. The Bill provides strong legislative protection against health insurance companies or employers discriminating against clients or employees based on genetic data. It recognizes "that all medical information, genetic or otherwise, should be afforded the same protections under the law".[135] Some argue that this legisla-

tive response is not sufficiently encompassing and should be expanded to cover any type of discrimination based on health information.[136] Most, including the U.S. Senate, believe that this is an effective, measured, and balanced response to an increasingly serious problem. It should be noted that the American system of health insurance demanded a quick and meaningful legislative response. It would have been very troublesome if American private health insurers had the capacity to discriminate against clients in this fashion. Canada does not have the same system of health insurance, making it unlikely that an identical statutory response is needed immediately. Nonetheless, Canada should heed the American response on this issue.

Canadian Policy Response

Canada has not been completely devoid of formal policy discussion.[137] In 1997, the Federal Privacy Commissioner contributed to the discourse with a substantial publication.[138] The Privacy Commissioner designed this document from a human rights perspective, which included a list of core principles that described basic rights and responsibilities regarding genetic privacy. The document went so far as to argue for the creation of a Charter of privacy rights. It advocated replacing staid and traditional responses to governing on privacy with more dynamic ones capable of reacting to quick developments caused by technological improvements.[139]

The Privacy Commissioner suggested many processes to assist in protecting genetic privacy, including public debate, research, education, sensitization, legislation, regulation, codes of practice, privacy-enhancing technologies, and pilot projects.[140] In terms of stakeholders, it required many to contribute: "politicians at all levels of government, corporations, educators, the media, privacy commissioners, technology and systems designers, bureaucrats, rights advocates, and individual members of the public".[141] Thus, protecting everyone's privacy rights would become everyone's responsibility through a multitude of formal and informal processes. The Commissioner eschewed an individualistic approach for a communitarian approach, and advocated a very complex response where regulatory response included a feedback loop. Both the response and the players would react to each other and have responses exercised on them. Any proposal to regulate genetic privacy must not ignore the Commissioner's deliberations on complexity.

Canadian Provincial Response — Ontario

I will examine Ontario as an example of how Canadian provinces approach privacy in general, and genetic privacy in particular. The movement towards protection of personal health information in Ontario began in the 1950s, albeit in a patchwork fashion.[142] Of course, early health legislation was not intended to protect genetic information. Nonetheless, there was some commitment on behalf of the Ontario government to regulate health information.[143] As early as 1944, confidential health information was regulated in Ontario public hospitals.[144] For the most part, the rules merely protected the unauthorized use and disclosure of health information, and not the information itself. Protection of general health law in Ontario has continued to evolve with much legislation passed to this effect.[145] All of these acts touched on the protection of health information but none did so in a complete and general manner. Instead, individual acts were passed for individual problems. No overarching legislation or policy directive for the issue of health information writ broadly was created.

By the mid 1990s, Ontario's approach began to change. Consumer and health care providers sought comprehensive personal health information legislation.[146] While the Ontario Ministry of Health and Long Term Care prepared consultation memos[147] to distribute to stakeholders and draft legislation, the federal government began legislating to protect health information.[148] Following this federal initiative, provincial regulation has not progressed. Formal provincial legislation does not currently exist regarding the precise issue of privacy of genetic information or genetic discrimination.[149]

Canadian Federal Response

The current state of regulation on the privacy of health information in Canada has been described as "regulatory chaos".[150] In addition to professional codes, "guidelines, standards of practice, as well as common law principles", there are currently five pieces of legislation that govern health information in Canada's private sector.[151] Despite the regulatory overlap of federal and provincial legislation, many observers do not believe it is sufficient to ensure the privacy of genetic or mere health information.[152] More specifically, these statutes are insufficient to explicitly bar employers and insurers from using genetic information to discriminate against employees.[153]

In 2000, the federal government passed wide-ranging legislation governing the privacy of personal information in the private sector.[154] Critics claimed that Bill C-6, while effective for certain types of information, was not prepared to deal with simple health information (let alone genetic information).[155] Centered on a consent-based system, the Bill does not reflect how health care delivery, planning, management, and research are organized in Canada.[156] There is little question that the Bill is insufficient to grapple with the increased complexities regarding privacy of genetic information. Despite these limitations, Bill C-6 is currently the statutory centerpiece for protecting the privacy of health information in Canada.

