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Selected Legal Issues in Genetic Testing: Guidance from Human Rights

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Author Biography

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Résumé

À mesure que les tests génétiques évoluent, que la recherche et le développement font place à leur diffusion et à leur application dans l'ensemble de la société, ces tests, à l'instar de nombreuses biotechnologies modernes, soulèvent d'importantes questions juridiques et éthiques dans de nombreux domaines : propriété génétique, sécurité, efficacité des tests, dépistage obligatoire par opposition au dépistage consensuel, laboratoires d'essai, utilisations pour l'emploi ou l'assurance. Ce document fait valoir que les principes modernes en matière de droits de la personne orientent de façon importante le débat sur ces questions en définissant des normes de corroboration et de processus. Ces normes reflètent des valeurs chères à notre société, notamment la confidentialité, la liberté, la protection de la vie et le débat démocratique. Afin de bien appliquer les principes des droits de la personne à l'utilisation d'une technologie en évolution, la précision est de rigueur. Il est important, entre autres, de savoir faire la distinction entre « information génétique » et « tests génétiques », ainsi qu'entre les tests diagnostiques, présymptomatiques et de susceptibilité. Ces tests sont effectués à diverses fins, dont la présélection, la détection en vue du traitement, le counselling, la surveillance, l'avertissement et l'exclusion. L'auteur suggère que la raison précise de la mise en œuvre d'un programme de dépistage ainsi que les modalités d'un tel programme déterminent en grande partie la validité du programme sur les plans juridique et éthique. L'étude d'un cas de dépistage génétique en milieu de travail sert de toile de fond à l'examen de ces questions. L'auteur se fonde sur des documents juridiques historiques de portée internationale pour évaluer les arguments des défenseurs et des détracteurs du dépistage génétique de la maladie de Huntington chez les pilotes de ligne. En guise de conclusion, il met de l'avant une série de recommandations pratiques. Ces recommandations portent, entre autres, sur l'importance pour le gouvernement du Canada de s'assurer que ses politiques en matière de dépistage génétique reflètent des principes directeurs comme le respect de la dignité humaine, la confidentialité de l'information génétique, la protection et la promotion de la santé, l'égalité génétique et la participation du public. Ce cadre devrait mener à des activités et à des réformes précises, par exemple la modification de la *Loi canadienne sur les droits de la personne* afin d'y inclure des dispositions explicites sur la protection de la vie privée ou la ratification d'un nouveau traité international sur la confidentialité des renseignements génétiques et la discrimination fondée sur les caractéristiques génétiques.

Abstract

As genetic testing evolves from the research and development stage towards general diffusion and application across society, it, as with many modern biotechnologies, raises important legal and ethical issues — among them claims of genetic ownership, the safety and efficacy of genetic tests, mandatory versus consensual testing, regulating testing labs, and employment or insurance uses. This paper argues that modern human rights standards provide important guidance on such issues. They do so by defining substantive and process norms. The norms reflect cherished societal values, such as fairness, confidentiality, liberty, the protection of life, and democratic deliberation. For optimal use of human rights norms to address this evolving technology, clarity is imperative. Thus, understanding how "genetic information" differs from "genetic testing" is helpful, as is understanding diagnostic, presymptomatic and susceptibility testing. Such testing may be done for several reasons, such as to screen, identify to treat, counsel, monitor, warn or exclude. The precise rationale for and implementing means of a genetic testing initiative, it is suggested, prove central to its legal and ethical validity. Such considerations are examined in a case study of genetic testing in the workplace. Historic international legal initiatives are drawn on to evaluate arguments for and against the testing of airline pilots for genetically transmissible Huntington disease. The document concludes with working recommendations. The author urges the Government of Canada to develop a framework on genetic testing and genetic information. It should be based on such guiding principles as respect for human dignity, genetic privacy, health protection and promotion, genetic equality and public participation. Such a principled framework should inspire specific initiatives and reforms. These might include modernizing the *Canadian Human Rights Act* by including an explicit protection of privacy or signing a new international treaty that addresses genetic privacy and discrimination issues.

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Introduction

> ...Les tests génétiques apportent des informations sur l'identité des personnes et soulignent leur diversité qui contribue à la richesse de l'humanité. L'utilisation de ces informations à des fins de sélection ou de discrimination dans la vie sociale et économique, que ce soit dans la domaine des politiques de santé, de l'emploi ou des systèmes d'assurance, conduirait à franchir une étape d'une extrême gravité vers la mise en cause des principes d'égalité en droits et en dignité, et de solidarité entre tous les êtres humains, sur lesquels repose notre société.... Il y va des droits de l'homme.
>
> French National Bioethics Committee, 1995[1]

Like many nations today, Canada faces important choices about managing the benefits and burdens of modern genetic technology. Like many other opportunities in the biotechnology revolution, genetic testing offers patients and providers the benefits of new insights into illness, disease and health. The discovery of genes for cancer, heart conditions, neurological disorders and similar ailments may move society closer to better treatments. When the research, development and application of testing advance health and well-being, they are in line with public values. Yet, even as genetic researchers and health specialists begin to understand the importance of the new diagnostic insights, serious questions are emerging about the social, ethical and legal issues associated with technologies such as genetic testing.

Three examples illustrate some of the issues. First, in what has become a landmark legal ruling in this biotechnology age, cancer patient John Moore sued his physician, a university hospital and a biotechnology company in 1988 for the alleged misappropriation of his tissue and genetic material.[2] He argued that, without his knowledge or consent, his physician had used DNA from his cancerous spleen cells to create and patent a multimillion dollar anti-cancer drug. Though Moore had alleged the wrongful conversion of "genetic property," a divided California Supreme Court ruled that the physician may have breached his duty of loyalty to the patient by not disclosing his conflict of interest related to research and the commercial development of Moore's tissue.

Second, questions surrounding the ownership of genetic information may soon go before the courts in Iceland. There, a diverse group of citizens, scientists, researchers and health professionals plans to challenge recent legislation that creates a national health and genetic database.[3] A key issue is likely to be whether the law violates basic human rights by legislatively presuming that citizens consent to having health and genetic data from their medical files included in the database that has been made available exclusively to a private genomic research

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[1] See France in Table A, below.

[2] *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990).

[3] Iceland. *Act on a Health Sector Database no. 139/1998.* See generally, Jonatsson H. Iceland's Health Sector Database: A Significant Headstart in the Search for the Biological Grail or An Irreversible Error? *Am. J. L. & Med*. 2000;26:31-67.

company. The laudable intent behind the law may be to further genetic research and eventual treatments. Still, some would argue that the legislation violates the medical privacy of patients and discriminates against those who lack the capacity to opt out of the legislative presumption of participation.

Third, genetic privacy and equity concerns have been increasingly noted in the employment and insurance domains. A recent U.S. government report indicates that people sometimes hide genetic information for fear of the effects of disclosure. For example, an 18-year-old man, at risk for inheriting Huntington's disease from one of his parents, who wished to enlist in the Marines to serve in the Persian Gulf War, believed that knowledge of his risk status would disqualify him from service, even though it was unlikely that he would become symptomatic during his tour of duty. He therefore answered "no" to questions regarding hereditary disorders on his application and did not include Huntington's disease in his family medical history.[4]

The concerns have not been limited to individuals; they have spawned increasing national initiatives. In recent years, such entities as the Danish and French national bioethics committees, the privacy or data protection commissioners in Australia, Britain and Canada, and research institutions such as the National Human Genome Research Institute of the U.S. National Institutes of Health have studied the issues.[5] All have recommended controls on genetic testing technology and genetic information. Such recommendations have been translated into laws in a growing number of nations, such as Austria, France, Norway, Denmark and the U.S.[6]

The legal concerns and initiatives have also transcended national borders. In 1997, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) adopted the *Universal Declaration on the Human Genome and Human Rights*. The *Declaration* embraces the principles of non-discrimination and genetic privacy, and urges nations to adopt means to implement those principles. The United Nations' initiative has been complemented by innovative international regional developments. Some 30 European nations, for instance, have signed an innovative treaty on human rights and biomedicine (see Table A) that prohibits genetic discrimination. Even international economic organizations have begun to address the associated legal and social questions, as illustrated by the convening in January 2000 of an international workshop on genetic testing policy issues by the Organisation of Economic Co-operation and Development (OECD). The OECD held this session as part of its oversight of biotechnology, science and society in its 29 member countries. If such developments suggest some of the unprecedented initiatives and trends that the international community has witnessed in genetic

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4 US Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice. *Genetic Information and the Workplace*. Washington, DC: 1998 (hereinafter DOL report).

5 See Table A, below.

6 Ibid.

testing law and policy over the past decade, they also raise questions about Canadian legal norms in this domain.

To sample some of these developments, the following explores selected legal issues that arise with the advance of genetic testing. The legal focus is on selected human rights issues largely in non-hospital settings under federal law. DNA testing for criminal law matters and genetic testing for paternity or like questions of family law lie beyond the scope of the current analysis. The discussion is informed by the laws and experiences of other countries. The medical focus is on so-called late onset diseases — that is, genetic-based diseases, the symptoms of which typically appear in adulthood. Hereditary breast and colon cancer, Huntington and Alzheimer diseases, polycystic kidney disease, some forms of heart disease, blood disorders and diabetes — are examples.[7] To illustrate potential legal issues, however, the analysis sometimes refers to conditions that are neither late onset nor genetic.

Part I begins with an overview of the leading legal issues presented by genetic testing. Part II reviews the privacy, discrimination and other major human rights norms implicated by genetic testing. Part III discusses issues associated with definitions and summarizes leading testing rationales and how they relate directly to law and ethics. Part IV applies these rationales, legal norms and related considerations to a case study of genetic testing and genetic information in the workplace. Part V concludes with recommendations.

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[7] Institute of Medicine, Committee on Assessing Genetic Risks. *Assessing Genetic Risk: Implications for Social Policy*. National Academy Press: Washington, 1994, pp. 86-94, 97.

I. Emerging Legal Issues and Questions

The academic literature and a growing number of reports from governments around the world highlight a variety of legal and ethical issues raised by genetic testing.[8] A sampling of them includes the following:

Law and language: What do the terms *genetic testing*, *genetic privacy* and *genetic discrimination* actually mean?

Health information: Does the nature of genetic information warrant legal standards beyond those accorded to other health information? [9]

Discrimination: Does a presymptomatic carrier of a late onset genetic disease enjoy protection under discrimination law?

Insurance: Do people have a right to basic health, disability and life insurance, regardless of their genetic status?[10]

Research and communities: If genetic testing is a societal mechanism for advancing knowledge, health and community development, do communities[11] have a right to define the genetic testing research agenda?

Consent: Are there instances that justify mandatory screening for late onset genetic disorders for which there are effective treatments?[12]

Health and safety: Does the law have a role in ensuring that genetic tests are safe and effective for their intended purposes?[13]

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[8] See the Bibliography in the Appendix and Table A, below.

[9] Gostin LO, Hodge JG. Genetic Privacy and the Law: An End to Genetics Exceptionalism. *Jurimetrics*. 2000;40:21-59. See also section III.A, below.

[10] Oneil O. Insurance and Genetics: The Current State of Play. *Mod. Law Rev*.1998 61:716-723.

