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Genetic Testing for Late Onset Diseases: In-depth Thematic Analysis of Policy and Jurisdictional Issues

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Health Canada
Policy Research Communications Unit
Tel.: (613) 954-8559
Fax: (613) 954-0813
rmddinfo@hc-sc.gc.ca

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Genetic Testing for Late Onset Diseases: In-depth Thematic Analysis of Policy and Jurisdictional Issues

Christine E. Jamieson
Concordia University

Author Biography

Dr. Christine Jamieson, BTh, MA, LTh, PhD (Ethics), is an assistant professor in the Department of Theological Studies at Concordia University in Montréal. She teaches courses relating to social and applied ethics, the work of philosopher and theologian, Bernard Lonergan, and the relationship between religion and culture. Her expertise is in the area of social ethics, with a particular emphasis on analyzing underlying structures that influence value and value judgement in culture and society. She has significant strengths in the areas of genetic technology and its impact on society, issues concerning violence against women, and the psychosocial dynamics of conflict. Dr. Jamieson is currently engaged in research to develop a framework of analysis that could serve as a basis for ethical deliberation in a pluralist context.

Résumé

Ce rapport fait partie d'une série commandée par la Division des politiques de la Direction des politiques de la santé et des communications de Santé Canada, dans le but de donner un aperçu de l'information de base sur les tests génétiques servant à détecter les maladies à déclenchement tardif (MDT). Il puise dans la documentation nord-américaine et européenne actuelle concernant les tests génétiques, ainsi que dans la documentation portant sur les cadres réglementaires du système canadien de soins de santé.

Le rapport, qui traite des questions relatives aux politiques et aux domaines de compétence, se divise en trois parties. La première partie porte sur la relation entre les politiques publiques et les technologies génétiques. Elle compte trois sections. La première section se penche sur la nature ambiguë de l'évaluation des technologies complexes comme les tests génétiques. La deuxième explore un modèle équilibré pour l'élaboration des politiques et des règlements concernant la génétique. La troisième présente quatre approches utilisées dans le passé pour prendre des décisions politiques et réglementaires. Dans ce rapport, on soutient que ces approches seules ne suffisent plus à l'élaboration de politiques et de règlements. Aujourd'hui, la prise de telles décisions doit s'appuyer sur un solide débat public qui fait intervenir au moins toutes les parties intéressées.

La deuxième partie du document expose quatre questions clés entourant l'élaboration de politiques en matière de tests génétiques. Bien que de nombreuses autres questions auraient pu être abordées, ces quatre questions sont assez larges pour englober les principales préoccupations auxquelles le gouvernement doit s'attaquer au nom des citoyens. La première question concerne le problème de la discrimination génétique, qui regroupe le respect de la vie privée, la confidentialité et la protection des populations vulnérables. La deuxième question porte sur le droit des brevets en ce qui concerne le matériel génétique. La troisième question est quelque peu liée aux brevets : elle concerne la commercialisation prématurée des tests génétiques et le problème qu'elle pose au chapitre de l'allocation des ressources. Enfin, la quatrième question est celle de la liberté scientifique; elle englobe les droits et l'autonomie de la personne.

La dernière partie du document analyse brièvement les questions relatives aux domaines de compétence en matière de tests génétiques de détection des MDT.

Abstract

This paper is part of a series of articles commissioned by the Policy Division of Health Canada's Health Policy and Communications Branch to provide background information on genetic testing for late onset diseases.[1] It draws on current North American and European literature pertaining to genetic testing as well as literature pertaining to regulatory frameworks within the Canadian health care system.

This paper on policy and jurisdictional issues is divided into three parts. Part one looks at the relation between public policy and genetic technology in three sections. The first section considers the ambiguous nature of evaluating complex technologies such as genetic testing. The second section looks at one attempt at a balanced approach to developing policies and regulations related to genetics. The third section presents four approaches that have been used in the past to make these policy and regulatory decisions. It is argued in this paper that these approaches alone are not adequate for the present-day task of policy and regulation development. Current decision making requires a robust public discourse that involves at least all interested parties.

Part two of the paper outlines four key ethical issues in policy development relating to the area of genetic testing.[2] While there are many issues that could be explored, the four chosen are broad enough to cover the major public concerns with which governments, on behalf of citizens, are wrestling. The first is the problem of genetic discrimination, which encompasses issues of privacy and confidentiality; also included here are concerns about the protection of vulnerable populations. Second, there is the issue of patent law in relation to genetic material. Third, and somewhat connected to the issue of patenting, is the premature marketing of genetic tests and the related problem of allocation of resources. Fourth, there is the issue of scientific freedom; also included here are issues of individual rights and autonomy.

The final part of the paper briefly analyzes jurisdictional issues related to genetic testing for late onset diseases.

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The Relation between Public Policy and Genetic Technology

This part of the paper comprises three sections. The first highlights the ambiguous and complex task of evaluating technologies such as genetic testing. What is the best way for governments, on behalf of citizens, to take advantage of the benefits of genetic testing? If genetic testing is to benefit human beings and not harm them, it is necessary to grasp the difference between a technology (such as genetic testing) that allows human kind to flourish and one that causes societal decline. The paper briefly explores some of the implications of this distinction. The second section discusses the need for what Timothy Caulfield calls "a balanced and informed approach to the development of genetic policies and regulations."[3] Given the tremendous hype associated with the genetic revolution, Caulfield cautions against reacting too quickly to either alarmist or utopian predictions. We need to explore the symbolic impact of the various genomic metaphors different players use. This will allow for more balanced judgments of the scientific, economic and cultural forces behind both the push for and the fear of genetic testing. The third section outlines four approaches to policy development that are emerging in response to biotechnology developments, which are drawn from a recent paper by Bartha Maria Knoppers.[4] The four approaches are as follows:

1. a constitutional, human rights approach that draws on already existing human rights protocols to make judgments concerning applications of new technologies;

2. a statutory-specific approach that is more direct and immediate in dealing with issues as they emerge by creating laws to prohibit, constrain or issue moratoriums;

3. an administrative and regulatory approach relying on governmental or professional bodies to monitor technologies and ensure quality assurance standards exist and are followed; and

4. a liberal, market-driven approach that puts its faith in proper, professional practices and litigation to restrain or limit new technologies.

Knoppers sees both strengths and weaknesses in each approach and asserts that the "choice between these approaches, or a combination thereof, depends not only on the degree of public trust in the credibility and effectiveness of such research, but on the state of the debate."[5] This paper gives an overview of Knoppers' discussion concerning the strengths and weakness of the four approaches and the reasons she recommends adopting a more consultative approach to policy development in relation to biotechnology developments.

The Ambiguous and Complex Nature of Technology Assessment

More often than not, public policy concerns arise when problems emerge and decisions need to be made about the best way to deal with them. Problems involving technological developments usually come to light after the technology has been developed, at least in its beginning stages.[6] Advances in technological development create the need for responsible decision making. This is primarily because there is a "gap between the ability to foretell and the power to act."[7] The power to *act* is constitutive of being human, and human action involves innovation. At their core, technological innovations are the fruit of the human need to act in the world. Technologies are always bound up with social, political and cultural dimensions of human living. The objective of technologies involves securing or transforming a standard of living within a social, economic, political and cultural context; technologies are solutions to concrete problems.[8] The gap between acting and the ability to foretell the consequences of our actions raises the many dilemmas that concern governments acting on behalf of the people. It is important to note that it is not necessarily a technology itself that raises difficulties. Rather, it is *how* a technology disrupts or transforms aspects of society, economy, polity and culture. This is often what policy decisions are concerned with – the disruptive power of technology. Although originally a solution to a problem (whether that problem had to do with maintaining or enhancing a standard of living[9]) – technology is now creating new problems (for example, the power to predict future illness) or putting new twists on old problems (for example, a new form of discrimination against asymptomatic persons or the "not-yet-ill"[10]). Thus, one might ask, does this technology promote progress – that is, does it help humanity flourish – or does it bring about a decline that leaves humanity more disrupted or debilitated?

Few technological developments have elicited as much public interest, excitement and concern as the rapid advances in human genetics. The technology of genetic testing, which is the concern of this paper, is raising tremendous hope in terms of innovative medical intervention for disease. Yet, in addition to standard health technology assessment issues, it is raising complex problems related to privacy, confidentiality and information control, autonomy and responsibility, discriminatory practices and the danger of eugenics, allocation of health-care resources, patenting of genetic material, and the commercial marketing of genetic tests. Underlying all these concerns, and what is perhaps the problem that needs to be addressed most urgently, is public mistrust of the power of science and the multinational companies investing millions in research.[11]

Genetic testing *appears* to benefit humanity by identifying at-risk individuals and populations and through its likely role in the eventual discovery of treatment for disease. However, at this time, the *potential* benefits far outweigh the *actual* benefits.[12] Therefore, there are two levels of concern that need to be addressed when formulating policy decisions: the long-term consequences of genetic testing and the immediate or short-term consequences. Both are significant and need to be taken into consideration. For example, the short-term benefits of genetic testing for most late-onset diseases appear minimal. There are several reasons for this. First, in most cases, there is little or no treatment available for people who test positive. Second,

there is a great deal of concern that merely undergoing genetic testing (regardless of the results) will somehow interfere with insurance and/or employment possibilities. Also, there are immediate concerns about the effect of genetic testing on family relationships and self-image.[13] Finally, various commissions and task forces are strongly recommending the necessity of counselling for people considering any form of genetic testing – prenatal, carrier or individual.[14] Yet, this need is undermined by limited resources (at least for now[15]), access to genetic tests over the Internet,[16] and the accessibility of commercial testing when counselling services appear insufficient.[17] Long-term benefits seem brighter. As the accuracy of genetic testing improves and treatment strategies grow, benefits might accrue that could exceed the risks or harms.