The federal government understands that legislation does not operate in a vacuum. A thorough understanding of the feedback loops is required to properly regulate technologically influenced issues. In response, the federal government established the Canadian Bio-

technology Advisory Committee to "provide expert advice to the federal government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology."[157] There are numerous other federal advisory bodies and working groups contributing to the discourse. The legal community in Canada is enjoying an increasingly important role, especially within the federal government.[158] It is important that Canada not forget the importance of ethics when committing to develop a legal discourse on genetic privacy.

There is a strong feeling on behalf of some lawyers that the federal government must play an overarching role in Canada, since not all genetic tests are done within a single province, and in many instances tests are sent across provincial borders to be processed. Having some federal standardization on such an important issue seems to be of great importance.[159] If criminal sanctions were to be used to regulate genetic information, that would be a federal responsibility as well. For now, genetic information remains largely unregulated in Canada. There is a "danger ... that, absent regulatory safeguards and quality controls, the forthcoming multitude of predictive genetic testing services will be overused ... and misinterpreted by patients, providers, insurance companies, and employers".[160] In the absence of sufficient existing legislation in Canada, what should drive a sophisticated regulatory response?

VI. Conclusion

Canada's response to the creation of genetic information and the possibility of its misuse has thus far been inadequate. This article has examined ethical and legal approaches that should inform the Canadian response. Unless Canadians either believe that no formal state-based regulation is necessary or they wish to submit to market regulation, a "sustainable and comprehensive regulatory policy is needed".[161] Assuming regulation is necessary, there are many competing ethical and legal values that any proposed solution must balance.

Consensus will be difficult to achieve regarding the appropriate mixture of regulatory approaches. There are scores of issues to consider, but the allure of simplistic solutions looms large.[162] Any solution must be informed and balanced. Many believe that there is a lack of public discourse in Canada. It is very difficult to create thorough legislation on new areas of regulation, even if there is full public participation. To do so without discourse is even more difficult. It is not unreasonable to suspect that "rational and effective policies will only result from additional basic scientific data being made available to a more informed and engaged Canadian public".[163]

There are many interesting efforts to resolve privacy of genetic information throughout the world, both in comparative law and international law.[164] When establishing ground norms for how Canadian institutions should regulate the privacy of genetic information, we should examine the content of UNESCO's *International Declaration on Human Genetic Data* very thoroughly. The *Declaration* is a sophisticated analysis that marries together the most contemporary thoughts on law and ethics. The federal government, with the assistance of the work done by others in the international community, must soon determine the most effective Canadian regulatory response.

Notes:

[1] The relationship between ethics and law is closely bound, especially as related to medical issues.

[2] Carlos María Romeo Casabona, "Genetics and the Law" in Carlos María Romeo Casabona, ed., *Biotechnology, Law and Bioethics: Comparative Perspectives* (Bruxelles: Bruylant, 1999) at 37.

[3] While this paper focuses on privacy in particular, one should not forget the importance of confidentiality and secrecy.

[4] A. L. Allen, "Genetic Privacy: Emerging Concepts and Values" in Mark A. Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven, Conn.: Yale University Press, 1997) 31 at 31. Privacy also encompasses an individual's right to decide whether to receive certain information about himself or herself from a third party. Confidentiality, on the other hand, can be considered "the right of an individual to prevent the redisclosure of certain sensitive information that was disclosed originally in the confines of a confidential relationship". Confidentiality concerns also arise when exploring whether there is a duty on behalf of a tested individual to alert relatives of relevant genetic information. See also Carol McCrehan Parker, "Camping Trips and Family Trees: Must Tennessee Physicians Warn Their Patients' Relatives of Genetic Risks?" (1998) 65 *Tenn. L. Rev.* 585 at 612-15.