[11] Foster MW, Bernsten D, Carter TH. A Model Agreement for Genetic Research in Socially Identifiable Populations *Am. J. Hum. Genet*. 1998;63:696-702.

[12] Allen K, Williamson R. Should we genetically test everyone for haemochromatosis? *J Med Ethics*. 1999;25:209-214.

[13] See section II.B.7, below (noting role of Canadian medical device law).

Protection of the vulnerable: What obligations does society have toward children[14] or those who otherwise cannot effectively speak for themselves about legal protection of their future genetic interests?

Process and substance: Through what democratic process(es) does society decide the ethical and legal norms that govern access to and the use of genetic information?

While many of these issues lie beyond the scope of this inquiry, it is important to note the breadth of the questions that society confronts. It is equally important to note that the questions and issues do not arise in a vacuum. Rather, as has been suggested for other biotechnologies, the issues tend to take on their particular form, force and content as genetic testing technologies progress from research to development to practical implementation and general diffusion.[15] Thus, issues of autonomy and consent will be constant across the spectrum of technological development, but the particular consent issues in the research stage of developing a test may differ markedly from the consent issues raised by applying the tests in the workplace or in public health initiatives. Context matters. The spectrum of technological development may assist in understanding and tracking the evolution of legal and ethical issues in genetic testing. It helps show, for instance, the current era during which society seems so preoccupied with genetic research issues, as symbolized by the international Human Genome Project. But the spectrum also indicates a trajectory. Genetic testing technologies for late onset diseases will likely progress from experimental to established, and then begin diffusing across the health sector and other sectors of society. The state-of-the-art of various late onset tests shows that each technology progresses at a different speed through the phases. One critical role the law may play is helping society structure the standards for the diverse uses of each technology as it progresses. The typical path of progress from the research and development phase towards the phase of general diffusion of the technology indicates that society exercises prudence today by analyzing emerging legal issues and what they may augur for challenges in the future.

The following gives examples of the issues at different phases of the technological spectrum:

Research and *Development*

- Legal standards for genetic research:
  – norms to govern the freedom of intellectual inquiry;
  – prospective research ethics review: consent, privacy and review process;
  – clinical trials law; and
  – norms to promote research and access to new technologies.
- Safety and efficacy of genetic tests: legal standards
- Storage, access and use of genetic research material
- Stigmatizing research and group defamation

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[14] Cohen CB. Wrestling with the future: should we test children for adult-onset genetic conditions? *Kennedy Institute Ethics J.* 1998;8:111-130.

[15] Jones DJ. *Ethics and Biotechnology: The Role of the Government of Canada.* Government of Canada: Ottawa, 1998. Online in PDF: http://strategis.ic.gc.ca/SSG/bh00195e.html

- Patenting of genetic markers
- Ownership of DNA, genetic material and the human genome
- Public participation and oversight of national genetic research policy

Diffusion and Implementation
- Quality assurance standards for genetic testing laboratories
- Population screening and rationales: consensual versus non-consensual testing
- Licensing genetic testing: technology, professionals and institutions
- Genetic testing: discrimination and privacy law in insurance and employment
- Genetic data banks
- Human eugenics law and institutions (health services, educational and correctional)
- Genetic testing and immigration
- Public participation and oversight of national genetic testing policy

On the basis of some of the leading issues, Part IV of this paper examines a case study of human rights issues posed by genetic testing in the workplace. Such case studies help to illustrate concretely the rights, duties, standards and even uncertainties of the law. Before turning to it, the interface between testing and basic human rights needs to be explored.

II. Human Rights and Genetic Testing

This section summarizes some of the basic human rights implicated by genetic testing. Some of them are familiar because of their substantive protection of bodily integrity, equality, autonomy and control of personal information. Others, involving process norms of human rights, may be less so.

A. Rights, Duties and Sources

Imagine that a government decides to perform genetic tests on blood samples collected for pre-employment medical examinations of workers at nuclear power plants and telecommunications laboratories. Does this violate human rights? What laws, if any, are broken? And if it is a legal wrong, how is the wrong repaired? Parallels to this scenario will be explored further below in Part IV. The questions this scenario raises underscore the important relation between human rights, institutional duties and the sources that define such rights and duties.

From a legal perspective, a violation of rights normally entails a breach of some legal duty. Rights, in other words, are intimately related to corresponding legal duties.[16] Consider the right to privacy. Practically, the right to privacy has a dual meaning: it functions to impose a zone of protection around private life. This affords us tranquillity, which is effected in part by imposing on others a corresponding duty to respect our privacy. In other words, legal rights are made meaningful because of the rights-duties dynamic they impose on human relations. This may not seem surprising, given that most human affairs involve diverse relationships between people. Still, as many diverse schools of modern legal thought have emphasized, "rights talk" sometimes becomes abstract and detached from human relationships.

Recognizing the right-duties dynamic is also important when identifying, analyzing and interpreting sources of law. International legal instruments, national constitutions, statutes and court rulings are all standard sources of law. Such sources are the reservoir for defining the particular rights and duties at issue. But only some sources of law may address a particular human right. All, some or none may apply in particular circumstances, because many laws have limited application. The point is illustrated by the protections of the *Canadian Charter of Rights and Freedoms*. Section 32 limits its application to government. By contrast, most human rights statutes generally apply to both government and the private sector. Thus, when a bank, provincial ministry, airline or telecommunication corporation is considered "government," then the *Charter* applies. When it is not, the *Charter's* protections do not bind that employee-employer relationship. When the jurisdiction in which the genetic testing take place lacks other sources of law to define privacy duties and rights, then the jurisdiction may have a void in law (see section II.B.3, below).

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[16] Hohfeld W. Some Fundamental Legal Conceptions as Applied to Judicial Reasoning. *Yale Law J.* 1913;23:16.

Even when a jurisdiction has one or more sources of law that define human rights, the laws must be analyzed and interpreted to understand whether they effectively define rights and duties related to genetic testing. For example, doubt that general discrimination and privacy laws afford sufficient protection against employment discrimination of those with genetic anomalies has led some jurisdictions to enact explicit genetic privacy or discrimination laws (see Table A). Finally, it should be noted that even when human rights provisions do not formally bind the parties in a legal matter, they may prove influential by their reasoning, their expression of consensus and their force of moral persuasion. It will be shown that non-binding legal declarations from some 50 years ago directly influenced UNESCO's 1997 *Universal Declaration on the Human Genome and Human Rights*. Such influence is consistent with the educative role of the law. It is a role that keeps the law dynamic and open to evolving schools of thought as new social, ethical, cultural, technological and public policy needs challenge society to evolve.

The following table illustrates how the UNESCO *Declaration* parallels and contrasts with other international and national legal or policy norms that have emerged in recent decades to redefine human rights in a modern genetic era.

Table A. Emerging Human Rights: A Sampling of Equality and Privacy Norms Regarding Genetic Testing in Selected Countries*

	Study and Policy Guidance	Genetic Discrimination Law	General Discrimination Law	Genetic Privacy Law	General Privacy and Confidentiality Law
Australia	D[17]		L[18]		L[19]
Canada	D[20]		L[21]		S[22], L[23]
Council of Europe	D[24]	C[25]	C[26]	C[27]	C[28]
Denmark	D[29]				L[30]
European Union	D[31]		C[32]		C[33]
France	D[34]			L[35]	L[36]
Norway	D[37]	L[38]		L[39]	
OECD	D[40]				
United Nations	D[41, 42]		C[43]		C[44]
United Kingdom	D[45]		L[46]		L[47]
United States	D[48]	L[49]	L[50]	L[51], S[52]	L[53]

Key: C = convention; D = ethical or policy guidelines; L = national legislation; S = provincial or state legislation.

*This table includes some of the primary, but not the exclusive, laws through which some nations address such issues as genetic equality and privacy. Thus, a country identified as having a genetic privacy law may also have general privacy laws. The research is generally current to July 2000.

Source: Excerpted in part from Jones DJ. *Laws, Conventions and Declarations on Biotechnology*. (Ottawa, Industry Canada: 2000), available online at http://strategis.ic.gc.ca/SSG/bb00002e.html.

17. Australia, Privacy Commissioner. The Privacy Implications of Genetic Testing, September 1996; National Health & Medical Research Council of Australia. Ethical Aspects of Human Genetic Testing: An Information Paper. Canberra, 2000, chp. 3-5.

18. Australia, *Discrimination Act*, 1991, ss. 7, 8 (impairment or perception thereof).

19. Australia. Privacy Act 1988, as amended by the *Privacy Amendment (Private Sector) Act 2000*, s.6 (health information). Section 14 & Schedule 3 of the revised Act outline privacy principles for the public & private sectors.

20. The Privacy Commissioner of Canada. *Genetic Testing and Privacy*. Ottawa, 1992; Law Reform Commission of Canada. *Human Dignity & Genetic Heritage*. Ottawa, 1992.Royal Commission on New Reproductive Technologies. *Proceed With Care*. Ottawa, 1993.

21. Canada. *Canadian Human Rights Act*, (1976), s. 3 (disability discrimination).

22. See, e.g.,: Québec. *Quebec Charter of Human Rights & Freedoms* (1975) as amended. RSQ, c. C-12, s.8; *Loi modifiant la Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels*, L.R.Q., c. A-2.1; *Loi sur la protection des renseignements personnels dans le secteur privé*, L.R.Q., c. P-39; Ontario: Information & Privacy Commissioner of Ontario. *Workplace Privacy: The Need for a Safety Net*. Toronto, 1993, interpreting the *Freedom of Information and Protection of Privacy Act*, Rev. Stats. Ontario, 1990, c. F. 31; Ontario Human Rights Commission. *Human Rights Issues in Insurance: A Discussion Paper*. Toronto, 1999.

23. Canada. *Privacy Act (1982)* and *Privacy Regulations*, SOR/83-508, s.12; *Personal Information Protection & Electronic Documents Act*, received Royal Assent April 2000, application to health data effective January 2002, excerpted in Appendix A, below.

24. Council of Europe. *Recommendation No R(92)3 of the Committee of Ministers to Member States on Genetic Testing & Screening for Health Care Purposes, of February 1992; Recommendation R(97) 18 on the Protection of Medical Data*. paras 4.5-4.9, 1997.

25. Council of Europe. *Convention on Human Rights & BioMedicine*. ETS No.164. Oviedo, 1997, arts. 11-12 (signed by 30+ countries).

26. Council of Europe. *Convention for the Protection of Human Rights and Fundamental Freedoms,* Rome, 4 November 1950. E.T.S. No. 5, 213 U.N.T.S. 222, art. 14.

27. Council of Europe. Draft Human Genetics Protocol in progress for the *Convention on Human Rights & BioMedicine*.

28. Council of Europe. *Convention on Human Rights & BioMedicine*, 1997, art.10; *Convention on the Protection of Individuals with Regard to the Automatic Processing of Information.* ETS 108: Strasbourg, 1981. art. 6 (sensitive personal data, like health information, warrants special safeguards).

29. Danish Council of Ethics. *Genetic Testing in Appointments***:** *Genetic Screening) A Report*. Copenhagen, 1993.

30. Denmark. *Law No. 286 of 24 April 1996 on the Use of Health Information on the Labor Market*, *International Health Digest Legislation.* 1996;47:371-72; Act No. 413 of 10 July 1997, *Act to Amend the Insurance Agreement Act and Act on the Supervision of Company Pension Funds*.