The term *technology assessment* – looking at "all the possible and probable effects on society of introducing or expanding particular technologies"[18] – is in some sense a misnomer. What is being assessed is not the technology itself but the impact – both positive and negative – of a particular technology on society. The roots of the ambiguity of technology lie not in the technology itself but in the multilayered impact of the technology. The subtle and nuanced evaluations that a new technology demands stem from this multilayered impact, and it is precisely the *impact* that needs to be understood in order to make decisions about the technology. What is significant about particular technologies – and what most probably accounts for the perception of the "power" of technologies – is that they "penetrate into the full range of meanings, values, customs, beliefs, and expectations of a culture, shaping the hopes, the aspirations and the sense of identity of their participants."[19] The power of technology itself comes from its subtle, yet at times overwhelming, transformative effect upon almost all elements of society.

Evaluating the short-term consequences of a technology calls for the familiar strategy of gathering available current data and assessing the actual impact of genetic testing on individuals and populations; whether it enhances the quality of people's lives or not. Thus, assessing short-term consequences involves exploring both the immediate benefits and the immediate harms. Evaluating the long-term consequences cannot rely on empirical data alone. Assessing long-term consequences must also rely on the imagination because it involves anticipating future possibilities that cannot now be known.

In his introduction to the May 2000 issue of the *McGill Law Journal*, Timothy Caulfield speaks of a shift to a "second generation" of legal analysis.[20] The papers in this special issue[21] of the journal represent this shift. While the first generation, because of the international focus on the Human Genome Project, identified "legal issues and [called] for a general governmental response,"[22] the second generation analysis is more sophisticated. No longer merely *responding*, this deeper level of analysis is "critiquing existing regulations and reconsidering the characterization of the identified social concerns."[23] More than merely a shift in approaches, second-generation analysis signals a shift in levels, from description to explanation. The shift is important and necessary because of the tremendous ambiguity of positive and negative aspects of human genetics. Analysis of the issues cannot remain at the level of "how this affects me" or "my community" or "my horizon of concern." It needs to encompass an analysis of the legal and policy issues "in their own right." Analysis must now attempt to understand the relations between the issues themselves. For example, technological change often creates value conflicts.

One significant value conflict in genetic testing is between the value of democracy and the value of liberty or autonomy. The uniqueness of this value conflict in genetic testing can be seen in the tension between an individual's rights and the rights of that individual's family, or the rights of the community. The conflicts themselves are not unique to genetic testing. What is unique is the set of relations that genetic testing sets in motion. It is precisely these sets of relations that need to be analyzed and understood for policy decisions to be made. This calls for a deeper level of analysis, beyond a first level of description to a second level of explanation. This is important in order to move toward the balanced and informed approach of genetic policies and regulations that is needed. The analysis also emphasizes the importance of collaboration in decision making.

The Need for a Balanced and Informed Approach

The Honorable Stephen Breyer, Justice of the U.S. Supreme Court, has noted the difficulty that science-related decisions present to the courts and legislature. The question that launched Justice Breyer's remarks was the following: "How best can legal institutions – which must give answers – interact with science – which so often poses difficult questions?"[24] Justice Breyer emphasized that difficult science-related choices can only be made when the courts and legislative bodies comprehensively understand the social and economic impacts of the choices. Decisions need to be "grounded in realistic predictions of what science will do, and not [in] fanciful prediction of what science might do."[25]

Genetic research is affecting many fields of law; family law and patent law are two notable examples. In addition, issues concerning genetic testing are relevant to various forms of law – civil, provincial and federal. As well, there are various ways to control technology using public policy. The most common controls are the allocation of funds and regulation or prohibition. Control can also occur through legislative enactments and judicial decisions. It is also possible to permit a technology such as genetic testing while still retaining some control through other measures. Yet, to properly direct control mechanisms, there need to be what Breyer calls "predictions of consequences" from those most involved and affected by the technology.

What is important here, for Justice Breyer, is not that the various "stories" of those involved bring about an agreement about what should be done. Rather, it is that these stories *raise the questions* that need to be asked and, thus, direct the courts and legislative bodies in that manner. As Breyer argues "often our court rides the coat-tails of an existing public debate. The result of the earlier discussion and debate was not agreement about the proper result; but it was agreement about the nature of the question and upon many of the relevant parameters."[26] Public debate informs and prepares the courts for responsible decision making.

Justice Breyer suggests that two sets of issues – the ability of genetic testing to forecast an individual's future chances of developing a serious or terminal disease and the inability of existing patent laws to handle the complexity of issues and rapid developments in genetic research – "may not yet have been subject to the kind of public discussion and debate that help to assure the soundness of a public policy decision." Besides the fact that many of the questions concerning genetic testing require interdisciplinary expertise, what makes them so difficult to answer is that, in most cases, the consequences are not yet known. As well, what molecular biologists are discovering and understanding about genetic testing is continually changing. Thus, Justice Breyer states that "not surprisingly, policy change so far seems to have occurred primarily in those areas of law where change is more easily revised or reversed – for example, government funding, professional responsibility, or ethics."[27]

Rather than the more traditional mode of interaction among scientists, courts, legislatures and other interested parties – the focus being on what can or cannot be permitted and so the various positions provide information in the hope of swaying the decision – Justice Breyer

proposes an alternative. He suggests an open forum in which "scientists, other experts, lawyers, legislators, perhaps judges too, engage in an on-going extended policy-oriented conversation – outside legislative or judicial forums." The forum is not for negotiating differences. Rather, the forum is "for the discovery of common approaches to the facts, identification of the relevant unknowns, and the creation of areas of agreement and disagreement."[28] The "conversation metaphor" that Justice Breyer is recommending must include more than scientists and legislators; it must include all affected groups. In this way, it will allow for both mature interactions – that is, true discourse – and innovative approaches to policy legislation – the "imaginative" approach to policy making discussed above.

In promoting the kind of discourse that Justice Breyer recommends, it is important to reflect on the power of language, especially metaphoric language. Language is not only descriptive, it is also performative – that is, language plays a role in bringing about what is intended. Language is the tool we use to structure and construct our world. Indeed, it is the tool we use to make sense of reality. Metaphoric language is a powerful tool in this respect. As all poets understand very well, many experiences can only be spoken about indirectly through metaphors. Yet, metaphoric language is not restricted to poetry. It is a tool used in all forms of communication, including scientific language. A rather long quote makes the point well:

> A belief long standing among geneticists (and one that has acquired greater currency in recent years for the public at large) is that genes are the primary agents of life: they are the fundamental units of biological analysis; they cause the development of biological traits; and the ultimate goal of biological science is the understanding of how they act. Such confidence in the power and agency of genes – codified in what I call "the discourse of gene action" – has been of immense importance to the history of genetics and, most recently, to the launching of the Human Genome Project. But what does attributing (or for that matter, denying) causal power to genes mean? To what extent does this way of talking reflect a set of "natural facts," and to what extent does it reflect the facts of a particular disciplinary culture? And is it just a way of talking? Is it not also a way of thinking, a way of seeing, and a way of doing science?[29]

The field of genetics draws heavily on metaphoric language. This is clear when one considers some of the very familiar language that has emerged from the Human Genome Project. For example, the common phrases "the code of codes" and "cracking the genetic code" suggest that the human person, made up of billions of genes, is a code that needs to be deciphered. Clearly, this is one way of talking about reality. Yet, it is a way of talking about reality that promotes the importance of science, especially human genetics. Some see the Human Genome Project as unlocking the "secret of life." Again, this shapes the value we place on this science. Unlocking the secret of life and knowing the future (two of the promises that accompany genetics) tap into one of humanity's deepest desires, and so genetics becomes the undisputed king of the biological sciences.

The purpose of highlighting the metaphorical character of scientific language is not to try to detract from the important contribution that a science such as molecular biology is making. Rather it is to emphasize Justice Breyer's recommendation concerning the importance of open fora for interdisciplinary dialogue. Interdisciplinary dialogue invites a variety of world views or horizons of concern into the arena. Thus, the metaphorical language of genetics or law or philosophy or theology is heard against the backdrop of other readings of reality. This will contribute significantly to the task of policy makers to develop well informed and thoughtful regulatory policy.

Four Evolving Approaches to Policy Development

Genetic testing poses concerns and questions that are difficult to circumscribe because of the evolving and dynamic nature of human genetics. If, in this context, Justice Breyer highlights the need for ongoing collaboration in an open forum, Bartha Maria Knoppers emphasizes the need for "a public policy framework which is as epigenetic as the subject matter and the social trends the policy would seek to address."[30] Knoppers outlines four approaches to policy development that are emerging in response to developments in biotechnology: a constitutional, human rights approach, a statutory-specific approach, an administrative and regulatory approach, and a liberal, market-driven approach. Each is outlined briefly below.[31]

Human Rights Approach

The human rights approach relies on court decisions that are based on already existing human rights codes, declarations or conventions at both the national and international levels. New applications of technology are restricted or limited when they pose some threat to human rights. For example, discrimination and confidentiality are issues that touch on the fundamental human rights of individuals. Right now, most governments prohibit or restrict access to genetic testing information by insurance companies and employers based on these rights.