[5] George P. Smith, II, *Genetics, Ethics and the Law* (Gaithersburg, Md.: Associated Faculty Press, 1981).

[6] Romeo Casabona, *supra* note 2 at 37.

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

[8] Roberta M. Berry, "Genetic Information and Research: Emerging Legal Issues" (2003) 15 Health Ethics Committee Forum 70 at 73. "[G]enetic health care information is in large part unexceptional. Much of it has been around for a long time and is accessible to casual observation: male or female, tall or short ...". This paper will discuss, however, important trends that are making genetic information wholly different than previous health information. See International Bioethics Committee, *Draft International Declaration on Human Genetic Information*, 32 C/29, UNESCO, 2003 [*Draft Declaration*] at art. 2. For a definition of genetic information: "Non-obvious information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis". See also *International Declaration on Human Genetic Information*, 32 C/Res. 22, UNESCO, 2003 at art. 2. For a definition of human genetic data: "Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis". [*Declaration*].

[9] *Draft Declaration, ibid.*

[10] *Ibid.*

[11] Jon Beckwith & Joseph S. Alper, "Reconsidering Genetic Antidiscrimination Legislation" (1998) 26 J.L. Med. & Ethics 205 [Beckwith & Alper].

[12] Timothy Caulfield, "Introduction" (2000) 45 *McGill L.J.* 343 at 344 [Caulfield, "Introduction"].

[13] Caulfield, "Underwhelmed", *supra* note 7 at 440.

[14] Mark A. Rothstein, "Genetic Privacy and Confidentiality: Why They Are So Hard to Protect" (1998) 26 *J.L. Med. & Ethics* 198 at 198.

[15] Caulfield, "Underwhelmed", *supra* note 7 at 440.

[16] *Ibid.* at 456, n. 102.

[17] Bartha Maria Knoppers, "Reflections: The Challenge of Biotechnology and Public Policy" (2000) 45 *McGill L.J.* 559 [Knoppers].

[18] Caulfield, "Underwhelmed", *supra* note 7 at 440.

[19] See *Ibid.*

[20] If we agree that genetic testing should exist, then we must consider how genetic tests should be administered. There are several broad options: mandatory testing, voluntary testing, or coercive testing (that is, as a precondition for certain services). Evaluating these methods is beyond the scope of this paper, but it is possible that in different contexts different approaches should be prescribed.

[21] See sections 5.5-5.6 on Canadian law (provincial and federal), below.

[22] *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [Charter].

[23] *Criminal Code*, R.S.C. 1985, c. C-46 [*Criminal Code*].

[24] See, for example, Eike-Henner W. Kluge, ed., *Readings in Biomedical Ethics: A Canadian Focus* (Scarborough, Ont.: Prentice Hall: 1999).

[25] *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5 [PIPEDA] (also known as Bill C-6).

[26] See Roderick A. Macdonald, *The Swiss Army Knife of Governance* (2002) [unpublished] for a thorough discussion on the general rationale about institutional governance.

[27] See *Declaration*, *supra* note 8 at art. 24.

> In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

[28] See Patrick S. Florencio, "Genetics, Parenting, and Children's Rights in the Twenty-First Century" 2000 (45) *McGill L.J.* 527 at 538-39 [Florencio] for a discussion on the risk of genetic discrimination.

[29] By middle ground I suggest that genetic testing and research will remain legal, but that the consequential information will be regulated to ensure against misuse.

[30] Caulfield, "Underwhelmed", *supra* note 7 at 441-43.

[31] This is but one reason why international law should be recognized as playing an important and legitimate role in the regulatory context.

[32] Julie Thorburn, "The *Personal Information Protection and Electronic Documents Act* and the Protection of Personal Health Information" (2001) 22 *Health L. Can.* 52 at 52.