31. European Commission, European Group on Ethics in Science & New Technologies. *Opinion on Genetic Testing in Employment*... in Progress.

32. European Union. *Treaty on European Union*, as amended. Amsterdam, 1997. art. 6 (equality); *Treaty Establishing European Community, as amended.* Amsterdam, 1997. art. 13 (disability discrimination).

33. European Union. *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*, art. 8.

34. France. Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE). *Avis nE 46. Avis et recommandations sur Génétique et Médecine : de la prédiction à la prévention*. Rapport. Paris, Oct. 1995.

35. France. *Loi no 94-653 du 29 juillet 1994 relative au respect du corps humain*, arts. 5-8; *Code de la santé publique*, arts. L.1131-1 - L.1131-6.

36. France. *Loi no 78-17 du 6 janvier 1978 relative a l'informatique, aux fichers et aux libertés*. *Journal Officiel*. 7 jan. 1978, as amended.

37. Norwegian Biotechnology Advisory Board. *Genetic Testing: When & Why?* Oslo, March 1996; *The Use of Genetic Information about Healthy People by Insurance Companies*. Oslo, April 1997.

38. Norway. *Biotechnology in Medicine Act of 1994*, s. 1.1.

39. Norway. *Biotechnology in Medicine Act of 1994*, ss. 6-2,6-4, 6-7.

40. Organisation for Economic Co-operation and Development (OECD). *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data*. Paris, 1980; OECD Workshop: Vienna 2000 on Genetic Testing -- Policy Issues for the New Millennium & Genetic Testing Regulations by OECD Member Countries.

41. UNESCO. *Universal Declaration on the Human Genome and Human Rights*. Paris, 1997, ss. 2, 6-7, 21-22. See also WHO, *Proposed International Guidelines on Ethical Issues in Medical Genetics & Genetic Services -- Report of a (1997) WHO Meeting on Ethical Issues in Medical Genetics*. Geneva, 1998.

42. International Labor Organization (ILO). *Code of Practice on the Protection of Workers' Personal Data*. Geneva, 1996; *Technical and Ethical Guidelines for Workers' Health Surveillance*. Geneva, 1997.

43. United Nations. *International Covenant on Civil and Political Rights*, 1966, ss. 2, 26, 999 U.N.T.S 171.

44. Ibid, s. 17.

45. Nuffield Council on Bioethics. *Genetic Screening: Ethical Issues*. London, 1993:90-92; United Kingdom, Department of Health. Human Genetic Advisory Committee (HGAC). *The Implications of Genetic Testing for Insurance*, December 1997; *The Implications of Genetic Testing for Life Insurance*, July 1997; *Implications of Genetic Testing for Employment.* London, 1999; Advisory Committee on Genetic Testing. *Genetic Testing for Late Onset Disorders*, 1998; The Personnel Policy Research Unit. *The Uses and Misuses of Personal Data In Employer/Employee Relationships.* Surrey, 1999.

46. United Kingdom. *Disability Discrimination Act*, 1995, c. 50, s. 1 & Schedule 1; *Human Rights Act 1988*, Schedule 1, art 14.

47. United Kingdom. *Data Protection Act 1998,* superceding *1984 Act*; *Human Rights Act 1988*, Schedule 1, art 8.

48. U.S. National Institutes of Health - Department of Energy Working Group on Ethical, Legal and Social Implications of Human Genome Research. *Promoting Safe and Effective Genetic Testing in the United States, Final Report of the Task Force on Genetic Testing*, September 1997; Department of Health & Human Services. Secretary's Advisory Committee on Genetic Testing. *Request for Public Comments on Genetic Testing*. *Fed. Reg.* 1 Dec. 1999; 64: 67273; *Preliminary Recommendations on the Adequacy of Oversight of Genetic Tests*. Washington, DC, 2000.

49. US Office of the President. *Executive Order: To Prohibit Discrimination in Federal Employment Based on Genetic Information*. 8 Feb. 2000.

50. *Americans with Disabilities Act*, 42 USC 12102, interpreted as generally prohibiting genetic discrimination in the workplace by the Equal Employment Opportunity Commission, *Compliance Manual: Section 902--Definition of the Term Disability*, 14 March 1995, sec. 902.8.

51. United States. See Executive Order in note 31. See also *Health Insurance Portability and Accountability Act* of 1996, PL 104-191, codified at 29 USCA, s. 1182(a)(1), (prohibiting health insurance discrimination on genetic information); Health Care Finance Administration, Interim Rules for Health Insurance Portability for Group Health Plans, *Fed. Register*, 8 Apr. 1997;62:16894.

52. See, e.g., New Jersey. *Genetic Privacy Act of 1996*, codified in pertinent part at N.J. Stat., titles 10:5-12, 10:5-43 to 10:5-48.

53. *Federal Privacy Act of* 1974, as amended. 5 *USC*, s. 552a. US Department of Health & Human Services. *Standards for Privacy of Individually Identifiable Health Information -- Final Rule* (2000)*,* codified at 45 CFR 160.101 et seq &164.102 et seq.

B. Historic and Emerging Human Rights Standards

Against this general background, several human rights standards in law prove relevant to genetic testing. Privacy and equality are illustrated in Table A, but these are complemented by other human rights that help to structure legal norms on testing. Many of the leading human rights that flow from formal legal instruments are outlined below. Some date from antiquity. Others are decidedly modern. Most are animated by common concerns and protect similar interests. Because the law may serve as both a dynamic agent of change and conservative agent of traditional values, the legal standards of human rights may sometimes diverge from and sometimes reflect popular views.

1. Human Dignity

Human dignity is the paramount public value in human rights law. It refers to the intrinsic worth and identity of humans. Following grievous violations of human rights in World War II, the concept of human dignity became a foundational principle of modern public international law when it was included in the charter that formally created the United Nations (UN) in 1945. The UN *Charter* proclaims that "we the Peoples of the United Nations determined... to reaffirm faith in fundamental human rights, in the dignity and worth of the human person...." In this context, human dignity functions as a concept whose recognition may arrest violations of the person and abuses of power. It thus serves as both a defence and celebration of individual worth. Similar themes echoed and were elaborated three years later, in 1948, when the UN General Assembly adopted the *Universal Declaration of Human Rights*. In the document, human dignity is the basis for outlining broad, inalienable rights that, it was argued, merit universal recognition. Though the *Universal Declaration* is not legally binding, it has exerted significant influence on subsequent moral, ethical and legal developments.[54] Indeed, many of the rights outlined in the *Universal Declaration* have become central to modern pluralistic societies. The themes and rights of the *Universal Declaration* have, moreover, had a precise effect on legal norms to which Canada is bound to adhere. In 1966, many of them were incorporated into the *International Covenant on Civil and Political Rights*.[55] Canada has signed the *Covenant*, which proclaims a range of inalienable human rights, such as liberty and security of person, equality, consent prior to medical experimentation and privacy. The *Covenant* explicitly recognizes "that these rights derive from the inherent dignity of the human person."

Neither genetics nor late onset diseases are mentioned in the *Covenant*, the *Universal Declaration* or the UN *Charter*. Still, it may have been that they were not far from the minds of

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[54] Humprey J. The UN Charter and the Universal Declaration of Human Rights in the *International Protection of Human Rights*. Luard D, ed. Evan Luard, ed. New York: Praeger, 1967:39-58.

[55] Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966,entry into force 23 March 1976.

those who crafted these international human rights instruments. The law had played an ignoble role before and during World War II, when it commingled with eugenic science to stigmatize, label and violate those already made vulnerable by genetic anomaly in Nazi Germany. Along with others, individuals who were screened and diagnosed as suffering from Huntington disease by the Hereditary Genetics Courts under the German *Law for the Prevention of Hereditary Diseased Progeny* (1933) were subject to compulsory sterilization and sometimes death.[56] This heritage helped to launch a modern human rights revolution after the war.

Today, the legal and moral concept of human dignity gives rise to a range of interests: bodily, psychological and informational integrity, and the general principle of inviolability of the human person. Genetic testing raises a familiar modern concern that well-intended technology might nevertheless be used to reduce people to their biological elements — that biology will confer social, civil and even legal status. In the extreme, to confer legal or civil status on the basis of one's genetic allotment is to allow biology to construct or determine social, economic and cultural opportunities, and human worth. Consistent with the heritage of principles born in another genetic age, the UNESCO *Declaration* invokes respect of human dignity to argue against reducing individuals "to their genetic characteristics," and proclaims that it is imperative to respect individual uniqueness and diversity.[57] Not surprisingly, the *Universal Declaration* of 1948 inspired the central place of human dignity in the UNESCO *Declaration* of 1997. Human dignity is not explicitly mentioned in the *Canadian Charter of Rights and Freedoms*, however. The Supreme Court of Canada has nevertheless held that human dignity is a touchstone value that animates both express and implied human rights norms in the *Charter*, such as liberty, equality, privacy and security of person.[58] In addition to being relevant to human rights, many of these norms are regarded as elements of modern relational existence that are instrumental to human flourishing. Respect of human dignity has also become a foundational principle in ethical deliberations on biotechnology.[59]

2. Liberty

Liberty is a legal principle that protects autonomy in diverse dimensions — from freedom to decline physical restraint or incursions on one's person, to preserving bodily and mental integrity, to free and informed decision making. Canadian courts have recognized that the explicit protection of liberty and security of person in the Canadian *Charter* generally protects individual rights to accept or reject governmental medical interventions on their person.[60] This parallels the general right to informed consent or refusal in health law. Recognition of such

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[56] Harper PS. Huntington Disease and the Abuse of Genetics. *Am J Hum. Genet*. 1992:50: 460-464.

[57] UNESCO, op. cited, art.2; see Table A, above.

[58] See, e.g., *Law v. Canada*, [1999] 1 SCR 597.

[59] See European Union, European Group on Ethics in Science and New Technologies. *Opinion No. 13: Ethical Issues of Health Care in the Information Society.* Brussels, 1999.

[60] See, e.g., *Rodriguez v. British Columbia (A.G.)*, [1993] 3 SCR 519.

rights imposes general duties so as to structure genetic testing initiatives to respect autonomy, informed consent or refusal and thus respect of the person. Since exceptions to the general rule of informed consent are usually limited to compelling and narrow circumstances such as emergencies, a major question is under what particular circumstances and legal standards, if any, should the law authorize non-consensual genetic testing or presumed consent thereto? At a broader level, a commitment to the values underlying informed decision making raises the societal challenge of ensuring meaningful citizen participation in defining national policies on genetic testing.

3. Privacy

> ...the use of a person's body without his consent to obtain information about him invades an area of personal privacy essential to the maintenance of his human dignity. Supreme Court of Canada, 1988.[61]

As the above quote from a case involving drug testing of blood samples illustrates, privacy is a fundamental right expressive of human dignity and autonomy. Often referred to as the right to be let alone, the right to privacy protects territorial, bodily, psychological and informational integrity and decision making.[62, 63] Many of these interests are directly implicated by genetic testing. Recognition of these interests in Canadian law parallels the expressive, informational and like privacy interests debated in the philosophy[64] and legal[65] literatures. Thus, "informational privacy" protects the access, control and diffusion of personal information. Health information entrusted to health professionals gives rise to an individual's reasonable expectations of privacy and corresponding duties on the part of health professionals to preserve confidences.[66] Indeed, partly because "privacy is essential to maintaining relations of trust,"[67] the Supreme Court of Canada has indicated that confidential therapeutic relations enjoy some *Charter* protection. As such, professional duties of confidentiality and loyalty, which codes of ethics impose on many health professionals, are also recognized in law.