This approach to policy development has several strengths. First, it gains support from public interest groups who participate in human rights cases. This helps the courts to read the "signs of the times" and identify public values related to the specific issue. Court decisions are then likely to reflect the values that these specific public interests represent – values that often reflect the broader social order. Second, when the courts are bold, the approach helps to set far-reaching precedents in the interpretation of human rights issues, such as privacy and discrimination. Also, it serves to help clarify the complexity of issues being debated.

The main weakness of this approach is that it tends to be reactionary rather than innovative – that is, the issue can only be challenged after it has already happened. In the case of a new technology, it can only be challenged after it has entered into research and health care programs and some right has been violated. Also, it is *ad hoc*, and so can be very limited in its effectiveness. Finally, when the courts are not bold and they refuse to go beyond the facts of the particular case, the effectiveness of the court decision is minimal despite much time and expense.

Statutory-specific Approach

The statutory-specific approach addresses scientific advances by implementing prohibitions, constraints or moratoria. This approach is not so much reactionary as resolute. It "takes the bull by the horns" and gets results faster. An example of this approach is former U.S. President Clinton's moratorium on research on human cloning. This approach relies on the government to take active steps to come up with specific statutes in response to new technologies. The advantage of this approach is that it is immediate, it brings with it certainty, clarification and precision, and it generally represents a political consensus. The U.S. moratorium is effective by blocking federally funded research.

There are, however, a few real disadvantages to this approach.[32] Of significance is the limited scope of the narrowly focussed statutes. On the one hand, legislation that includes prohibitions or moratoria can create a false sense that the issue has been dealt with, when in fact only a very specific aspect of the issue has been addressed. Therefore, other potentially more socially and ethically problematic aspects of the issue are left unaddressed. On the other hand, if governments react too quickly, highly beneficial research may be stifled.[33] The important point here is that the complex and ambiguous nature of genetic research and genetic testing warrants the need for less hasty procedures. As Knoppers indicates, "if such statutes are adopted in rapid succession, there is a risk of enacting contradictory positions and definitions." Clearly, it is difficult, in such a process, to cover every angle. In the desire to close off debate, especially when dealing with a "moving target" such as genetic research, decisions will lack a "proper foundation based on scientific risk assessment."[34]

Administrative and Regulatory Approach

The administrative and regulatory approach relies on the mechanisms of quality assurance, standardization and monitoring through governmental or professional bodies. Thus, professional codes of ethics and quality assurance (for example, in laboratories that offer genetic testing) are forms of this approach. The key advantage of this approach is that it operates at a grassroots level. The focus here is on the professionals themselves and the procedures. Consequently, this approach meets with little resistance from those it affects because regulatory decisions emerge gradually from within the ranks. Thus, it ensures greater effectiveness and integration of recommendations into practice. The problem with this approach is that it emphasizes practice to the detriment of theory. The emphasis here is on *administering* technologies, yet the deeper level analysis of value choices and value conflicts tends not to be addressed. Also, when codes or standards are drafted by the professionals involved, they can be self-serving as ways to avoid lawsuits, to limit restrictive legislation and to "appear" responsible.

Market-driven Approach

Finally, the market-driven approach advocates a *laissez-faire* strategy – that is, the less governmental control the better. James Watson resigned as director of the Human Genome Project in part because he felt that decisions concerning patenting of genes (or, as some argue, of genetic *information*) should be left to scientists and not to politicians and bureaucrats.[35] The justification for this approach is that, in the end, proper professional practices involving new technologies will prevail if not because they are morally convincing then at least because they

afford some protection against litigation. The advantage of this approach is that it offers the least resistance to innovative scientific research. Thus, this approach attracts public and private investment of technological development. The key difficulty is that it is heavily influenced by those who stand the most to gain, either financially or ideologically. Often, "special interest" groups heavily involved in either promoting a new technology or restricting it are not open to public debate or any form of government-initiated oversight.

Each approach has strengths and weakness. The choice of approach depends "on the degree of public trust in their credibility and effectiveness and on the state of the particular debate."[36] The problem, according to Knoppers, is that in Canada "there is no debate, at least no public debate." She indicates that there is a "current lack of visibility and transparency on the contentious fundamental issues." She calls for "a structured and rational process" to addressing these issues, not through providing more information but through "procedural mechanisms (such as regional fora, media debates, websites, and public referenda) that are both participatory and consultative."[37] What both Justice Breyer and Bartha Knoppers are indicating needs to be stressed. The rapid advances in the science of genetics call for a response that is, if not as rapid, at least as dynamic. The four approaches to policy development that have been emerging in the last two decades in response to genetic technology are useful in particular cases. Yet, overall, the best approach may emerge in a completely new form and will be the result of the dynamic process of interdisciplinary, multilayered discourse. That, in fact, is what a democracy is all about: voices being heard, positions being stated and counter-positions being heard. In the end, legislators and policy makers will decide based on a collaborative framework.

Key Ethical Issues in Policy Development and Genetic Testing

As indicated in first part of this paper, when discussing the concrete issues that affect policy decisions, there are two levels of analysis needed: the immediate impact or consequences of genetic testing and the longer range impact. The first level relies on already established empirical evidence. The second level relies more on imagination, yet not the extreme, dire predictions of science fiction. According to Timothy Caulfield, dire or extreme "[hurts] the debate around ethical issues and the development of regulatory policy by deflecting discourse and policy-making momentum toward the extreme and away from immediate, practical concerns."[38] Yet, if we do not look beyond our immediate horizon of concern, our understanding may suffer from short-sightedness. There is a need to consider the immediate practical concerns about genetic testing and to anticipate how genetic testing might affect us in the future. Making sound and balanced judgments relies not only on immediate data, but also on the ability to anticipate future directions of genetic testing. Our decisions need to be based on both the immediate and the future impact.

Particular issues that consistently appear in policy discussions regardless of the national or international affiliation of the policy-making bodies tend, on the surface, to reflect immediate, practical concerns. However, the issues consistently point beyond the immediate to future concerns that also require attention. This, in part, accounts for the deepening of analysis that is happening, which Caulfield refers to as "second generation" analysis. The issues remain constant yet the level of analysis gets continually deeper. New questions emerge that broaden and deepen

our understanding of the impact of genetic testing on society. This part of the paper discusses some of these issues. The purpose is not to elaborate on the various components of issues concerning genetic testing since a literature review has already been done.[39] Rather, the goal is to look at the links between particular aspects of issues and the three steps outlined in the first part of this paper. The analysis pays particular attention to the following: first, how issues call for both immediate and long-range analysis and an understanding of the shifts in thinking that have taken place as the debates have matured; second, Justice Breyer's recommendation concerning the need for open forums of interdisciplinary discourse; and, third, Bartha Knoppers' four approaches to policy development and her recommendations concerning public policy discussions.

There are four main issues. The first concerns the problem of genetic discrimination, which encompasses issues of privacy and confidentiality; also included here are concerns about the protection of vulnerable populations. Second, there is the issue of patent law in relation to genetic material. Third, and connected to the issue of patenting, is the premature marketing of genetic tests and the related problem of allocation of resources. Fourth, there is the issue of scientific freedom; also included here are issues of individual rights and autonomy.

Genetic Discrimination

Many national and international organizations have written policy statements on genetic discrimination.[40] Genetic discrimination is discrimination on the basis of a person's genotype. It is "directed against an individual or family, solely because of their apparent or perceived variation from the 'normal' human genotype."[41] The recognition that genetic discrimination poses a threat to the insurability and employability of persons prompted many countries to pass legislation regulating the use of genetic information.[42] The prompt action on the part of government bodies against the threat of genetic discrimination is an example of both the human rights and the statutory-specific approaches to policy development. However, these actions are having ramifications that were not anticipated. There are two sources of criticism. The first is that while the legislation's aim is to prevent one type of discrimination, it may be inadvertently promoting or bringing about another. As one article describes it, "with the exception of the relatively rare single-gene diseases, it is difficult if not impossible to distinguish genetic from nongenetic diseases and tests." Therefore, "it may be unfair to protect individuals from the use of genetic information but not from the use of nongenetic medical information."[43] The second critique concerns discrimination in relation, indirectly, to privacy. The major medical contribution of sequencing and mapping the human genome will come from "the power of sophisticated diagnostic and prognostic tools and of informatic capabilities within medicine." This promises the following:

> 1) genetic screening of asymptomatic populations for carrier status and prevention of the onset of genetic conditions; 2) knowledge of susceptibility status for specific and individualized drug targeting; and 3) genetic testing for individual treatment, reproductive, and lifestyle choices.[44]

As has been noted already, these are *promises* not accomplishments. However, in order for these goals to be realized, research must advance – research that depends on population data collection and data banks. Yet, fear of discrimination and privacy violations set up obstacles to this kind of data collection and storage. Paradoxically, it is precisely these obstacles that may, inadvertently, lead to discrimination and privacy violations. According to Bartha Knoppers, restrictions on the availability of population data will push genetic researchers and informatics into the private sector, making public oversight impossible. Thus, promoting government-sponsored and -regulated population screening may contribute to averting or dismantling discrimination and privacy violations that would result if the information were only accessed by those in the private sector. According to Knoppers, population database systems could be created that would conform to modern privacy goals and thus, not be misused by discriminatory practices. Protection of vulnerable populations can only be ensured when data collection and information storage is regulated. Public willingness to participate in data collection will only develop when the public is assured that it is safe, confidential and will not lead to discrimination against them. Achieving this goal is not straightforward. Neither a human rights approach nor a statutory-specific approach to policy development is sufficient. Thus, new ways of dealing with discrimination are needed.