[33] Caulfield, "Underwhelmed", *supra* note 7 at 442-43.

[34] There is a very remote possibility of government transparency through the *Freedom of Information Act*.

[35] See Knoppers, *supra* note 17.

[36] See, for example, Robert Klitzman "Questions That Have No Answers" *N.Y. Times* (21 January 2003) (Lexis-Nexus). A woman who was genetically tested for Huntington's disease struggled to keep the results private. The clinician wondered if a patient does not tell a spouse or child about carrying a gene, will he have to intervene? The clinician argues that many doctors do not arrange for genetic testing because of uncertainty over the right way to proceed and protect the information. Other doctors order tests without considering how to handle the results. It is noted that "laws alone will not protect people from the problems that emerge in personal relationships, and public attitudes will have to change to reduce the chances of genetic discrimination". Also see Gena Kolata "If Tests Hint Alzheimer's, Should a Patient be Told?" *N.Y. Times* (24 October 1995) A1, a classic situation where genetic tests revealed more information than what the patient originally consented to receiving.

[37] See, for example, Steven Morris "Taking DNA by stealth 'should be outlawed': Genetic watchdog's report calls for control on testing" *Guardian* (22 May 2002) 10.

[38] See, for example, Sheryl Gay Stolberg "Panel Breaks Logjam for Bill on Employees' Genetic Histories" *N.Y. Times* (22 May 2003) (Lexis-Nexus) [Stolberg].

> A bill barring employers and insurance companies from discriminating against people based on their genetic histories won unanimous approval of a Senate committee, breaking a logjam that had held up the measure for six years. The details were difficult to work out, Congressional aides said, because the issues surrounding genetic testing and privacy are so complex. Many people had avoided the tests, fearing the loss of health insurance or a threat to their work.

[39] See, for example, Helena Kennedy "Big Brother: The Black market in your personal data: Part Three: Genetics: The Secret Life of Samples" *Guardian* (21 September 2002) 10 (Helena Kennedy QC is chair of the British Human Genetics Commission); Andrew Pollack "DNA of Blacks To Be Gathered To Fight Illness" *N.Y. Times* (27 May 2003) (samples must be collected in a standardized procedure with the informed consent of the donors).

[40] See, for example, Barron H. Lerner "When a Doctor Stumbles on a Family Secret" *N.Y. Times* (16 September 2003)

> A group of health professionals were evaluating potential donors for a kidney transplant recently when they received a surprise. Through routine genetic testing, the group inadvertently learned that one of the adult children was not the child of the man with kidney failure. The transplant team struggled with the question of what to do with this information. Should the family be told? To whom did the knowledge belong? Was it ethical to use the child's kidney without telling him? Keeping family secrets used to be a routine part of medicine. But over the past few decades, as patient autonomy and informed consent have come to dominate clinical practice, disclosure has become more commonplace. Every now and then, however, physicians confront complicated family secrets. What they should do about them is far from clear.

[41] See, for example, Tim Radford "British Association: DNA database 'has to cover everyone': Father of genetic fingerprinting says global approach fairest in fight against crime" *Guardian Home Pages* (13 September 2002) 8.

[42] See, for example, William Safire "Privacy Invasion Curtailed" *N.Y. Times* (13 February 2003). "Among other abominations, Ashcrofts' 'Patriot II' would computerize genetic information without court order or ... consent".

[43] Caulfield, "Underwhelmed", *supra* note 7 at 457, n. 103.

[44] Knoppers, *supra* note 17 at 562.

[45] *R. v. S.A.B.*, [2003] 2 S.C.R. 678 [*S.A.B.*].

[46] Knoppers, *supra* note 17 at 562.

[47] *S.A.B.*, *supra* note 45.

[48] See Radford, *supra* note 41. But see Caulfield, "Underwhelmed", *supra* note 7 at 444. Results varied according to when studies were done, what questions were asked, and what the sample was.