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61 *R. v. Dyment*, [1988] 2 SCR 417.

62 *Ibid.*

63 R. v. Mills, [1999] 3 SCR 668.

64 DeCew JW. *In Pursuit of Privacy: Law, Ethics and the Rise of Technology*. Cornell University Press: Ithaca, 1997:73-80.

65 Rothstein MA., ed. *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era*. New Haven, CT: Yale University Press, 1997.

66 McInerney v. *MacDonald* [1992] 2 SCR 138.

67 Mills, op. cited.

Although privacy and confidentiality rank high in the hierarchy of public values, they are not absolute. Recognized exceptions include those authorized in law, an individual's consent or waiver of privacy rights, and overriding duties to third parties or similar pressing public interests. How does the law reconcile the potential conflict between individual privacy and the legitimate interests of family members, institutions, researchers and others, in genetic information, especially when disclosure would likely avert harm to the health or life of others? Such dilemmas present conflicts between rights and diverse public values, such as privacy, health and safety. One important way to reconcile and manage such conflicts is to structure applicable privacy and confidentiality norms so that exceptions to the general duty to preserve secrets are narrow and limited to objective instances of necessity. As such, a broad and general assertion of public safety, for example, would prove insufficient to override the duty. Rather, under the narrow exceptions approach, a claim that genetic testing is justified by public safety would be judged on a narrow and precise legal standard, such as whether the risks were "clear, imminent and serious."[68] As is elaborated in section II.B.8, such an approach accords with the basic legal principles for balancing human rights conflicts.

Privacy rights, duties and standards typically flow from five kinds of laws: i) human rights instruments, ii) privacy or data protection statutes, iii) health professional, health services or medical records laws, iv) common law and civil law confidentiality and privacy standards, and v) genetic privacy laws. As Table A suggests, explicit protection of genetic privacy in statutes — in countries such as Norway, Denmark and the U.S. — marks a leading trend today in legal privacy protections. Since Canada has yet to join this trend, it currently tends to rely on sources i) through iv), above. A few examples illustrate how.

In terms of federal human rights instruments and privacy laws, for instance, the *Canadian Charter of Rights and Freedoms*, the *Canadian Human Rights Act* and the *Privacy Act* offer varying standards and protections. The *Charter* does not specify the protection of privacy. Still, the *Charter* right to be "free from unreasonable search and seizures"(section 8) and rights to liberty and security of person (section 7) have been interpreted as affording a range of privacy protections. The interpretation is consistent with the recognition of privacy as a fundamental human right in the *Universal Declaration of Human Rights* (article 12). It is consistent, as well, with the treaty obligations of Canada, under the *International Covenant on Civil and Political Rights*, to respect human privacy.[69] Indeed, the implied privacy rights of the *Charter* have been interpreted by the Supreme Court of Canada as protecting access to and control over the information contained in one's bodily tissues.[70] As such, the *Charter* likely affords some

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[68] See *Jones* v. *Smith* [1999] 1 SCR 455. See also section IV.C.1, below.

[69] See Table A, above.

[70] See *Dyment*, op. cited.

protection of individuals' reasonable expectation of genetic privacy against undue government intrusion. The highest reasonable expectation of privacy is likely to lie in "identifiable" genetic information — that which may be linked to identity.[71] As indicated, the privacy interest would need to be weighed and balanced against other compelling societal interests. Because no genetic and few analogous medical testing cases involving *Charter* issues have been decided by high courts in Canada, the precise degree of *Charter* protection of genetic privacy remains uncertain.

Beyond the *Charter*, federal statutory protections of privacy vary. The *Canadian Human Rights Act* offers few, if any, privacy protections. It resembles most provincial human rights acts,[72] and is more accurately described as an equality statute because it prohibits discriminatory practices. By contrast, the federal *Privacy Act* offers informational privacy protection by imposing data protection standards on the federal government. It is intended to prohibit the unwarranted collection, use and disclosure of personal information. The Act requires the government to a) collect only the personal information it needs to operate its programs, b) tell the individual how that information will be used, and c) take all reasonable steps to ensure the accuracy and completeness of the information collected. Section 4 of the Act says that "no personal information shall be collected by a government institution, unless it relates directly to an operating program or activity of the institution." Personal information includes that relating to the medical or employment history of the individual.[73] The Act may thus indirectly regulate the processing of genetic information within the government, but the extent of such regulation is open to interpretation. The Privacy Commissioner of Canada has taken an expansive view of the protections offered by the Act, arguing that government institutions should only collect personal information if specific statutory authority exists to do so.[74] This would require analysis and interpretation of potentially relevant federal statutes. What seems clear is that with regard to genetic testing the federal *Privacy Act* offers the general limitations of data protection statutes. The Act may define relevant standards for the use and disclosure of genetic information, yet it offers neither prohibitions nor specific regulations to govern the introduction of genetic testing in the first instance. As the Privacy Commissioner of Canada has noted, the Act was simply not designed to take account of the privacy threats posed by new biotechnologies.[75] Such legal limitations and uncertainties have prompted other nations to enact novel laws to directly address both genetic data and broader issues of genetic privacy.

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71 *Mills*, op cited.

72 Quebec is the notable exception, since its human rights act explicitly protects privacy: 'Everyone has the right to respect for his private life'. See Table A, above.`

73 *Privacy Act*, s. 3, op cited.

74 Privacy Commissioner of Canada. *Genetic Testing and Privacy*. Ottawa, 1992:58-59, rec. 13.

75 Ibid. p. 58.

To complement the application of the *Privacy Act* to government, the Government of Canada recently adopted data protection legislation for the federally regulated private sector. Perhaps not surprisingly, the new federal *Personal Information Protection and Electronic Documents Act* (excerpted in Appendix A) has both strengths and limits regarding genetic privacy concerns. On the one hand, the Act begins to respond to OECD, European and other international norms on personal data protection. It also begins to fill a serious legal void in privacy protection in Canada. The void has meant that for years banks, telecommunications companies, airlines, transportation entities and other companies involved in federally regulated matters have not been obliged to respect public law privacy standards. Such institutions are not bound by the *Canadian Charter*: they are not "government" and do not perform government functions. Nor are they bound by the federal *Privacy Act*, for it also applies only to federal government entities. What is more, as federally regulated entities such companies have generally fallen outside the jurisdiction of provincial privacy laws. This jurisdictional and privacy hinterland was made clear several years ago. Then, an employee of a Montréal-based telecommunications agency sought to invoke the privacy protections of Quebec law to test the legality of a company-imposed drug testing policy. The Quebec courts dismissed the suit, finding that the company was subject to federal regulations.[76] The employees had no recourse under federal privacy law because of the limitations of the *Privacy Act*. The *Personal Information Protection and Electronic Documents Act* will help to address this void by establishing federal privacy protection for the federally regulated private sector.

On the other hand, the new Act would seem to have important limits regarding genetic data. Its title and statement of purpose reveal that it has broad goals that are neither primarily nor significantly directed to health information (see Appendix A). The Act makes no mention of genetic data, though its definition of *health information* likely encompasses genetic testing results and genetic information. The definition includes, for example, "information derived from the testing or examination of a body part or bodily substance..." and information collected in the course of the provision of health services. The Act exempts health data from its provisions for a year. It treats health information like other personal information, meaning that it provides *few* explicit substantive standards, duties or rights on health information *per se*. This stands in contrast to specific legal norms on health and genetic data in European law and guidelines, and those proposed in U.S. law (see Table A). Second, the Act would seem to deviate from the Canadian human rights law tradition of strictly limiting infringements on basic human rights. This is done by creating narrow exceptions to their enjoyment. The Act does generally seem to require consent to the collection, use and disclosure of personal information, but the language in the Act uses leaves important ambiguities and relies on undefined standards. Its exceptions are broad and many, meaning that they may not be sufficiently narrow for the specific sensitivity needs of genetic information. An approach more consistent with the fundamental rights related to the collection and use of health or genetic data would be to explicitly prohibit their collection, save in strictly narrow and compelling circumstances. This approach has support in international

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[76] Kealty v. SITA (1991) R.J.Q. 397 (C.S.)

data protection laws[77] and Canadian privacy law.[78] Third, the remedies for alleged violations of the Act may prove to be incommensurate with the vital privacy needs of those whose health or genetic privacy is infringed. The Act does allow those aggrieved to file written complaints for an investigation by the Privacy Commissioner, but it may not provide a sufficiently expedited process for preventing or stopping egregious violations of health or genetic privacy that cause irreparable harm. Finally, the Act might provide optimal protection of informational privacy if it were to apply clearly across the country as a minimal standard for health information. Such an approach would directly harmonize with provincial laws that impose higher standards for health information.[79] With the issuance and implementation of regulations under the Act some of these concerns may effectively be addressed. But these and related matters of health data, combined with the novelty of the law, suggest the need for further analysis, consultation, scrutiny, and likely reform. Any such review should ensure that the law also harmonizes with the health data and confidentiality standards of other federal laws and the basic principles of human rights law and the *Canadian Charter*.

4. Property

> Personal health data must be considered in the framework of the rights of personality... since personal data continue to reflect the data subjects' identity, they cannot be treated as entirely separate from her/him. Thus, some countries regard sensitive personal health data as inalienable in order to protect the dignity of the individual. European Union. European Group on Ethics in Science and new Technologies, 1999.[80]

As suggested in the Introduction, the *Moore* case from a decade ago opened debate on whether concepts of genetic ownership would promote or erode human rights in this biotechnology age. The concept of property as a human right has received mixed legal support in Canada. Article 17 of the *Universal Declaration on Human Rights* declares that all individuals have a right to property and are not to be arbitrarily deprived thereof. In 1960, this principle was adapted into the *Canadian Bill of Rights*. It refers to the enjoyment of property as a fundamental human right.[81] The *Canadian Bill of Rights* has been largely, but not entirely, superceded by the *Canadian Charter*. Property was not explicitly incorporated into the *Charter* when it was adopted in the 1980s. As shown in section II.B.3, above, however, in interpreting the human privacy protections of the *Charter*, the Supreme Court of Canada has not rejected property concepts in its analysis of the dignitary informational interests of patients who entrust medical

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77 See Table A, above: e.g., article 8 of the European Union Privacy Directive and article 6 of Council of Europe data processing treaty.

78 See McInerney v. MacDonald [1992] 2 SCR 138.

79 Cf. s. 30(1) of the Act and *Kealty,* op cited.

80 *Opinion No. 13: Ethical Issues of Health Care in the Information Society.* Brussels, 1999.