The intertwining of issues concerning discrimination, privacy and confidentiality reveals that addressing these difficult matters requires the kind of sophisticated analysis that comes only from collaborative efforts. The immediate areas of concern here are insurance and employment. However, the danger of genetic essentialism can lead to a variety of other forms of discrimination – for example, discrimination against the disabled and a heightening of racial discrimination. It can also lead to an uncritical acceptance of what is "normal" and "acceptable" about being human. Policy discussions need to anticipate and address these developments.

Patent Law in Relation to Genetic Material

The difficult questions associated with patent law concern the *nature* of what is being patented. Do products of genetic research have the status of "protectable invention" or "useful device," or are they an existing aspect of nature? Should scientists be allowed to claim property rights over natural phenomena such as molecules, genes or even whole organisms?

Susan Greenfield, a high-profile neuroscientist in England, working at Oxford University, recently sought a patent on "a brain molecule." Her justification for the application was that she was patenting a piece of information, not the molecule itself. "It's more accurate to call this the patenting of an idea rather than the patenting of part of nature."[45] According to Greenfield, the patent is necessary to prevent others from prospering from her research. Also, the need for funding to promote important medical research necessitated her decision. "The problem is that there is always a shortage of funding with any kind of research that involves risk of eventual failure. By seeking a patent and setting up a company, we are attracting long-term risk funding through commercial investment: and the commercial backers will want a dividend if it works."[46] Oxford University will also benefit. It will receive 30 percent of all profits. Patent law gives the owner exclusive use of the patented material for 20 years. It gives the owner the opportunity to recuperate costs and to make a profit without fearing direct competition.

The Greenfield case highlights the dilemmas concerning patenting in relation to genetic material. On the one hand, there are ethical and social concerns about exclusive ownership of, if not a part of *nature*, than at least *knowledge* of that part of nature – knowledge that may significantly benefit humankind. (Greenfield's work may lead to treatment for Alzheimer disease.) Excluding other researchers from working on that particular aspect of nature raises concerns because it limits the advance of research. Also, there is the issue of respect for genetic material as part of the person and of humanity.[47] On the other hand, should scientists, universities and governments not be rewarded for the efforts and funding that went toward the advance in research? The often-cited case of the British molecular biologist, Cesar Milstein, who discovered monoclonal antibodies (a "process that led to the development of universally used diagnostic testing procedures for immunological diseases") reveals something of the dilemma.

> "The Medical Research Council (MRC), under which Milstein was working, disdained to copyright the discovery. Then a patent was taken out by the Americans. Huge sums of money accrued to the patent holders, which helped fund America's burgeoning biotech industry. It has been claimed that hundreds of millions of dollars were lost to British biotech research funding as a result."[48]

One key tension here is between, on the one hand, the stake each one of us has in information on our own nature and, on the other hand, the stake that scientists and investors have in circumscribing that information. Another dilemma is whether current patent law can even apply to biological material. The patent law was certainly not originally written with this in mind. Does it need revision to address patents on biological material or do we need some new mechanism to address the issue? The legal complexity introduced through the patenting of genetic materials highlights the need for new frameworks of analysis. Can something as new as patenting genes and living organisms fit into a framework that was built for something completely different? The issue of patenting has implications in areas beyond merely patenting. It again addresses the complexity of genetic technology and the uneasy fit between this new technology and traditional frames of reference.

E. Richard Gold's article "Biomedical Patents and Ethics: A Canadian Solution" is one attempt to work through the issue of patenting in order to recommend a framework that addresses the complexity of the Canadian scene. Gold states that the practical need for provincial government approval of medications and biomedical tests and services "provides Canada with a unique (at least as compared with the United States) opportunity to incorporate ethical considerations into debates over the use of biomedical materials."[49] The provincial insurance plan could require that certain ethical standards be met before approving a specific service. In other words, the provincial governments could set the standard that a company, with a patent on a particular medication or genetic test, must meet.

> For example, the vendor may be required to demonstrate that university researchers and competitors have access to the biomedical material to develop preventative measures or alternative therapies to the illness in question. In the case of genetic tests, vendors could also be required to establish that their marketing is limited in scope, that all those who take the test will be given genetic counselling, and that issues of family access to the results of the test will be discussed with patients prior to the administration of the test.[50]

Gold's proposal is an innovative attempt to use the strength of Canada's jurisdictional layout and the medicare system to shift the state of the debate. It does not fit with any of the policy development approaches laid out. Rather it is an intermingling of them, the result being something that addresses the legal complexity of the patenting frenzy without stifling the free-market concern of the investors.

Premature Marketing of Genetic Tests and Allocation of Resources

Related to the commercialization of genetic research is the issue of the premature introduction of genetic testing as seen in the marketing of genetic tests. Genetic testing technologies are the frontrunners in the payout stemming from genetic research. They are probably the best known and the most utilized aspect of genetic research. However, the benefits of genetic testing are still uncertain. Thus, the question of allocation of resources is important. If the main benefit of genetic testing is psychosocial, should other treatments, more directly beneficial to the actual illness, take precedence? Even the psychosocial benefits remain ambiguous. One example is the use of the tests for BRCA1 and BRCA2 mutations in relation to breast and ovarian cancer. It is estimated that 5 to 10 percent of these types of cancer manifest the gene mutation. Yet, there is considerable debate about the relationship between the gene mutations and the cancers.

> [A] considerable proportion of the familial risk of breast cancer is not attributable to mutations in the BRCA1 and BRCA2 genes…. Only a small proportion of patients with early-onset breast cancer carry a mutation in one or the other gene, and only a small proportion of the familial risk of breast cancer is attributable to these genes.[51]

In a recent survey in Canada by the financial and managerial firm PricewaterhouseCoopers, the majority of respondents welcomed genetic testing for medical purposes. More than 90 percent of respondents favoured genetic testing to diagnose illnesses earlier, to determine the risk of transmitting a disease to one's children, and to determine an individual's risk of acquiring a disease some time in the future.[52] In British Columbia, the Hereditary Cancer Program has a seven-month waiting list at its Vancouver site and a five-month waiting list in Victoria. Until December 1998, the then two-year-old program had only one counsellor, who was seeing only half of the 60 people referred each month. A second counsellor was hired in December 1998. A growing number of referrals from the Fraser Valley and the B.C. interior is exacerbating the problem. Patients can opt to be tested in the United States for $3,000 or, if a doctor rates a case as urgent, a patient can be fast-tracked to the front of the line.

The importance of women with a strong family history of breast cancer knowing with greater certainty whether they are likely to develop the disease motivates them to seek genetic testing. Women who test positive must decide whether to undergo preventative bilateral mastectomies and ovariectomies to lessen their chances of developing the disease.[53] Despite this benefit, concern remains that many genetic tests, including the BRCA1 and 2 tests, are premature.[54] Given the ambiguity of the relationship between BRCA1 and 2 and cancer, and the invasive treatment that may be ineffective, two questions emerge that apply to many other forms of genetic testing. First, was genetic testing for breast cancer introduced prematurely? Second, given the ambiguity of the benefit, should health care resources be allocated to this type of testing? Again, the complexity of these issues raises concerns and questions about public understanding of the benefits of genetic testing and open discussion concerning its immediate benefits. There are two approaches to policy development that are influencing this situation. Certainly the market-driven approach is operative here. Myriad Genetics, which markets genetic tests, advocates "a broad definition of the 'at risk population' … and will test anyone so long as the request comes through a physician"[55] even though the Stanford Program in Genomics, Ethics, and Society recommends against testing for most people.[56] Also, human rights enters into the discussion here. Is genetic testing a right and, so, is withholding testing somehow a violation of that right? Indirectly, the human rights approach played a role in Fiona Webster's fight to have the Ontario Health Insurance Plan pay for a genetic test for breast cancer in Utah (because it was not available in Ontario except in a research setting and a patient could wait up to two years for the results). The case also opened access for other women to receive the test and prompted the Ontario government agency that advises on and coordinates programs in cancer detection, care and research to ask the government for $4.5 million to provide this clinical testing service.[57]

Scientific Freedom

Connected with premature entry of genetic testing into the marketplace are policy development issues related to scientific freedom. What is science's responsibility on an issue such as the premature entry of genetic testing into the marketplace? A major component of the science of genetics is its relationship to big business. The relationship between health care and business is not new. What is significant in terms of genetics is the enormous amount of money that has been invested in the development of genetic technology, with genetic testing of particular interest for investors because of its more "immediate" returns. It is not only professional enthusiasm that leads to premature implementation of genetic testing, but it is also the enthusiasm of investors.