[49] Caulfield, "Underwhelmed", *ibid.* at n. 32.

[50] It should be noted that there are circumstances where the individual who is tested may want to exercise their right "not to know". This right is becoming more accepted in the international legal community. See *Declaration*, *supra* note 8 at art. 10.

[51] See Lerner, *supra* note 40.

[52] See Parker, *supra* note 4. In the U.S., courts have found that "the duty to warn of avertable risk from genetic causes, by definition a matter of familial concern, is sufficiently narrow to serve the interests of justice". How this complicated balancing will inform specific circumstances is unclear and likely open to wide interpretation. Also see Lori B. Andrews, "Legal Aspects of Genetic Information"(1996) 64 Yale J. Biology & Med. 29 at 30.

> How far should this duty be extended? If a father has a high cholesterol level, would he be under a duty to warn his children? Other difficulties include identifying the relatives who are entitled to a warning, determining the duration of the duty, determining whose responsibility it is to convey the warning (physician or individual).

[53] In the case of Burlington Northern Santa Fe Railway (BNFSR), the employer required any employee with carpal tunnel syndrome to submit to a genetic test. BNFSR was worried about paying increased health insurance costs for employees who may have been genetically predisposed to the affliction. This would potentially be a bigger problem in the U.S. than in Canada, since Canada's health system ensures that employers

do not cover the costs of health care for employees. See Stolberg, *supra* note 38.

[54] See Berry, *supra* note 8 at 76–82.

[55] *Ibid.* See also Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social Policy* (Cambridge, MA: MIT Press, 2004).

[56] Such as DNA banks, and invasive and non-invasive genetic collection mechanisms.

[57] *S.A.B.*, *supra* note 45. The Canadian Supreme Court has recently supported the government's contention that the state has a role in being able to compel individuals to submit to genetic testing.

[58] Caulfield, "Underwhelmed", *supra* note 7 at 457 n. 105.

[59] Margaret Somerville, *The Ethical Canary* (Toronto: Penguin, 2000) at 5.

[60] See *Declaration*, *supra* note 8.

[61] Somerville, *supra* note 59 at 203.

[62] *Ibid.* at 5.

[63] *Ibid.* at 7.

[64] *Ibid.* at 8-9.

[65] Modernism is closely related to communitarian ethics, while post-modernism is closely linked with intense individualism. *Ibid.*

[66] George Khushf & Rosemarie Tong, "Editors' Introduction: Setting Organizational Ethics Within a Broader Social and Legal Context" (2002) 14 Healthcare Ethics Committee Forum 77 at 78.

[67] See Romeo Casabona, *supra* note 2 at 48.

[68] Macdonald, *supra* note 26. See also Klintzman, *supra* note 36.

[69] B. M. Knoppers, M. Hirtle & K. C. Glass, "Commercialization of Genetic Research and Public Policy" (1999) 286 Science 2277.

[70] We see the language of human rights in the important recent contribution by UNESCO. See *Declaration*, *supra* note 8.

[71] A slightly different formulation of the constitutional approach is examined in the context of Switzerland, below.

[72] Macdonald, *supra* note 26.

[73] This concern is typical of postmodern arguments, which seek to look beyond merely state-driven solutions. Many *loci* of governance, they argue, are ignored by overly relying on the state to orchestrate a solitary solution. See Macdonald, *ibid.*

[74] Trudo Lemmens, "Selective Justice, Genetic Discrimination, and Insurance: Should we Single Out Genes in Our Laws?" (2000) 45 *McGill L.J.* 347. The author argues that anti-discrimination legislation is not the best approach to resolve genetic discrimination.

[75] *Declaration*, *supra* note 8 at art. 23(a).

[76] These organizations could be governmental administrative agencies or professional bodies.

[77] Michael Carey, "The Limits of Doctor-Patient Confidentiality in Canada" (1998) 19 *Health L. Can.* 52 at 52.

[78] *Ibid.*

[79] Smith, *supra* note 5 at 120.