81 Stats Canada 1960, c.44. s.1.a.

information to health professionals, or when government non-consensually compels the taking and analyzing of bodily fluids. Such notions have inspired some to ask whether the recognition of limited "property interests" might actually advance human dignity and other societal values.[82] If DNA were stolen, for instance, should the criminal theft provisions of the law apply? Should an indigenous community not have the lawful authority to repossess blood samples that are wrongfully submitted to genetic testing? The desire and need for community repossession might arise when the community has consented to provide blood samples for one kind of testing only to learn that a whole range of unauthorized genetic tests has been conducted in violation of a research agreement.[83] In such instances, should the community have lawful authority to reposses and otherwise control wrongfully acquired genetic information?

Some may argue that recognition of "genetic property" rights in such instances would foster the selling and commercialization of DNA and tissue that may be genetically tested. The claim warrants consideration both legally and practically, even leaving aside the associated ethical[84] issues. Practically, since genes for testing for late onset illnesses such as cancer[85] are patentable[86] and confer exclusive property rights under federal patent law, one may argue that society already recognizes the legal right of some to commercialize genetic processes and materials. Recent reports from the U.S., for instance, indicate that patents have already led to more than 700 genetic tests coming on the market or being developed.[87] Still, we need to be mindful that from a legal perspective property and commerce are not synonymous. One may control, possess and transfer objects, and still not have the right to sell them. Rental apartments are a common example. Thus, property interests might be precisely defined for particular circumstances. Such views are based on the modern legal concept of property, which is less about material objects and more about constructing the rights and duties on how we relate to each other about such things as genetic material. This perspective helps explain why some people have begun to formalize genetic property as a human right — as a bulwark against the increasing ability to access, decipher, store, use and transfer personal genetic information. Indeed, such logic has moved some professionals and legislators to consider or adopt the view that one generally owns one's genetic material and information. Oregon, for instance, originally

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82 See Law Reform Commission of Canada, op cited, pp. 73-76,187. See also Ontario Law Reform Commission. *Report on Genetic Testing*. Ottawa, 1996.

83 See Alphonso C. Natives and Doctor Locked in Blood Feud. *Globe & Mail*, 22 Sept. 2000, p. A1.

84 Poland SC. Gene, Patents and Bioethics -- Will History Repeat Itself? *Kennedy Institute Ethics J*. 2000;10.2.

85 In 1998, for instance, the company Myriad Genetics was awarded U.S. patent number 5,837,492, entitled, "Chromosome 13-Linked Breast Cancer Susceptibility Gene", by the U.S. Patent Office, after having discovered the so-called BRAC 2 gene.

86 Knoppers BM. Status, Sale and Patenting of Human Genetic Material. An International Survey. *Nature Genetics* 1999;22:23-26.

87 Brown K. The Genome Business Today. *Scientific American*, July 2000: 50-55.

relied on broad property language in its genetic privacy statute and has since modified it.[88] Other U.S. states continue to use property concepts for genetic information. Florida law provides that the results of genetic tests are "the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested...."[89]

5. Equality

Evolving notions of justice have given rise to modern standards of equality in discrimination law. Discrimination law and equality theory evolve, even when their basic ends are constant. Hence, the term *genetic discrimination* is decades old,[90] but exploded in the literature and in public laws in the 1990s. The explosion resulted from heightened concerns that existing equality protections may prove insufficient to respond to the growing diffusion of genetic technology and information into various sectors of society. *Genetic discrimination* is a term that uses modern language and emphasis to restate, in a new context, an old and basic proposition: that respect of human dignity means that individuals should not be burdened, mistreated or oppressed due to prejudicial attitudes about such attributes as biological status, race, religion, gender, age or disability. The commitment to non-discrimination as a modern democratic ideal is illustrated by the formal protection of equality in international, national and regional laws (see Table A).

Thus, in Canada, equality protection is encoded in the *Canadian Charter* and in federal laws such as the *Canadian Human Rights Act* (CHRA). Both prohibit discrimination in government action or federally regulated services. They prohibit discrimination on such grounds as race, gender, religion, colour, marital status, disability and family status. Applied to genetic testing for late onset conditions, such prohibitions raise a number of important questions. First, under what specific grounds is one protected against genetic discrimination, because neither law specifically prohibits it? For genetic disorders that are prevalent in particular sexes or identifiable ethnic communities, sex or ethnicity may be one grounds. Race as a grounds has precedent in historic legal cases involving genetics testing (see section IV.C.2, below). Otherwise, the most likely ground is genetic disability or the perception thereof. As in other countries that have parallel disability discrimination laws — such as Australia, the U.K. and the U.S.[91] — the precise definition of *disability* may make it more or less difficult for one suffering from a presymptomatic genetic disorder to come within the coverage of the law. Some jurisdictions have by statute (Australia) or court rulings (Canada) equated actual disability with being perceived or

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[88] See, e.g., Oregon*, Genetic Privacy Act* of 1995. Ore. Rev Stat. 659.700, 659.715, as amended, (effective 2002 the statement "an individual's genetic information and DNA sample are the property of the individual..." is amended to read .."an individual's genetic information is private information that must be protected.")

[89] 44 Flor. Stat. 760.40 (1999).

[90] National Academy of Sciences. *Genetic Screening: Programs, Principles & Research*. Washington, DC, 1975.

[91] See Table A, above.

treated as if one were disabled. This approach broadens the protection. Moreover, as will be shown below in part IV, authoritative Canadian case law on presymptomatic or latent medical disorders makes it likely that individuals with latent or asymptomatic genetic disorders would benefit from the disability or analogous protections of the CHRA.

Second, assuming that one is generally protected by the CHRA, what are the scope and limits of such protection? The CHRA prohibits disability discrimination in such areas as employment and public services. Yet, as with many provincial human rights codes, it exempts some areas from its coverage. Pension and insurance programs are examples.[92] As such, unless the law is altered or unless such exclusions are found contrary to the *Charter*, genetic-based exclusions from disability and life insurance plans, based on actuarially accurate and reasonable guidelines, may not run afoul of the CHRA or analogous provincial[93] human rights acts. The intersection of human rights law and insurance law in Canada defines a novel area for society for which there is little authoritative legal guidance. The Supreme Court of Canada has, based partly on differing provincial human rights laws, ruled that restricting employee disability insurance benefits is discriminatory,[94] and that age- and sex-based differential car insurance premiums are not.[95] A recent review of the CHRA noted the risk of systemic discrimination in actuarial-based exceptions, along with the need to scrutinize statutory exceptions under the *Charter,* and thus the need for broad consultation, rigorous analysis and a full inquiry into the issues.[96]

Third, such exceptions raise the broader issue of lawful discrimination under human rights law due to competing or paramount interests. There may arise instances when pressing societal or institutional interests, such as health and safety, prompt genetic testing or screening that seems discriminatory. The possibility raises questions of whether genetic testing and genetic information are sometimes relevant to legal duties to others. To address such potentially competing interests, the CHRA parallels most Canadian human rights laws by providing an exception to discrimination on grounds of a "good faith and reasonable justification."[97] The mere assertion of a bona fide justification is insufficient to justify an otherwise discriminatory practice. To give full effect to equality, the law demands more. Among other things, the defence generally requires the one asserting it to show that i) a legitimate goal is being advanced ii) by means,

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92 CHRA, ss. 20-22 and implementing regulations. See *Canadian Human Rights Benefit Regulations* SOR/80/68, as amended.

93 See, e.g.,Ontario Human Rights Commission. *Human Rights Issues in Insurance: A Discussion Paper*. Toronto, 1999.

94 *Battlefords & District Cooperative Ltd. v. Gibbs* [1996] 3 SCR 566.

95 *Zurich Insurance v. Ontario* [1992] SCR 321.

96 La Forest G et al. *Promoting Equality: A New Vision --The Report of the Canadian Human Rights Act Review Panel*. Ottawa, 2000:118-121.

97 CHRA, op cited, ss.15(1)-15(2).

standards or practices that are both iii) "rationally connected" and iv) "reasonably necessary" to accomplishing the goal.[98] The reasonably necessary requirement includes an important duty: accommodation up to the point of undue hardship.[99] Thus, as is explored in Part IV, if an employer were to seek to defend an otherwise legitimate genetic testing program on grounds of public safety — and if there were some merit to the claim — the law would still generally require the employer to show that accommodating a genetically susceptible employee would be unreasonable because it would impose "undue hardship." The CHRA refers to health, safety and costs as factors in undue hardship, and the duty to accommodate is "up to the point of undue hardship." These expansive duties are not happenstance, however. By including the duty to accommodate in the defence of good faith and reasonable discrimination, legislators and courts intend to restrict justified discrimination to narrow and compelling circumstances. As with the protection of privacy and autonomy, maintaining narrow exceptions to the infringements of equality gives full and broad effect to human rights.

Finally, assuming that existing federal equality laws offer some protection against genetic discrimination, what practical legal remedies may an individual have? Remedies under the *Charter* and human rights codes vary in terms of cost and process. Filing a formal law suit is the standard remedy for *Charter* violations. Litigation tends to be reactive, slow and costly, however, meaning that *Charter* protection of genetic equality rights may demand considerable resources. The more practical avenue in federally regulated areas is filing a formal human rights complaint with the Canadian Human Rights Commission. This prompts an investigation, a preliminary finding by the Commission and attempts at resolution. If these avenues fail, the Commission would take the complaint to an administrative tribunal, whose findings may ultimately be reviewed in court. The complaint process may thus offer more initial access to protecting genetic equality rights. Still, the novelty of genetic discrimination claims in Canada, and associated uncertainty over the breadth of protection, make it likely that judicial scrutiny may be required to resolve points of law and uncertainty. Of course, some of the legal uncertainty would be reduced by amending the CHRA to clarify its protection against genetic discrimination. Some conflicts over genetic testing under the current CHRA might be avoided if the Commission were to outline in regulations or a policy statement how genetic testing may constitute discrimination in various contexts. This would offer some authoritative guidance on genetic testing practices that are consistent and inconsistent with the Act. As of 2000, while the Commission had outlined analogous standards for drug testing and HIV/AIDS testing, it had yet to do so for genetic testing.

6. Justice

Justice is an ancient democratic concept with multiple facets. Its basic notion of fairness embraces "distributive," "procedural" and "reparative" justice, and substantive standards of equity. Equality has been discussed above. These other dimensions of justice are also pertinent to

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98 British Columbia v. CGSEU, [1999] 3 SCR 3.

99 Ibid. See also *CHRA*, s. 15(2).

genetic testing technology. For example, the distributive justice concern about fairly distributing benefits and burdens is relevant to how society allocates the risks, benefits and burdens of genetic testing. Distribution issues may range from access to genetic testing services, to unduly burdening populations, to the allocation of genetic testing benefits and burdens between generations. "Reparative justice" in this context refers to the right of just reparations for those aggrieved or otherwise wronged by genetic testing initiatives. This parallels the right outlined in the UNESCO *Declaration* to "just reparation for damage sustained as a direct and determining result of an intervention affecting his or her genome."[100] "Procedural justice" refers in part to fair process and procedure for adjudicating alleged legal wrongs from testing. It also raises more general questions about meaningful, inclusive and fair processes of decision making on genetic testing at the individual, institutional and societal levels.