Autonomy of research in any discipline must be guaranteed for a number of reasons.[58] Scientists, or any researcher, must be autonomous; otherwise they would not be able to make their own unique contribution and so advance the field. But autonomy does not mean a lack of criterion. Rather it calls for the accountability of other scientists and it works within the framework of professional codes of behaviour (the administrative and regulatory approach). Also, autonomy demands responsibility. Scientists are responsible for "keeping their own house

in order" and for the influence they have on those who are affected by their work. Again, regulation through professional standards, but also through the human rights approach, is required. For example,

> does society have a "right," as the "affected party," against a "producer of research" who has developed – or is threatening to develop – a new technique? What kind of right? Is it a right to "participate" in, to govern, or to control the decision to develop and implement the technology?[59]

Genetics evokes both awe and fear in the public realm and so policy decisions are made in an effort to control both extremes. Given this scenario, one might ask, is it science's responsibility to educate the rest of the population concerning its methodologies, frameworks of analysis and values?[60] Or, is it the public's responsibility to be vigilant about scientific research and new technologies? For example, some feel that the Ethical, Legal, and Social Implications Task Force of the Human Genome Project was merely a strategy to prevent criticism of the science – that genuine concern about ethical and social issues is placed a far second behind the scientific endeavour itself.[61] Yet, as discussed in the first part of this paper, science must dialogue with policy makers and others. Scientists "cannot be solely accountable for the (ab)uses of ensuing technologies."[62] Policy decisions cannot be made wisely without the interdisciplinary dialogue that informs all parties of the relevant legal, ethical, scientific and social issues. Autonomy is a prized value in the Western world. It is a right that brings with it awesome responsibility, for science no less than for all disciplines. The freedom of thought and of research that science needs does not have to conflict with or undermine the rights and freedoms of all concerned. However, this balance will only come from *public* discourse.

Jurisdictional Issues Related to Genetic Testing for Late Onset Diseases

One of the leading sources of tension that has evolved from the Human Genome Project is data sharing. The complexity of this tension is the result of economic, ethical and social implications (for example, the issues of patenting, discrimination, and familial and community relationships). The tension emerges from the differing views of those involved in both researching the human genome and utilizing the fruits of that research (for example, genetic testing). It is also the result of differing visions of the purpose of the Human Genome Project. One commentator describes the difference this way: "[T]he human genome project seeks to serve two frequently conflicting purposes – international cooperation, which is a proxy for the ideals of open science, and national competitiveness, which turns on the acquisition and protection of self-interested advantages."[63] Yet, more complex levels of tension also come into play. The complexity stems from a plurality of differing views concerning the purpose of genetic research – at one end of the spectrum is the altruistic incentive of promoting health and, at the other end, the profit-oriented incentive of multinational companies and their investors. The many national and international efforts to establish guiding principles and policy recommendations concerning genetic research and genetic testing[64] were brought into play precisely to moderate the progress of the Human Genome Project and to moderate the "conflicting purposes." The Human Genome Organization was founded precisely to have an international organization involved in the Human

Genome Project. It was christened the "U. N. for the human genome" by an American biologist.[65] One of the key concerns, and sources of tension, about the Human Genome Project was its "bigness" and its centralization.[66] This particular tension stems from conflicting views about private, small-scale initiatives versus "state-controlled," large-scale operations that the Human Genome Project represents.

This complexity of "visions" concerning the Human Genome Project is a fitting backdrop against which Canadian jurisdictional issues can be considered. In thinking about genetic testing in relation to policy development in Canada, the relationship between the federal and provincial/territorial health care jurisdictions plays an important role. (Also included here could be the relationship between regional and local jurisdictions.) What is striking about the complex interactions at these various levels in the Canadian health care system is that there are parallels at the international level. One recognizes the need, given the reality of globalization and multinational companies, for truly international dialogue. The Human Genome Project, which involves the work of many nations, demonstrates, for Canada as well as other nations, the collaborative efforts involved both in regulating the science of human genetics and in research initiatives. At the same time, one recognizes the important role of national, provincial and regional initiatives. Even with its size, the Human Genome Project cannot escape the concrete reality of the everyday lives it is affecting. In this context, two broad issues come to fore that have a bearing on jurisdictions in Canada. The first concerns health care funding and policy frameworks and the difference between centralized control of health care and regional initiatives. The second concerns regulatory frameworks and the role of federal and provincial/territorial jurisdictions in these frameworks. Both of these issues are discussed below.

Centralization, Decentralization and Regional Initiatives

The history of the Canadian health care system is one of gradual integration among diverse realities, even though the integration is more implicit than explicit. The 10 provincial and three territorial health care systems in Canada represent a multiplicity of visions, yet they share several basic features. The shared features revolve around the five principles of medicare: comprehensiveness, universality, accessibility, portability and non-profit public administration. Yet, while the legislation changing the funding of medicare was implemented on the grounds of "good faith" between the federal and provincial governments, it did not take long for this good faith to break down and the need for enforcement to occur.[67] Initially, the breakdown and the enforcement measures had to do with extra billing on the part of physicians. Now, the breakdown has to do with different visions of what Canadian health care should be. The great majority of Canadians agree that Canada has an obligation to provide citizens with basic health care. In fact, "[h]ealth care has become a metaphor for Canada itself in a way that is true of no other social program. In the public mind, the way we care for the ill is representative of the essential principles of Canadian social democracy."[68] The commitment to providing basic health care appears to be solidly part of Canadian self-identity. However, a significant part of the current disagreement concerns *how* funding of basic health needs should take place and *what* is considered necessary and unnecessary health care.[69]

In reality, the Canadian health care system involves more than the federal government and the provinces and territories. There are community-based systems for decision making evolving in most provinces.[70] This trend will most likely continue. As well, group practices that provide comprehensive 24-hour, 7-day care are being launched in many places in Ontario: Paris, Kingston, Hamilton, Ottawa, Thunder Bay and Parry Sound. These pilot projects are funded jointly by the federal and provincial governments and established under the auspices of the Ontario Medical Association, and involve around 200 doctors and serve approximately 450,000 patients.[71] In addition to these various social structures, the Canadian health care system involves members of the general public and professional providers of care. Thus, we see a system that is multilevel and multidisciplinary.

It is precisely this mixture of levels that offers the potential for both divisions and integrations within the health care system. On the one hand, there are those who feel that the health care system must decentralize. Former Ontario premier Bob Rae is representative of this group:

> [O]ver time, the central locus of health care decision-making will devolve to a new form of regional structure that can accommodate consensus and enact appropriate decisions, something that cannot take place at levels of provincial and national government where issues become too abstract. Instead, new types of regional health and social service authorities will have to have real power, as well as real money.[72]

On the other hand, the fear of what devolution will do to the health care system is well expressed in the following statement by the former federal health minister Monique Bégin:

> [T]here are a number of questionable concepts and theories circulating these days, but the one that worries me most stems from the provincial premiers' enthusiasm for the Access paper which led to the current discussions on the "Social Union." The provinces are essentially saying that they want to enforce the *Canada Health Act* amongst themselves, a stance that will most likely collapse into cozy, reciprocal compromises which do not take the common good – Canadians' health – as the foremost concern. The proposal's premise that the 10 Canadian provinces are true equal partners is pure fantasy, and the whole concept presents an array of serious problems.[73]

The strengths and weakness of each level are highlighted when one considers a health care issue such as genetic testing. The tension between these two visions (or various configurations of these visions) of health care in Canada – one decentralizing and the other centralizing – has always existed.[74] The tension itself remains even while the concerns shift. The evolution that has taken place in health care since the late 1940s when publicly funded health care started in Saskatchewan and gradually evolved into Canada's current system of universal health insurance has been described as "revolutionary."[75] This revolution has partly contributed to some of the dilemmas and tensions concerning health care.

> Much of the discussion about health care today has to do with what Dr. Maurice McGregor once called "the costs of our success." We live in an age in which medicine has become so successful in achieving its aims, and so specialized, that our society now cannot afford to do everything that it is possible to do for everyone.[76]

Regulatory Frameworks

Genetic testing is implicated by Dr. Maurice McGregor, cited above. Some predict that the future of medicine is in the science of genetics. Genetic testing, even though the development of preventative strategies is in its infancy,[77] is leading the way. According to one commentator, "biotech policy will inevitably become linked, if not intimately tied, to general health policy in Canada."[78] In this context, an important issue that figures into the federal-provincial/territorial debates concerning implementation of health care and the implications for genetic testing has to do with concerns over regulating genetic testing. The health care system in Canada has been described as

> a patchwork quilt of non-systems…. Within the limits laid down by the *Canada Health Act*, each province can spend its health care dollars as it sees fit and organize its health care delivery any way it wants. In true Canadian fashion, every province is different, and within provinces there are all sorts of variations.[79]

Amid this "patchwork quilt," the task of regulating genetic testing is important for several reasons. First, it is important because given the "uncertainty" surrounding the benefits and accuracy of genetic testing,[80] careful regulatory frameworks need to be set in place. Due to the particular difficulties of genetic testing for late onset diseases, stricter regulation and monitoring of laboratories is recommended not only in Canada but also in the United States and in Europe.[81] Also recommended are more stringent personnel and quality-control requirements, certification of laboratories and standardization, and formal training and board certification in genetics for individuals responsible for laboratories that offer genetic tests.