[80] *Ibid.*

[81] See Lee M. Silver, *Remaking Eden: Cloning and Beyond in a Brave New World* (New York: Avon Books, 1997). Silver is a famous advocate of marketplace ethics.

[82] Smith, *supra* note 5 at 121.

[83] We have already seen that there are significant problems regarding the role of corporations and the state in implementing genetic technology in a non-transparent fashion, above.

[84] See Romeo Casabona, *supra* note 2 at 49.

[85] For the risks associated with passing legislation that appears to be excessively top-down, see the recent furor over Bill C-68, the federal gun registry, in Canada. See *Reference re Firearms Act* [2001] 1 S.C.R. 783.

[86] See Somerville, *supra* note 59 at 238 regarding the marked change in informed consent laws.

[87] The Canadian Institutes of Health Research (CIHR) is currently examining "initiatives that address issues related to collection, use and disclosure of personal information for health research purposes". Although this article reaches beyond examining privacy as related to health research, CIHR's program demonstrates that the debate regarding privacy of genetic information is being reengaged in Canada. See Canadian Institutes of Health Research, "Compelling Values: Privacy, Access to Data and Health Research", online: Canadian Institutes of Health Research http://www.cihr-irsc.gc.ca/e/16344.html.

[88] See Michael Kirby, "Human Genome and Human Rights" *Fundacion B.B.V.* (30 June 1998), online: Justice Kirby's Papers http://www.lawfoundation.net.au/resources/kirby/papers/19980630_genombol.html.

[89] Romeo Casabona, *supra* note 2 at 56-57.

[90] See *Declaration*, *supra* note 8 at arts. 8-9.

[91] Caulfield, "Underwhelmed", *supra* note 7 at 459. See also section 2, above. There is a danger that people will explore genetic testing without considering the potential ramifications of the consequential information.

[92] This is to help ensure that people have rational expectations. See *Declaration*, *supra* note 8 at art. 11 regarding genetic counselling.

[93] Smith, *supra* note 5 at 121. See *Reibl v. Hughes* [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1, a leading Canadian common-law case regarding informed consent. See also George Annas, Leonard H. Glantz & Barbara F. Katz, *Informed Consent to Human Experimentation: The Subject's Dilemma* (Cambridge, Mass.: Ballinger, 1977).

[94] See *Declaration*, *supra* note 8 at art. 10.

[95] See Caulfield, "Underwhelmed", *supra* note 7 at 457; Lori B. Andrews, "Compromised Consent: Deficiencies in the Consent Process for Genetic Testing" (1997) 52 *J. Am. Med. Women's Assoc.* 39.

[96] Margaret M. McGovern *et al.*, "Quality Assurance in Molecular Genetic Testing Laboratories" (1999) 281 *J. Am. Med. Assoc.* 835 at 835.

[97] Timothy Stoltzfus Jost, *Readings in Comparative Health Law and Bioethics* (Durham, N.C.: Caroline Academic Press, 2001) at 109 [Jost]. See also World Health Organization — Regional Office for Europe, *A Declaration on the Promotion of Patients' Rights in Europe: Principles of the Rights of Patients in Europe: A Common Framework* (Copenhagen: WHO Regional Office for Europe, 1994), online: http://whqlibdoc.who.int/euro/1994-97/EUR_ICP_HLE_121.pdf.

[98] Jost, *ibid.* at 189–91.

[99] The modern concept of privacy originates to a large extent from secrecy.

[100] Florencio, *supra* note 28. The author concludes that legislation is the most appropriate method for defining the extent of parental rights in these circumstances, rather than leaving it to individual circumstances.