7. Health

Article 25 of the *Universal Declaration of Human Rights* makes reference to health, well-being and medical services, thereby giving some support to claims that modern human rights encompass a fundamental right to health. Article 27 of the *Declaration* states that "everyone has the right to share... in scientific advancement and its benefits." The article would seem to bolster claims that citizens have a right to participate in the health benefits of genetic testing and similar biotechnological developments. Any such rights are not mentioned in the *Canadian Charter*, however; nor are they mentioned in the *Canadian Human Rights Act*. The disjuncture between the *Universal Declaration* and most human rights codes leads to several inferences. It may suggest a) that health is not a human right, b) that societal values and legal thought have not sufficiently coalesced to include health in binding legal human rights instruments, or c) that if there is a human right to health, it would either be implied in existing sources or derive its legal authority from sources other than formal human rights instruments in Canada.

How would a right to health apply to genetic testing issues? Arguably, it implicates at least four interests. First, as the World Health Organization Expert Working Group has suggested, it may translate into reasonable access to basic genetic testing health services to promote individual and public health. Such services may affect prenatal, maternal, child, population and occupational health. Second, it may translate into a right to participate in defining the genetic testing research agenda and public policy on genetic testing. Such a right has particular importance for communities targeted for genetic research. Third, such a right may translate into a public health law requirement that a testing technology not be made generally available until there is evidence that a particular genetic test is not harmful or ineffective. This would apply the oversight, review process and standards of national therapeutics law, such as the Canadian *Food,*

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[100] *UNESCO Declaration*, para. 8, cited in Table A, above.

Drug and Medical Devices Act, to the licensing of genetic testing technologies,[101] laboratories[102] and personnel.[103] Regulations adopted under the Act generally require manufacturers of genetic test kits to show, on the basis of objective evidence, that the kits are "safe and effective" for their intended purposes before they are imported, sold or advertised in Canada.[104] Such legal standards complement professional quality assurance standards,[105] and are intended to harness the benefits of scientific progress for the protection of human life and health. Fourth, a right to health in the genetic testing context may also mean that individuals and professionals involved in genetic testing have rights, and corresponding duties, regarding basic elements of modern health relations: namely, professional competency and integrity, and respect for autonomy and informed consent, integrity, privacy and confidentiality, and equality principles with regard to the development, diffusion and use of genetic testing technology. Legally, these four interests derive from general principles of human rights law and relevant provisions of laws governing health research, services and professionals, privacy, public and occupational health.

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[101] Cf. US Department of Health & Human Services, National Institutes of Health, Secretary's Advisory Committee on Genetic Testing. *Preliminary Recommendations on the Adequacy of Oversight of Genetic Tests*. Washington, DC, 2000.

[102] See, e.g.,US Department of Health & Human Services, Centers for Disease Control. Genetic Testing Under the Clinical Laboratory Improvement Amendments. *Fed Reg*.2000;65:25928-25934.

[103] Mark HF L, Kelly T, Watson MS et al. Current Issues of Personnel and Laboratory Practices in Genetic Testing. *J Med. Gen*. 1995;32:780-786.

[104] Health Canada. *Medical Devices Regulations*. Ottawa, 1998, ss. 9-12,26-32,36 & Schedule I. The revised regulations classify medical devices from Class I-IV, based on the level of risk. Class I present the lowest risk. Class IV devices present the highest risk; accordingly, they are subject to the most stringent regulatory requirements. In general, the regulations classify genetic testing kits a class III in vitro diagnostic medical devices. Compare *Medical Devices Regulations, op cited* and Gutman S. The Role of Food and Drug Administration Regulation of In Vitro Diagnostic Devices—Applications to Genetic Testing. *Clinical Chemistry* 1999; 45(5): 746-749. The regulations and recent trends in genetic testing raise a number of legal and policy issues: e.g., (1) Are national voluntary controls sufficient for the societal regulation of genetic testing laboratories and personnel? (2) If not, what role does and should federal law play? See Centers for Disease Control, op cited. (3) Are current standards sufficient, as a matter of law and ethics, to guide the development of genetic tests through the research and investigational phases? See *Medical Device Regulations*, ss.79-87. (3) How should society regulate "direct genetic testing"-- that is, testing over the Internet or home tests? See Barber JCK. Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public *J Med. Genet.* 1998;35:443-445 (UK). As to the latter, are there helpful lessons from the recent experience of developing regulatory norms for home testing of HIV/AIDS? See Schopper D, Vercauteren G. Testing for HIV at Home: What are the Issues? *AIDS* 1996;10:1455-1465.

[105] See McGovern MM, Benach MO, Wallenstein S et al. Quality Assurance in Molecular Genetic Testing Laboratories. *JAMA*.1999;281:835-840.

8. Weighing and Resolving Human Rights Conflicts

Perhaps because the evolution of modern pluralistic and democratic society depends partly on the resolution of important legal clashes, the law has adopted approaches and standards to identify, weigh and reconcile human rights conflicts. First, legislatures and courts have established a hierarchy of laws. Under the hierarchy, the *Canadian Charter* and provincial human rights codes are respectively of constitutional and quasi-constitutional status. Practically, this means that in cases of direct conflict, human rights laws usually trump other laws. This is consistent with the high public values, if not supremacy, that society has placed on human rights. Second, to give full effect to that supremacy, the courts have generally adopted a "purposive approach" to interpreting human rights laws. The purposive approach means that the courts will generally give an expansive and broad interpretation to human rights provisions, to give full effect to human rights and duties.[106] Thus, for example, in arguments about whether an asymptomatic individual afflicted with a genetic anomaly, HIV or a latent physical defect[107] meets the impairment requirement of some disability discrimination laws, courts applying a purposive approach would tend to find that such an individual is impaired and thus disabled as a matter of law, so that the purposes of curbing discrimination and protecting the individual are advanced. A purposive approach also means that recognized exceptions to human standards are interpreted narrowly. The approach has been largely adopted in equality law, the law of informed consent and privacy law, as noted above.

Third, the fact that there are legitimate and recognized exceptions to human rights standards means that, even with the high public value that society places on them, human rights are not absolute. Rather, to accommodate other important societal interests and values, courts and legislatures have set forth standards and mechanisms to weigh the competing considerations in particular contexts. International human rights law makes provisions for "public safety" and "public order" limitations on some human rights, when the necessities of democracy compel them.[108] In Canada, under the constitutional human rights principles of section 1 of the *Charter*, governments may infringe fundamental rights and freedoms only when strictly necessary — that is, "by reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society." The Supreme Court of Canada has interpreted this language, it generally requiring governments to justify violations of fundamental *Charter* rights by proving the following: that the legislation or government policy in question 1) addresses a "pressing and substantial" objective, 2) employs means that are "rationally connected" to the government

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106 *Action Travail des Femmes v. Canadian National Railway* [1987] 1 SCR 1114.

107 See *Quebec v. Montreal*, noted in Section IV.C.1, below.

108 See, e.g., *Universal Declaration of Human Rights*, op cited, art.29.

objective, 3) impairs rights and freedoms "as little as possible," and 4) is grounded on "proportionality" between the positive and injurious effects of the legislation.[109]

The requirements for justifying invasions of human rights offer insight into genetic testing proposals. The insight is that while the *Charter* makes the requirements technically binding on government testing programs, the standards on which these requirements are grounded help to structure all genetic testing programs so that they are consonant with modern human rights. As the analysis of equality in section II.B.5 indicates, many human rights statutes provide for a defence of "good faith and reasonable justification." Elements of this analysis were invoked to determine whether mandatory drug testing of employees by a federally regulated bank in Canada was justified or unlawful discrimination.[110] Such standards should thus inform both government and non-government testing programs. Hence, genetic testing programs need to address issues of objectives, means and proportionality: How invasive is the particular testing procedure? What precise purpose(s) does it serve? Is the testing method or means rationally related and reasonably necessary to the purpose(s)? Does the information generated narrowly advance the stated objective in a way that minimally impairs human rights? The importance of the kinds and objectives of testing are elaborated in Part III and Table B, below.

The tests for justifying reasonable infringements of human rights also generate a basic question about genetic tests that reveal information about the risk of succumbing to a genetic disorder in the future. If a testing program were intended to advance public safety, for instance, by testing public transport workers for whether they carry the gene for Huntington disease, would the information revealed be reasonably pertinent to risk evaluations about current disabling impairments that may imperil public safety? Or, would it be too remote to be "rationally connected"? The question is explored in Part IV below. Arguably, the increased risk of future disability as revealed by some genetic tests fails to present a direct or significant threat to public safety. Yet, such tests may still invade individual and familial privacy. The information revealed may also be stigmatizing. Significant disproportionality between an invasive test, the information revealed and the stated objective of such testing arguably indicates a testing program would likely be unacceptable and unlawful. Such concerns have prompted some countries to enact legal prohibitions against some kinds of genetic testing for late onset diseases (see section III.B and Part IV, below).

The tests used to determine justifiable infringements of human rights may not always or easily indicate when genetic testing invades privacy or discriminates unlawfully. But they do establish a general approach and precise standards by which claims of human rights infringements and such countervailing justifications as safety may be scrutinized and judged. They may thus help to guide the formulation of genetic testing policy so that it respects basic human rights norms.

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[109] *R. v. Oakes* [1986] 1 SCR 103; *Thomson Newspapers Co. v. Canada* [1998] 1 SCR 877. See generally, Hogg PW. *Constitutional Law of Canada*. Carswell, 1992: ss. 35.10-11.

[110] *Canada v. Toronto Dominion Bank*, [1998] 4 F.C. 205 (FCA).

9. Public Process Norms and Values

The weighing and resolving of human rights conflicts, outlined in the foregoing section, also afford insights into the relationship between substantive values and the democratic process of developing national genetic testing policy. Absent a universally determinative hierarchy of substantive rights in genetic testing, we are likely to have healthy pluralistic conflicts resulting from the occasional clash of privacy, public safety, equality, public health and autonomy. The clash of human rights often resounds with underlying value conflicts. In the face of such likely contests, society needs a fair and effective process to weigh, mediate and resolve them. Canada does have some established process mechanisms for addressing conflicts. The *Charter* and most human rights statutes provide a procedural right to file a legal or administrative claim and be heard in a formal forum, so as to protect against alleged violations of human rights. Such processes give practical meaning and content to fundamental principles. They further suggest that part of the core infrastructure of human rights consists of both substantive and process values.