Second, given the difficult task of matching health care resources with health care needs, systematic regulation across Canada (and indeed, moving toward international norms) will allow a standardized system to be set in place in order to lessen wasteful repetition of a variety of protocols across the country. The example of drug approval in Canada serves as a model here. Rather than one national drug approval system, there are 10, causing replication and wasting of time and resources. As well, some drugs are approved in one province and not in others.[82] This is not to suggest that centralization and "bigness" are always better. Rather, it is to suggest that in certain circumstances, centralization creates efficiency that, in turn, frees regional bodies to focus on regional needs.

An important aspect of the regulation of genetic testing concerns product safety. Looking at how product safety is regulated in Canada provides insights into regulation issues for genetic testing. Product safety in Canada is determined by "market forces (desire to satisfy consumers), government regulation, industry standards and tort litigation."[83] Because product-specific

regulation has proven slow and unpopular in a climate of deregulation, there has been more emphasis on tort law ("a form of civil liability which allows a victim to sue a wrongdoer who caused his/her loss or injury and to recover compensation"[84]). Tort "doctrines of negligence" prevails in seven out of ten provinces. This measure puts the onus on the victim to show that the injury or loss was caused by a fault of the manufacturer – that is, the manufacturer failed to take reasonable precautions. The strength of this measure is that it does not rely on a contract between the manufacturer or distributor and the consumer. The courts will recognize that the manufacturer has a responsibility beyond a direct contractual relationship between seller and buyer.

There are three levels of product defect. There are construction defects: only *some* units of the manufacturer's product are defective. There are design defects: all the units are defective by design itself. This takes two forms. First, the product does not perform as the consumer would expect it to and, second, the manufacturer did not demonstrate clearly that the benefits of the injury-causing design outweighed the risks. Finally, there are warning defects: adequate warnings are not given by the manufacturer concerning the inherent risk of a product. The warning defect comes into play when the manufacturer fails to inform consumers of either the risk level that the product poses or the type of use that is safe.

In Canada, tort doctrines of negligence predominates rather than strict liability. Thus, the victim is only required to prove that the product is defective, and is not required to prove negligence on the part of the manufacturer. Also, Canada discourages nuisance suits through "Anglo-Canadian cost rules" – that is, the loser bears all the costs of the trial.

Another important issue to consider here is that while product liability improves safety performance, it also reduces product innovation.[85] Some studies have shown that withdrawal of products or firms from the market because of increased product liability costs has been socially detrimental.[86] Other studies indicate that other measures "outside the tort system, including government regulation and concern about reputation, are primarily responsible for safety improvements."[87]

Drawing on studies conducted in Canada, the United States and Europe, Dewees and Trebilcock conclude the following:

> The evidence tends to suggest, therefore, that it would be desirable for Canadian provinces to retain the negligence regime, preferably accompanied by a fairly robust regulatory compliance defence which would create a presumption of no negligence where a product was found to comply with regulations addressed to the risks in question at the time that it was sold to the consumer. In this way, primacy would be accorded to safety judgments reached by specialized regulating agencies that have specifically addressed the risk at issue. Such a regime would sacrifice few if any socially desirably safety incentives. At the same time, it would avoid some of the perverse incentive effects associated with the US regime while saving vast public and private transactions costs associated with the US strict liability system.[88]

Concerning the effects of regulations, there are a number of problems that a regulatory agency confronts that thwart its ability to improve product safety. First is the problem of hazard identification. How does a regulating agency determine which products represent an unreasonable risk and so warrant regulatory action? This is an especially difficult issue in the area of genetic testing. What is the meaning of hazard in connection to genetic testing? For example, how hazardous is identifying a predisposition to a late onset disease without the necessary counselling or follow-up or without the consumer adequately understanding the potential of false negatives and false positives? Do these constitute hazards?

The second problem concerns determining a product's risks and the cost of controlling those risks. In some cases, as in genetic testing, there is genuine scientific uncertainty concerning the risk. Third, adopting regulations for individual product standards is costly and time consuming. This deters the implementation of regulations even though regulation is considered highly desirable. The rapid advance of genetic research is causing an influx of genetic testing on the market. Certainly, there have been many calls for regulation not only in Canada but also internationally. Yet, the slow pace and the costliness of regulation remains a deterrent. Finally, there is the problem of enforcement. This is especially problematic for genetic testing because of both the accessibility of genetic testing over the Internet and the different provincial approval mechanisms.

In addition to government regulations, whether federal or provincial, there is the self-regulation of industries. Although also slow in development, self-regulation offers some measure of improvement over government regulations, as generally there is a "non-adversarial process" that uses "information more efficiently than the adversarial process of development of government regulations."[89] At both the national and international level, companies offering genetic testing could be persuaded to meet standards developed by regulating bodies through incentive strategies. For example, as discussed earlier, E. Richard Gold has suggested that Canada is in a unique position to enforce regulatory frameworks precisely because of its complex jurisdictional set-up. According to Gold, Canada's medicare system offers a regulatory scheme that can provide a partial solution to the slowness of regulating genetic testing itself.[90] In Canada, it is the provinces that decide which genetic tests are paid for. The services that provinces choose are covered by provincial health insurance plans. Thus, the provinces, through those plans, have a certain amount of leverage with providers of genetic testing. Regulating conditions can be set in place at a more manageable level because of payment incentives.

There is an additional measure that may be effective in ensuring only **safe** products are placed on the market. It is called the General Safety Requirement (GSR). The GSR draws on the United Kingdom's *Consumer Protection Act,* 1987. The rationale for the GSR is the following:

> As at **present**, the safety of a range of consumer goods continues to be controlled by regulations setting out in detail how specific types of goods must be constructed and what instructions and warnings must accompany them. It is not practical or desirable to make such regulations for every type of consumer product; the General Safety Requirement therefore closes a gap in the existing safety legislation.[91]

There are two disincentives for adopting this at the federal level for genetic testing. First, it is too vague and so, in Canada, "may well be open to constitutional challenge under s. 7 of the Charter of Rights and Freedoms on the grounds that potential suppliers have not been given sufficient notice of how to alter their conduct so as to avoid infringing this criminal prohibition."[92] Second, the net social gains of enacting a GSR are limited.

Another mechanism that may be more effective is the Quick Response Mechanism (QRM). "A QRM would permit the administrators of the *Hazardous Products Act,* on reasonable apprehension of a serious product hazard, to temporarily ban goods from sale and if necessary to seize them, and in appropriate cases, to recall them from retailers, pending fuller evaluation of the risks apprehended."[93]

Both GSR and QRM may bring about short-term and long-term advantages when used with genetic testing. Yet, a careful balance between these mechanisms is necessary for maintaining incentives for both research into genetic testing and the marketing of genetic testing in Canada. The federal government can use a mechanism such as GSR to ensure the safety of products being sold or offered in Canada (including genetic tests) since it does not have jurisdiction to legislate changes in civil liability. Yet, provinces can legislate changes in civil liability and can rely directly on the effectiveness of tort law as a deterrent to the production and supply of hazardous consumer products, including genetic testing.

Conclusion

John Ralston Saul, in an address to the first Directions for Canadian Health Care Conference, stated that he is "not convinced that there is anything wrong with the fundamental ideas behind Canada's public health system."[94] He indicates that medicare's current difficulties are not the result of either a shortage of money or tensions between federal and provincial/territorial governments. Rather, according to Ralston Saul, the root of the problem is that health care policy is no longer driven by ideas. According to Ralston Saul, "the moment that a public policy is administration-driven, which is to say form-driven as opposed to content-driven, it doesn't work, no matter how hard you try to apply all of the administrative solutions being proposed."[95] Whether or not Ralston Saul is correct in his analysis of the Canadian medicare system and the federal and provincial/territorial relationship, one insight that needs highlighting in relation to genetic testing for late onset diseases is the importance of *thinking* about what we are doing. The desire at *every* level of decision making is to ensure, as far as possible, that genetic testing is appropriate, safe, effective and ethical. This requires thought and the generating of ideas across every kind of boundary – regional, provincial and national. The decision to call the Universal Declaration of Human Rights a *universal* rather than *international* declaration highlights *individual* rights and *individual* responsibilities, rights and responsibilities that were seen as transcending national and even international boundaries. The Declaration addresses people everywhere. This is precisely the vision that needs to be highlighted as the thoughtful exchange of ideas takes place concerning policy development in relation to genetic testing. It needs to underlie collaborative efforts both within Canada and beyond. The tension highlighted at the beginning of the third part of this paper concerning jurisdictional issues is a source not only of division but also of integration. This is because it offers a point of departure for fruitful dialogue. Differences are not only sources of division; they potentially offer us divergent views of reality. It is this kind of divergent dialogue that is needed in the revolutionary world of genetic technology.

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The author identifies, explores and critiques four possible positions Canada could adopt on the patentability of biomedical material.

Human Genetics Commission. *The UK Regulatory and Advisory Framework for Human Genetics*. (London: Health Departments of the United Kingdom, 2000).

This document provides brief descriptions of the main bodies in the U.K. regulatory and advisory framework for human genetics, including current developments in their work relevant to the Human Genetics Commission.

Jonas, Hans, *Imperative of Responsibility: In Search of an Ethics for the Technological Age*. (Chicago: University of Chicago Press, 1984).