[101] In several countries, a patient can require the erasure or destruction of data that are incomplete, incorrect, or irrelevant or whose collection, recording, communication, or storage is prohibited. Statutes in the Netherlands and Sweden restrict this right, but patients in Sweden can appeal to an administrative court if their requests are refused. An example of strict regulation of the recording of data is found in a Belgian draft bill that requires the written consent of the patient for the automatic processing of medical data, to third parties without the patient's written consent. The need for legislation on privacy has been widely recognized in Europe. This recognition relates mainly to the privacy of data, but the privacy concept also applies to the administration of medical procedures and the stay in the hospital or other establishment. In one Scandanavian country, the protection of hospitalized patients is regarded as covered by the penal code provisions. See Jost, *supra* note 97 at 189–91.

[102] *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Council of Europe, Oviedo 4.IV.1997, ETS n. 164, online: http://conventions.coe.int/treaty/en/treaties/html/164.htm [*Convention*].

[103] See Council of Europe, "Chart of Signatures and Ratifications", online: Legal Affairs — Treaty Office http://conventions.coe.int. The largest Member States of the Council of Europe have thus far not ratified the convention. Seventeen Member States have nonetheless ratified the convention, including: Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Greece, Hungary, Lithuania, Moldova, Portugal, Romania, San Marino, Slovakia, Slovenia, and Spain.

[104] See *ibid.* Zero non-European countries have ratified the convention, including Canada.

[105] See Romeo Casabona, *supra* note 2 at 51-52 for a list of some advantages.

[106] The *Declaration* is very clear that it is firmly based in a commitment to human rights. See, for example, *Declaration*, *supra* note 8 at art. 27

> Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity

or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.

[107] *Report by the Director-General on the UNESCO Study Concerning the Elaboration of an International Instrument on Genetic Data*, UNESCO, 156th Sess., 2002, 165 EX/11 at 2.

[108] The UN General Assembly endorsed the *Declaration* on 9 December 1998, imbuing it with significant legitimacy. UN GA, *Universal Declaration on the Human Genome and Human Rights*, GA Res. 53/152, 1998, UN Doc. A/RES/53/153 [*Universal Declaration on the Human Genome*].

[109] See *Declaration*, *supra* note 8.

[110] See *Universal Declaration on the Human Genome*, *supra* note 108 at arts. 1–3.

[111] It should be noted that human dignity might be a difficult concept to define and realize through legal instruments.

[112] See *Universal Declaration on the Human Genome*, *supra* note 108 at art. 5. See also *Declaration*, *supra* note 8 at art. 6d.

[113] See *Universal Declaration on the Human Genome*, *ibid.* at art. 9.

> In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

[114] *Ibid.* at arts. 17–19.

[115] See *Draft Declaration*, *supra* note 8.

[116] See *Declaration*, *supra* note 8.

[117] *Ibid.* at preamble.

[118] *Ibid.*

[119] *Ibid.* at art. 24.

[120] *Ibid.* at art. 6a.

[121] *Ibid.*

[122] *Ibid.* at art. 6b.

[123] *Ibid.* at art. 6d.

> It is ethically imperative that clear, balanced adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data ... are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned.

[124] *Ibid.* at art. 7a. Many scholars advocate increased protections to ensure that employers and insurers do not use genetic information to discriminate against employees and clients. See Patrick S. Florencio & Erik D. Ramanathan, "Secret Code: The Need for Enhanced Privacy Protections in the United States and Canada to Prevent Employment Discrimination Based on Genetic and Health Information" (2001) 39 *Osgoode Hall L.J.* 77 [Florencio & Ramanathan]. But see Knoppers, *supra* note 17.

[125] See *Declaration*, *supra* note 8 at arts. 8-12.

[126] *Ibid.* at arts. 13–15.

[127] *Ibid.* at arts. 16–19.

[128] Ibid. at arts. 20–22.

[129] Nuffield Council on Bioethics, "Frequently Asked Questions," online at: http://www.nuffieldbioethics.org/aboutus/faq.asp.

[130] Nuffield Council on Bioethics, online at: http://www.nuffieldbioethics.org/home.

[131] Romeo Casabona, *supra* note 2 at 40. Article 119, Medical Assistance to Procreation and Gene Technology in the Human Field; Constitution, Switzerland.