Such public process norms are vital to national genetic testing policy in ways that may not be readily apparent. Two examples illustrate how. First, most of the reports referenced in Table A have emerged from the public law process of administering, making and reforming law. The reports have largely come from privacy commissioners, parliamentary commissions, advisory committees to ministries of health, human rights commissions and national ethics bodies in diverse nations. Many of these entities, including the national bioethics committees of France and Denmark, are creatures of public law. Governments have resorted to such interdisciplinary expertise for assistance with their legislative, regulatory or general public law responsibilities. The process side of the law has thus played an influential role in fostering deliberation and studies on genetic testing. When such deliberation leads to concrete statutes, directives or regulations — as illustrated in Table A — public process yields new legal norms governing genetic technology, human rights and health standards. This public process of investing resources in i) accountable and interdisciplinary public committees, ii) in research that examines the scientific and ethico-legal challenges of the genetic revolution, and iii) in public reflection that informs and eventually shapes national law and policy is consistent with the responsibilities and roles of government as fiduciary of the public monies and powers with which it is entrusted in a pluralistic democracy.[111]

The second example relates to core aspects of such deliberative processes. It concerns the democratic right of free speech, which has value beyond the important search for truth and the airing and collision of ideas. This right is fundamental to democracies in part because freedom of thought and expression help individuals to relate to others, to define individual and community paths of development, and to foster citizen identity. Again, substantive values relate to democratic process. Indeed, our valuing of speech is complemented by the rules that we craft to define who participates in public debate, government reflections and the ultimate societal

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[111] Jones DJ. *Towards a Coherent Ethics Framework for Biotechnology in Canada*. Canadian Biotechnology Advisory Committee: Ottawa, 1999 (public law model of ethical reflection on biotechnological applications).

direction on science or genetic policy. As some have recognized regarding health policy, "the right of citizens and patients to participate in the decision-making process affecting health care... must be viewed as a fundamental and integral part of any democratic society."[112] Inclusiveness, accountability, transparency, citizen education and participation are thus increasingly regarded as fundamental process norms in the ethics of biotechnology.[113] This echoes the procedural justice concerns noted above. When such elements guide the development of public policy and public laws on genetic testing, they serve the underlying values of human rights in democracy. Process norms thus have particular importance for ministries and advisory committees involved in developing public policy on genetic testing.

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[112] Council of Europe. *Recommendation No. R (2000) 5 of the Committee on Ministers to Member States on the Development of Structures for Citizen and Patient Participation in the Decision-Making Process Affecting Health Care.* Strasbourg, 2000.

[113] Jones, op cited.

III. Testing and its Rationales: Law and Ethics

This section reviews three related and important facets of genetic testing: its definitions, its consequences and its underlying rationales.

A. Language and Definitions: Genetic Testing, Genetic Information

For the law to play an effective role in the societal regulation of genetic biotechnology, it is important that legal standards be directed as precisely and clearly as possible to the relevant activities. This raises questions about the definitions and legal standards of genetic testing. For the licensing of genetic tests, for example, federal law in Canada defines *genetic testing* as " the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis."[114] For some purposes a general definition of *genetic testing* may suffice. But is all genetic testing the same? Standards from the international community suggest not. National advisory committees in Britain[115] and the U.S.,[116] guidelines from the World Health Organization expert committee,[117] genetic testing statutes in such countries as Norway,[118] and even international law,[119] now identify various kinds of genetic testing: diagnostic testing, presymptomatic testing, predictive or susceptibility testing and carrier testing. For instance, the proposed international guidelines from the WHO expert committee defined two kinds of genetic testing that are particularly relevant to late-onset diseases:

> *Presymptomatic testing* refers to the identification of healthy individuals who may have inherited a gene for a late-onset disease, and if so will develop the disorder if they live long enough (e.g., Huntington's disease). *Susceptibility testing* identifies healthy individuals who may have inherited a genetic predisposition that puts them at increased risk of developing a multifactorial disease, such as heart disease, Alzheimer disease or cancer, but who, even so, may never develop the disease in question.[120] (emphasis added)

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114 Canada. *Medical Devices Regulations*, s.1, noted in Section II.B.7, above

115 See British Advisory Committee, under "Policy Guidance" in Table A, above.

116 See US Secretary's Advisory Committee on Genetic Testing. *Request for Public Comments"..,* under "Policy Guidance" in Table A, above.

117 See United Nations, under "Policy Guidance" in Table A, above.

118 See Table A, above.

119 See *Council of Europe Convention on BioMedicine* in Table A, above.

120 See United Nations (WHO), opt cited, in Table A, above.

Such technical terms have been crafted into laws to assist in defining legal standards of conduct. Indeed, when such terms are accurate, generally recognized, used and refined by professional and health authorities, the distinctions they make may add clarity to the purposes and functions of genetic testing initiatives for late onset diseases. Some of these purpose(s) and functions, and the reasons why some applications have been restricted by laws in Europe, are further outlined immediately below.

Beyond the insight that language and workable definitions are instrumental to effective legal standards, some genetic testing laws from abroad further underline the crucial relation between testing and genetic information. The relationship has been noted in the privacy analysis in section II.B.3, above. Thus, the act of taking blood or tissue samples for genetic testing risks invading one's autonomy, and bodily, mental and informational integrity. The consequences of the test may reach more broadly, however. The test results may reveal the genetic heritage of persons both tested and untested. Those tested may have consented to the revelation of genetic information. But the very nature of genetic information also means that relatives who have neither consented to the test, nor undergone it, may have their disease heritage revealed. For such reasons, Norwegian law — like many modern genetic statutes — addresses both genetic testing and genetic information (see Table A). The standards governing genetic information prove relevant to genetic privacy even without testing. A medical questionnaire may ask whether one has undergone particular genetic tests. It may also ask whether one has a family history of diabetes, breast cancer or Huntington disease, meaning that questionnaires alone may reveal personal, familial or community genetic information. When the context for such questionnaires moves beyond the ethical and legal protections of the traditional therapeutic relationship, the risk for abuse may increase. Indeed, as section IV.C.3 indicates, such questionnaires have been implicated in recent legal cases involving wrongful violations of genetic privacy in the workplace. For such reasons, the Norwegian statute follows the trend of modern genetic testing laws by outlining specific controls on genetic information, such as a general prohibition on inquiries about genetic tests. The fundamental relationship between genetic testing and genetic information makes the challenge of setting societal norms more daunting because of its breadth: on what legal grounds should it be lawful to i) undertake genetic testing, and ii) to collect, use, store and disclose genetic information? Yet, if society is concerned about furthering the values reflected in terms such as *genetic privacy*, then its norms and legal controls to do so are more likely to be effective and coherent when they target both "genetic testing" and "genetic information." Legal and public policy norms on both are likely to be informed by different genetic testing rationales.

B. Testing Rationales

As the discussion in Part II and Table A illustrate, there would appear to be a consensus within the legal, ethical and public policy literatures that genetic testing raises human rights issues. In particular, the discussion in section II.B.I — which summarizes some of the standards tests relied on to weigh and resolve human right conflicts — indicates that the kind and weight of the objectives, the necessity of the chosen means and whether they relate rationally to the stated objectives, potential alternatives, and the balance between positive and negative effects, are some

of the critical factors in determining the lawfulness of practices that infringe human rights. Accordingly, a major challenge for genetic testing policy is to articulate, precisely, the rationales and means of testing interventions. This is important for coherent health policy initiatives based on rational decision making. It is also important ethically. For example, if it can be shown that a chosen means of genetic testing (technique A) is more invasive of human rights than another equally effective and less invasive intervention (technique B), then there would seem to be an ethical duty to use technique B. Technique B would afford the more beneficent[121] approach. It would best advance health benefits and best minimize the infringement of human rights. The less invasive, equally effective technique seems ethically preferred. The less invasive, equally effective technique is also legally preferable, if not required. The legal duty is based on the minimal impairment principle of human rights law[122] — that is, the law also adopts the logic of beneficence by generally preferring initiatives that minimally impair human rights in the pursuit of legitimate objectives. This is another means by which human rights law formally balances competing societal values.

Table B outlines some of the leading rationales for testing.

Table B. Testing and Screening Rationales

Screen and Identify
- to treat
- to counsel or educate
- to isolate or segregate
- to monitor or trace
- to warn or protect third parties
- to exclude, disqualify, transfer, discharge

Screen and Not Identify
- to count, survey, or track diseases
- to study or research

Jones DJ. *Medical Screening and Monitoring in the Federal Workplace*. Internal report prepared for the Department of Justice Canada: Ottawa, 1994. National Academy of Sciences. *Genetic Screening: Programs, Principles and Research*. Washington, DC, 1975.

These rationales are directly relevant to genetic testing and information issues for late onset diseases. Five examples show how.

[121]See World Health Organization, op cited,1998. (beneficence as a guiding ethical principle for medial genetics).

[122]See section II.B.8, above.

First, all the rationales are premised on effective testing. Indeed, whether the test is conducted in the hospital, a provincial laboratory or another nation, the professional and the public share a compelling health interest in ensuring the accuracy, reliability and efficacy of various genetic tests. Laws that regulate the licensing of the testing personnel, laboratories and technology[123] thus help advance public health. Once testing has moved beyond an experimental phase, various late onset tests will begin to yield results at an individual and population health level. Testing rationales and means then prove particularly important.

Second, then, how should Statistics Canada and Health Canada in conjunction with provincial epidemiological authorities secure data to profile and count the evolution of late onset genetic anomalies? The Government of Canada may help to do so, for example, through federal law that operates in part on a "screen and count" rationale. The privacy, non-discrimination and statistic-gathering provisions of the federal *Statistics Act*[124] legally facilitate the generation of national epidemiological and health data, such as the Canadian Cancer Registry, which was developed through cooperative programs with provincial health interests.[125] A screen, not identify and count rationale advances this legitimate public health need in a manner less invasive of privacy rights than testing that identifies and counts: anonymity matters legally. Laws and policies to this effect thus advance the twin goals of advancing public health and respecting confidentiality and genetic privacy.

Third, the state-of-the art of therapeutic uses of test results helps to define the rationale(s) on which particular tests are premised. Public health screening of haemochromatosis,[126] a genetic disorder of iron metabolism, may rationally be based on a screen, diagnose and treat rationale, because dietary and early medical intervention may prevent disabling liver disease. A screen and treat rationale may also support testing for predisposition to breast and colon cancer, because early interventions, counselling and monitoring are developed therapeutic interventions. As therapy moves from innovative to established and effective, the precision and cogency of the testing rationale may evolve.

Fourth, depending on the context of application, the cogency of the rationale and its relationship to the means and overall effects of testing may legitimize or discredit a testing proposal. The WHO expert working committee has advised limiting,[127] and some European laws have generally prohibited, susceptibility and carrier testing in non-therapeutic contexts. Why

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123 See *Canadian Medical Devices Regulations*, noted in section II.B.7, above.

124 Rev. Stats. Can. 1985, c. S-19, ss. 6(1), 9(1), 11, 22 (3), as amended.

125 Hagey J. Privacy and Confidentiality Practices for Research with Health Information in Canada. *J Law Med. & Ethics*. 1997;25:130-38.

126 Cogswell ME, McDonnell SM, Khoury MJ et al. Iron Overload, Public Health, and Genetics: Evaluating the Evidence for Hemochromatosis Screening. *Annals Internal Medicine* 1998;129:971-979. See also Allen, op cited.

127 See United Nations (WHO), opt cited, in Table A, above.

would they do so? They may do so with the view that a testing rationale is less compelling in particular contexts, and the information revealed by particular tests is fraught with uncertainties that are likely to have more ill than positive effects. Indeed, the Council of Europe has taken the view that when undertaken not for the health benefit of the individual, predictive or carrier testing for late onset diseases is so disproportionately invasive of the human right of privacy as to be unjustified, save in limited instances such as the protection of public health or safety. Accordingly, it has included a general ban on such tests in its innovative treaty, the *Convention on Human Rights and Biomedicine*.[128] This illustrates a specific application in international law of the proportionality principles relied on in Canadian human rights law to balance conflicts between competing rights and values (see section II.B.8).