Explores the importance of responsibility in a technological age, a responsibility to the future. Suggests an ethics of caution in face of the potential damage of technology for future generations.

Kevles, Daniel J. *The Code of Codes: Scientific and Social Issues in the Human Genome Project*. (Cambridge: Harvard University Press, 1992).

Fourteen essays exploring the substance and possible consequence of the Human Genome Project in relation to ethics, law and society.

Knoppers, Bartha Maria, "Reflections: The Challenge of Biotechnology and Public Policy," *McGill Law Journal* 45:2, May 2000, 559–566.

The article outlines three major developments in relation to scientific advances in biotechnology that will characterize the next decade: the proliferation of genetic choice, the emergence of complex systems pertaining to genetics, and an increasing public concern and interest in the definition of what is "human." Cognizance of these developments is necessary to understand and analyze the need for a public policy framework. She identifies four approaches to policy development that have emerged and notes the underlying need for greater transparency and public participation. Rational and effective policies will only result from additional basic scientific data being made available to a more informed and engaged Canadian public.

Knoppers, Bartha Maria, Hirtle, Marie, Glass, Kathleen Cranley, "Commercialization of Genetic Research and Public Policy," *Science* 286, December 17, 1999, 2277–2278.

Explores four emerging approaches to policy making in relation to the appropriateness of commercialization of genetic research. Also considers possible strategies for dealing with three specific issues: the status of genetic material as it relates to commercialization, patents and conflicts of interest.

Lemmens, Trudo, "Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?" *McGill Law Journal* 45:2, May 2000, 347–412.

This article discusses the desirability of legislation focussing on genetic discrimination, in particular in the context of insurance.

Melchin, Kenneth R. "The Challenges of Technological Society for the Understanding of Christian Faith" in *Défis présents et à venir de l'université* and *Future Challenges Facing Catholic Universities*, Jacques Croteau (ed.) (Ottawa: Saint Paul University, 1990) 123–38.

Addresses the link between technology and human meaning.

Rothstein, Mark A. (ed.) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era*. (New Haven: Yale University, 1997).

Because our techniques for identifying human genes are so much more advanced than our abilities to alter them, the immediate challenge that the Human Genome Project presents for policy makers pertains to the control of genetic information. This volume addresses this question. It consists of a series of essays providing a comprehensive exploration of ethical, legal and social issues emerging in relation to advances in genetic research and issues of privacy and confidentiality.

Roy, David J. et al. "Bioethics on the Frontiers of the Human Genome Project," *Bioethics in Canada*. (Scarborough: Prentice Hall Canada Inc., 1994) 437–464.

Situates the Human Genome Project historically, sketches the scientific developments leading up to the project, and reviews the evolution of ethical concern that followed closely upon the heels of these developments. Raises social and ethics issues in relation to presymptomatic diagnosis and screening.

Shapiro, Michael H., "Introduction to the Issue: Some Dilemmas of Biotechnological Research," *Southern California Law Review* 51, 1978, 987–1006.

Although written more than 20 years ago and commenting on dilemmas accompanying recombinant DNA technique, the article is significant to the topic of genetic testing as it highlights value conflicts that technology presents society. In attempting to answer the complex questions and assess the changes that new technologies present, the author reveals certain predicaments. Technological changes, in fact, often create, intensify and/or highlight value conflicts. What is the relationship between society and a technology that pushes it to value quandaries? What is the role of science, society, governing bodies, etc.?

Somerville, Margaret A., *Do We Care? Renewing Canada's Commitment to Health* (Montreal: McGill-Queen's University Press, 2000).

A compilation of presentations given at the first conference on Directions for Canadian Health Care: A Framework for Sound Decisions. The presentations examine the major issues concerning Canada's health care system from a variety of perspectives. Many of the articles address jurisdictional issues.

World Health Organization. *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services*. Report of a WHO Meeting on Ethical Issues in Medical Genetics, Geneva, December 15–16, 1997. Available online at <http://www.who.org/ncd/hgn/hgnethic.htm>.

This document is the result of an original draft that was circulated worldwide and commented on by all regions and WHO staff. This feedback formed the background of the WHO meeting, Ethical Issues in Medical Genetics, held in Geneva, December 15 to 16, 1997. The participants at the meeting were experts in this field from both developing and developed countries.

Endnotes

1 Only this paper and *Genetic Testing for Late Onset Diseases: Current Research Practices and Analysis of Policy Development* are published by Health Canada. The other two thematic analyses will be published separately by the author.

2 The topic of genetic testing for late onset diseases falls within the broader subject of genetic testing. This report considers the specific focus of genetic testing for late onset diseases against the backdrop of the broader concerns related to genetic testing, the overlap of issues necessitating this strategy.

3 Timothy Caulfield, "Underwhelmed," p. 440.

4 Bartha Maria Knoppers, "Reflections," pp. 559–566.

5 Ibid, p. 565.

6 For example, the debates concerning human cloning, reproductive technologies and nuclear power were spurred on by advances that had already taken place in these areas.

7 Hans Jonas, *Imperative of Responsibility,* p. 8.

8 Kenneth R. Melchin, "The Challenges of Technological Society," pp. 123–38.

9 Two examples are the Internet and cell phones. E-mail has radically altered the economic need for surface mail. Thus, the postal system is faced with the challenge of changing its business organization. The economic affordability of cell phones increases the possibilities that more members of society can be continuously connected to a city's 911 system, thereby systematically extending the benefits of emergency response.

10 Ted Schrecker et al. *Biotechnology, Ethics and Government*. Report to the Interdepartmental Working Group on Ethics. (London: Westminster Institute for Ethics and Human Values and McGill Centre for Medicine, Ethics and Law, 1997) 69.

11 Sir Gustav Nossal, in his introduction to *Human Genetic Information: Science, Law and Ethics,* Ciba Foundation Symposium 149 (Chichester: John Wiley & Sons Ltd., 1990) 2, speaks of public perception of genetic testing as ambiguous and highlighted by extremes. Fear and mistrust is one extreme and unbridled enthusiasm the other. Of the former, he states: "There are three bases to this fear and mistrust. First, there is the realization that the depth of knowledge about the human person's most fundamental life processes produced by the DNA era signals a wariness about the power this information represents. There is a public wariness concerning the "owners" of this power. The public is well aware that large, multinational companies pour millions into this research. There is concern about the implications of that. Second, the rapid pace of technological change can create confusion,

uncertainty, and a general sense that 'things are moving too fast.' Third, communication between science and the public is often minimal, leaving, at times, a gap between the two and creating an uncertainty within the public about science's agenda."

12 Caulfield, pp. 437–460.

13 Timothy Caulfield, "Gene Testing in the Biotech Century: Are Physicians Ready?" *Canadian Medical Association Journal* 161, 1999, 1123.

14 See, for example, the Advisory Committee on Genetic Testing, *Genetic Testing for Late Onset Disorders* (London: Health Departments of the United Kingdom, 1998); Neil A. Holtzman and Michael S. Watson (eds.), *Promoting Safe and Effective Genetic Testing in the United States,* Final Report of the Task Force on Genetic Testing, (Bethesda: The National Human Genome Research Institute, 1997); the Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services, 1993); the Committee on Assessing Genetic Risk, Institutes of Medicine, *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington: National Academy Press, 1994); and the Science and Technology Committee, *Third Report: Human Genetics: The Science and its Consequences* (London: British House of Commons, 1995).

15 "[F]ew (if any) provincially funded genetic centres have the counselling resources to meet the anticipated demand. The counselling provided by commercial services may be insufficient." Caulfield, "Gene Testing in the Biotech Century," 1123.

16 Bryn Williams-Jones, "Re-framing the Discussion: Commercial Genetic Testing in Canada," *Health Law Journal* 7, 2000.

17 Francis Giardello, et al. "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis," *New England Journal of Medicine* 336, 1997, 823–7.

18 Edward Leroy Long, "Technology" *The Westminster Dictionary of Christian Ethics*, James F. Childress and John MacQuarrie (eds.) (Philadelphia: The Westminster Press, 1986) 617.

19 Melchin, p. 130.

20 Timothy Caulfield, "Introduction," *McGill Law Journal* 45:2 May 2000, 344.

21 The entire volume is dedicated to issues concerning genetics and the law. The articles in the journal are, according to Caulfield, "second generation" analyses.

22 Ibid., p. 344.

23 Ibid.

24 The Honorable Stephen Breyer, "Genetic Advances and Legal Institutions."

25 Ibid.

26 Ibid.

27 Ibid.

28 Ibid.

29 Evelyn Fox Keller, *Refiguring Life: Metaphors of Twentieth-Century Biology* (New York: Columbia University Press, 1995) 3.

30 Knoppers, p. 566.

31 Along with the article cited in the previous footnote, the text draws on another article by Knoppers and two others, Marie Hirtle and Kathleen Cranley Glass. "Commercialization of Genetic Research and Public Policy," 2277 –2278.

32 Critics of the U.S. moratorium on human cloning note that it does not prohibit privately funded institutions from conducting such research.

33 Justice Breyer gives the example of groups in the United States in the 1970s that lobbied Congress to enact moratoria or prohibitions on certain genetic research. The efforts did not succeed but, according to Justice Breyer, "one can easily imagine the harmful consequences to which bans might have led. Genetic research so far has not led to the creation of the 'mosquito-man' nor does cloning seem likely to produce multiple carbon copies of General Franco as once was feared. Rather that research has led to enormously beneficial discoveries related to our health and well-being."