[132] Jost, *supra* note 97 at 191-92. See also Department of Energy, "Genetics Privacy and Legislation" online: Genetics Legislation http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml for a thorough list of legislative history of American genetics legislation.

[133] U.S., S. Res. 1053, *Genetic Information Nondiscrimination Act of 2003*, 2003 (engrossed as Agreed to or Passed by Senate). The bill is divided into two sections: one centering on genetic non-discrimination in health care, and the other prohibiting employment discrimination on the basis of genetic information. [*Nondiscrimination Act*].

[134] See Tourette Syndrome Association, Inc., online: http://www.tsa-usa.org.

[135] *Nondiscrimination Act*, *supra* note 133.

[136] Beckwith & Alper, *supra* note 11 at 205

> With the exception of the relatively rare single-gene diseases, it is difficult if not impossible to distinguish genetic from nongenetic diseases and tests. In addition, it may be unfair to protect individuals from the use of genetic information but not from the use of nongenetic medical information. To overcome these weaknesses in genetic and antidiscrimination laws but still retain their strengths, we recommend that the laws be redrafted to prohibit discrimination on the basis of *any* type of predictive medical information.

[137] The Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa: Queen's Printer, 1992).

[138] *Ibid.*

[139] *Ibid.* The publication used the analogy that regulating privacy should be more like maintaining a garden than managing a production site.

[140] *Ibid.*

[141] *Ibid.*

[142] Gilbert Sharpe, "Regulating Health Information: The Ontario Approach" (2000) 20 Health L. Can. 69 at 69 [Sharpe] details the interaction between interest groups and the eventual response of the provincial government.

[143] *Ibid.*

[144] *Ibid.* at 70. The obligation placed on hospitals to ensure confidentiality was not absolute as certain persons could have access to the records under specified circumstances. See also *Public Hospitals Act*, R.S.O. 1990, c. P-40.

[145] See, for example, *Independent Health Facilities Act*, S.O. 1989, c. 59; *Health Cards and Numbers Control Act*, S.O. 1991, c. 1; *Health Professions Act*, S.O. 1991, c. 18; *Long Term Care Act*, S.O. 1994, c. 26; *Health Care Consent Act*, S.O. 1996, c. 2, Sch. A.

[146] Sharpe, *supra* note 142 at 71.

[147] Ontario, Ministry of Health, *A Legal Framework for Health Information: Consultation Paper* (Toronto: Queen's Printer for Ontario, 1996).

[148] PIPEDA, *supra* note 25.

[149] Caulfield, "Underwhelmed", *supra* note 7 at 457.

[150] Anita D. Fineberg, "Personal Health Information: The 'Scope' Issues" (2003) 23 *Health L. Can.* 53 at 53.

[151] *Ibid.*

[152] Florencio & Ramanathan, *supra* note 124 at 77.

[153] *Ibid.* at 79.

[154] PIPEDA, *supra* note 25.

[155] Sharpe, *supra* note 142 at 73.

[156] PIPEDA, *supra* note 25.

[157] Canadian Biotechnology Advisory Committee, "About Us," online: CBAC http://www.cbac-cccb.ca.

[158] Caulfield, "Introduction", *supra* note 12 at 344.

[159] Both the Charter and the *Criminal Code* would likely remain central to regulating privacy of genetic information in Canada. See Charter, *supra* note 22; *Criminal Code*, *supra* note 23.

[160] M. Malinowski & R.J.R. Blatt, "Commercialization of Genetic Testing Services: The FDA, Market Forces and Biological Tarot Cards" (1997) 71 Tul. L. Rev. 1211 at 1218-19; Caulfield, "Underwhelmed", *supra* note 7 at 459.

[161] Caulfield, "Introduction", *supra* note 12 at 345.

[162] *Ibid.*

[163] Knoppers, *supra* note 17 at 559.

[164] Postmodern theory suggests that formal legal regulations will not by themselves be sufficient to resolve privacy of genetic information.