34 Knoppers, Hirtle and Cranley Glass, p. 2277.

35 Robert Cook-Deegan, *The Gene Wars*, especially chapters 13 and 20.

36 Knoppers, p. 565.

37 Knoppers, p. 565–566.

38 Caulfield, p. 440.

39 Christine E. Jamieson, *Genetic Testing for Late Onset Diseases: Current Research Practices and Analysis of Policy Development*, prepared for Health Canada, May 2000.

40 For example, the United States Task Force on Genetic Testing, *Promoting Safe and Effective Genetic Testing in the United States*, 9, and the Privacy Commissioner of Canada, who recommend that "personal genetic information collected by government institutions or private sector physicians providing ordinary medical care should be used only to inform a person's own decisions about medical care. This information must not be used for any other purpose." Quoted in Trudo Lemmens and P. Bahamin, *Genetics in Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis*, report

prepared for the Medical, Ethical, Legal and Social Issues Committee of the Canadian Genome Analysis and Technology Program (Montréal: Université de Montréal, Centre de Recherche en Droit Public, 1996) 25, footnote 95.

41 Roy, David J. et al. "Bioethics on the Frontiers of the Human Genome Project," p. 454.

42 For an exhaustive list of both policy statements and legislation, see Trudo Lemmens, "Selective Justice," pp. 347–412.

43 Jon Beckwith and Joseph S. Alper, "Reconsidering Genetic Antidiscrimination Legislation," *Journal of Law, Medicine & Ethics* 26, 1998, 205. Lemmens, 349, concurs when he states "that statutes singling out genetic susceptibility as a category, and offering it much wider protection than other similar health conditions, although intended to promote equity in access to social goods, may themselves be ineffective and to some extent even inequitable."

44 Knoppers, p. 566.

45 John Cornwell, "Patents, Profits and Genes," *The Tablet*, March 4, 2000, 305.

46 Ibid.

47 For example, UNESCO's 1997 *Universal Declaration on the Human Genome and Human Rights*, the European *Directive on the Legal Protection of Biotechnological Inventions* and the *Convention on Human Rights and Biomedicine* all concur that the genome is the common heritage of humanity. The latter two go further to say that the human genetic material is part of the person and is not property. The European *Directive on the Legal Protection of Biotechnological Inventions* was adopted by the European Parliament and the Council of the European Union on July 6, 1998. "The *Directive* constitutes a legal and social policy landmark in biotechnology, taking an explicit position on the contentious issue of the patentability of higher life forms. It fails, however, to provide definitive statements on the legal status of human genetic material or the possibility of personal financial gain in relation to such material." Bartha Maria Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey," *Nature Genetics* 22, May 1999, 23.

48 Cornwell, p. 306.

49 E. Richard Gold, "Biomedical Patents and Ethics" p. 431.

50 Ibid., p. 432.

51 This statement is made in the National Cancer Institution of Canada Report, *Prevalence of BRCA1 and BRCA2 Gene Mutations in Patients With Early-Onset Breast Cancer*, J. Peto et al., 91, 1999, 948–949, as cited in Caulfield, "Underwhelmed," p. 447.

52 Shelley Martin, "Most Canadians Welcome Genetic Testing," *Canadian Medical Association Journal* 163:2, July 25, 2000, 200.

[53] Some women opt for the preventative treatment without the benefit of genetic testing. They base their decision strictly on the strong presence of breast cancer in their family.

[54] See, for example, Francis Collins, "BRCA1 – Lots of Mutations, Lots of Dilemmas," *New England Journal of Medicine*, 334, 1996, 186; Bernadine Healy, "BRCA Genes – Bookmaking, Fortunetelling, and Medical Care," *New England Journal of Medicine*, 336, 1997, 1448; and Mendel Singer and R. Cebul, "BRCA1: To Test or Not to Test, That is the Question," *Health Matrix* 7, 1997, 163.

[55] Caulfield, "The Genetic Revolution," p. 455.

[56] Barbara A. Koenig et al. and the Breast Cancer Working Group of the Stanford Program in Genomics, Ethics and Society, "Genetic Testing for BRCA1 and BRCA2: Recommendations of the Stanford Program in Genomics, Ethics, and Society," *Journal of Women's Health* 7, 1998, 531.

[57] Margaret Somerville, *The Ethical Canary: Science, Society and the Human Spirit* (Toronto: Penguin Books, 2000) 225–226.

[58] This draws on insights from Bernard Lonergan, *Method in Theology* (Toronto: University of Toronto Press, 1971) 330–333.

[59] Michael H. Shapiro, "Introduction to the Issue" p. 996.

[60] Drawn from a statement made by Patricia King, "Ethical and Legal Constraints on Research," *Preparing for Science in the 21st Century*, D. C. Harrison, M. Osterweis, and E. R. Rubin (eds.) (Washington: Association of Academic Health Centers, 1991) 116–125.

[61] Robert Cook-Deegan, 248.

[62] Knoppers, "Biotechnology and Public Policy," 565.

[63] Daniel J. Kevles and Leroy Hood, "Reflections," *The Code of Codes,* p. 311.

[64] For example, the *Interim Principles of the Task Force on Genetic Testing* of the National Institute of Health–Department of Energy Working Group on Ethical, Legal, and Social Implications of Human Genome Research, available on the Internet at <http://www.med.jhu.edu/tfgtelsi/principles.html>. Date accessed: November 14, 2000; the Council of Europe's Convention for Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Biomedicine: Convention on Human Rights and Biomedicine, *Kennedy Institute of Ethics Journal*, 7:3, 1997, 277–290; the *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services. Report of a WHO Meeting on Ethical Issues inMedical Genetics*, Geneva, December 15–16, 1997, available on the Internet at <http://www.who.org/ncd/hgn/hgnethic.htm>. Date accessed: March 1, 2000. Also noteworthy here is the international human rights law on health care protection and

individual integrity, which is reflected in the Canadian Charter of Rights and Freedoms. Also important are the federal and provincial human rights code and professional codes of conduct and of ethics.

65 Kevles, "Out of Eugenics: The Historical Politics of the Human Genome," *The Code of Codes*, p. 28.

66 Ibid., p. 29.

67 This is noted in a comment by the Honourable Monique Bégin at the Directions for Canadian Health Care conference in 1998: "I once asked senior Cabinet colleagues why the 1976 legislation funding Medicare (the *Established Program Financing Act*) was passed without a provision for enforcing its five cardinal conditions. I was told that there was such good faith at the time between the provinces and federal government when they went from cost sharing to block funding at the negotiating table, that no one thought there would ever be a problem." Cited in Margaret Somerville, *Do We Care?* p. 104.

68 The Honourable Bob Rae, "Health Policy in the Consumer Era," Somerville, p. 91.

69 Somerville, p. xii.

70 Rae, p. 92.

71 Carolyn Bennett and Rick Archbold, *Kill or Cure?* pp. 122–123.

72 Rae, p. 92.

73 The Honourable Monique Bégin, "Redefining Entitlement to Health Care," Somerville, pp. 97–98.

74 This is not to suggest that the tensions that result from various levels of involvement in health care delivery can be reduced to only two visions. Rather, considering this specific tension, which looms large in efforts at regulating health care delivery, is useful when exploring jurisdictional issues related to genetic testing.

75 See Timothy Caulfield's comments in "The Genetic Revolution," *McGill Law Journal*, 45:2, May 2000, 437–460.

76 Somerville, p. xii.

77 David E. C. Cole, et al., "Genetic Counselling and Testing for Breast, Ovarian, and Colon Cancer Susceptibility: Where are We Today?" *Canadian Medical Association Journal* 154, 1995, 149–155.

78 Timothy Caulfield, "Tensions in Ethics Policy: the Consumer vs. the Citizen," Somerville, p. 119.

79 Bennett and Archbold, p. 18.

80 See Christine E. Jamieson, *Genetic Testing for Late Onset Diseases: Medical and Social Issues*, a paper for Health Canada that discusses some of the uncertainty concerning genetic testing.

81 See Christine E. Jamieson, *Genetic Testing for Late Onset Diseases: Current Research Practices and Analysis of Policy Development*, a paper for Health Canada, in particular "Regulation and Monitoring of Laboratories."

82 See Bob Rae's criticism concerning this in "Health Policy in the Consumer Era," Somerville, p. 93.

83 Donald N. Dewees and Michael J. Trebilcock, *Study on the Effectiveness of Tort*, p. iii. This section of the paper draws almost exclusively from this report.

84 Ibid., p. 1.

85 Ibid., p. 27.

86 Ibid., p. 28.

87 Ibid., p. 30.

88 Ibid., p. 37.

89 Ibid., p. 24.

90 Gold's article deals with the issue of patents, but this theory can be applied more fully to genetic testing.

91 From the United Kingdom *Consumer Protection Act,* 1987, cited in Dewees and Trebilcock, p. 45.

92 Ibid., p. 45.

93 Ibid., p. 48.

94 John Ralston Saul, "Health Care at the End of the Twentieth Century: Confusing Symptoms for Systems," Somerville, p. 3.

95 Ibid., p. 10.