Finally, as suggested, some of the rationales and their means for implementation are more likely than others to invade fundamental rights. A rationale to "test, identify and exclude" genetically susceptible workers on the basis of risks to third parties or the public — thus protecting the health and safety of those who may be less well equipped to protect themselves — would seem more compelling than a rationale to test, identify and exclude on the basis of potential risks to the tested individual. Public health and safety laws have long been grounded on such public paternalism of third parties who cannot protect themselves. In similar regard, the public may have a more compelling — and likely a more lawful — interest in the genetic condition of a pilot with a familial history of Huntington disease when the pilot's age is clearly within the general age for late onset than when the pilot is younger. The varying ages raise varying risks and legal justifications for not testing, testing and monitoring, or testing and excluding. As will be shown in a case study below, such rationales prove relevant to the lawfulness of testing in the workplace.

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[128] See COE Convention, arts. 12,26, in Table A, above. See also, Council of Europe, *Explanatory Report to the Convention on Human Rights and BioMedicine*. Dec.1996.

IV. Case Study on Testing in the Workplace: Health, Privacy and Discrimination

The law plays diverse roles in genetic testing in the workplace. Here, the notion of "genetic testing" encompasses genetic screening and monitoring in the workplace. Screening refers to a test usually taken once in a target population to screen those with a likelihood of susceptibility to disease or injury.[129] Monitoring refers to repeated interventions and periodic surveillance to detect unfavourable trends that might be altered. As such, genetic screening may be undertaken first to identify applicants or employees genetically susceptible to workplace hazards. Workers may then be monitored, periodically, to evaluate and minimize harmful exposures and potential genetic damage. As suggested in Table B, above, the theoretical rationales underlying these testing initiatives range from exclusion, to protective reassignment, to research, to counselling and employee health education. This case study examines arguments for and against genetic testing in the workplace. It then examines how those arguments and issues have been applied in particular contexts. The case study reveals important interdisciplinary roles for the law.

A. Arguments For and Against Testing

Workplace screening and monitoring proposals raise several arguments for and against their use. On the one hand, employers may argue that legal, health and safety duties, costs considerations and reasonable use of enabling technology legitimize genetic testing. Employers might argue, for instance, that they have a legal duty to provide a safe workplace[130] and safety duties to the public, and that such duties include a necessity to consider some genetic testing to ensure job fitness. Annual medical exams are required of pilots, and medical screening and monitoring to control exposure to radiation is currently required for some nuclear power workers under Canadian federal law.[131] Similar genetic screening initiatives might be proposed for those genetically predisposed to respiratory illnesses, cancer or heart ailments. Such laws and initiatives are based, it might be argued, on safety and ethical concerns about protecting the vulnerable. If those genetically susceptible to workplace hazards may be identified by modern diagnostic technology, then they may be informed and buffered from the risks by a series of interventions.[132] The use of such technology may thus help enhance health, and avoid the economic costs of absenteeism or higher pensions from illness.

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[129] Ashford NA, Spafador CJ, Hatts DB, Caldart CC. *Monitoring the Worker for Exposure & Disease*. Baltimore: John Hopkins University Press, 1990:3-14.

[130] *Canada Labour Code*, R.S.C. 1985, c. L-2, ss. 124-125.

[131] See Case Study 1, below, in Section IV.C.1.

[132] Rawbone RG. Future impact of genetic screening in occupational and environmental medicine. *Occup Environ Med*. 1999;56:721-4.

On the other hand, employees may first challenge the contours of any applicable legal and safety duties, and then argue that respect for basic human rights and occupational health principles may ensure both safety and equity. For instance, even if the legitimacy of safety arguments were acknowledged, it may be argued that employers have a duty in the first instance to discharge their responsibilities by voluntary screening, health education, joint employee-employer occupational health programs and similar risk-reduction initiatives more accommodating of voluntarism and human rights. Informed employee participation would include the right to know about hazards that might trigger or exacerbate genetic susceptibility. As will be shown, the mandatory versus voluntary basis for screening has long been a prominent issue. In a similar challenge to the means, employees may contest the predictability, accuracy, pertinence and utility of genetic testing for employment standards. These concerns have led, among others, an expert advisory committee to the World Health Organization, the International Labour Organization and the British Nuffield Council on Ethics to question, advise against or urge restrictions on genetic testing applications in the workplace (see box Table C, below). Weighing the invasions against the benefits, workers may thus argue that such testing is unwarranted or should be strictly regulated by law and public policy. Indeed, the general medical screening jurisprudence and literature indicate that employees are most likely to invoke invasion of privacy[133] and discrimination[134] claims to resist non-consensual occupational genetic testing proposals.

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[133] See International Labour Office in Table A, above. See also, Sections II.B.3 & B.5 above, & IV.C, below.

[134] See Rothstein, MA. Genetic Discrimination in Employment and the American With Disabilities Act. *Houston L. Rev*. 1992; 29:24-84.

B. Historical Insights

To understand how society sometimes addresses and resolves arguments for and against genetic testing, they may be examined in an historical context and informed by particular cases on how screening initiatives have been applied. Table C highlights some relevant historical developments in international public policy and laws on genetic testing in the workplace.

Table C. Genetic Testing in the Workplace: Selected Historic Highlights

1964: U.S. chemical manufacturer undertakes cytogenetic monitoring of employees through pre-employment medical exams, to build thousands of chromosomal profiles of workers.

1968: The UN adopts a resolution inviting the international community to study, among other things, the protection of human integrity in light of advances in biology and medicine.

1970: A test is developed to screen for sickle cell carriers.

1970–75: As part of a major public health initiative, several U.S. states pass mandatory screening legislation for sickle cell anemia for marriage applicants and school children, among others. Many states later amend the laws to encourage voluntary approaches. Some laws specifically forbid employment discrimination against carriers of sickle cell.

1976: In response to the 1968 UN resolution, the World Health Organization issues a report on health aspects of human rights. The report identifies a dozen biomedical technologies or interventions that risk imperilling the inviolability and integrity of humans, including compulsory medical examinations.

1983: In a study of ethico-legal standards for genetic testing, the U.S. President's Commission on Bioethics calls for strict confidentiality of genetic testing results, such that employers and other third parties have no or limited access to genetic health data.

1988: The Supreme Court of Canada rules that the information contained in one's tissues and cells falls within the privacy protections of the *Canadian Charter of Rights and Freedoms* (see section II.B.3, above).

1990: The U.S. Congress Office of Technology Assessment updates and expands its 1983 report on genetic testing in the workplace. While it finds little change in the small numbers of employers using or having used screening, the report projects increased interest and use in the future as accurate, cost-effective technologies advance.

1991

- Roughly a dozen states in the U.S. enact laws to restrict genetic testing in job settings.
- In a report on genetics in health care, the Science Council of Canada highlights issues of genetic screening in the workplace, and underscores the need for an appropriate legislative framework.
- The American Medical Association issues a formal statement in which it deems it generally inappropriate to exclude workers with genetic risk of disease from the workplace.

1992

- In a report on genetic privacy, the Privacy Commissioner of Canada calls for a general prohibition on collecting personal genetic information in the employment setting, unless done on a voluntary basis (recommendations 12 and 13).
- A Law Reform Commission of Canada study refers to "genetic discrimination" in the workplace and advocates a principle of genetic justice for public policy development.
- The Danish Council of Ethics comments on proposed legislation to govern genetic testing in employment: "From an ethical point of view, the bill may be considered the consequence of a view of society and humankind according to which there must be equal access, to work and social security, regardless of biological differences...."

1993

- The Nuffield Council on Ethics in Britain finds little use of employer genetic testing, and recommends that it be contemplated only in limited instances when the test serves as a last resort for addressing serious health and safety risks.
- The Royal Commission on New Reproductive Technologies of Canada urges that the "control of workplace hazards not be sought through discriminatory personnel policies"(recommendation 35). It calls for increased research to understand and monitor reproductive hazards in the workplace.
- Researchers identify the gene for Huntington disease, a fatal neurological disorder, and the gene for hereditary colorectal cancer.

1994

- Hereditary breast cancer gene (BRCA1) discovered.
- Physicians from the American Society of Clinical Oncology endorse legislative efforts to prohibit employer discrimination based on inherited susceptibility to cancer.
- Norway adopts broad genetic testing legislation. It requires consent to genetic testing, limits access to genetic data, and restricts the use of predictive testing.

1995: Four years after first addressing genetic testing, the French National Bioethics Committee releases a formal ethics opinion in which it argues that genetic diversity contributes directly to the richness of humanity. The use of genetic information for discriminatory ends, it insists, would severely undermine the societal commitment to equality, human dignity and solidarity.

1997:

- The UNESCO *Universal Declaration on the Human Genome and Human Rights* calls for informed consent, no discrimination based on genetic characteristics and respect for confidentiality.
- The Council of Europe *Convention on Human Rights and Biomedicine* proclaims the right to respect for private life, stipulates that predictive genetic tests be undertaken only for health or health research purposes, and explicitly prohibits "discrimination on grounds of genetic heritage"(articles 10–12).
- An International Labour Organization report notes that current scientific knowledge on genetic testing is insufficient to warrant its use for an occupational health purpose (Technical and Ethical Guidelines, para. 3.20).

1998: WHO convenes an international, interdisciplinary group of experts to review ethical issues in medical genetics. The resulting proposed international guidelines state, on the basis of the ethical principles of non-malificence, that employers and other institutional third parties should not be given access to the results of presymptomatic and susceptibility genetic testing.

1999: The Government of Canada adapts legislation to extend national privacy protection to the private sector. In the U.S., a majority of states adopt varying forms of legislation to protect against genetic discrimination and to preserve genetic privacy.

2000: The U.S. President signs an executive order that generally bans the use of genetic information in hiring or employment actions within the federal government.

The highlights in this selected chronology capture some important trends. They indicate, for instance, that although genetic discrimination and like concerns are decades old, the legal and ethical issues provoked by potential genetic testing in the workplace are increasingly before governments in many countries. As suggested above, new and specific legal and ethical dilemmas are likely to arise as genetic and like biotechnologies move from the research and development stage towards general application in particular sectors of society. How do governments and societies respond to issues associated with genetic testing in the workplace?

The chronology underscores at least three kinds of formal substantive responses. One response involves recourse to studies and developing ethical or policy declarations to guide genetics policy and professional practice. The UNESCO *Declaration*, the Danish Council on Ethics opinion, the proposed policy statement from the WHO experts, and the policy studies of

the privacy commissioners of Canada and Australia illustrate this response.[135] The expansion of existing health and human rights laws to medical and genetic testing is a second response. This may be achieved by court interpretation or by broader enactment of general medical testing legislation. The 1996 enactment of Danish legislation[136] to govern the use of health information in the workplace further illustrates the approach. Doubt that existing policy, health laws or human rights laws offer sufficient clarity or protection prompts a third response: some jurisdictions have enacted new and explicit laws on genetic technology, testing or information. France, Norway and the U.S. have adopted this approach. This latter response is clearly in ascendency. Indeed, the declarations and laws on genetic protection by nations and international organizations evidence an emerging legal and bioethical norm in the international community.

How do some of the established and emerging human rights norms on genetic discrimination and privacy actually apply in concrete instances? It would seem premature to venture a definitive answer. But some indications of their strengths and limits may be seen through a comparative law lense focussed on three historic occupational medicine cases from North America. The first case focusses on genetic testing of pilots for Huntington disease on public safety grounds. The second and third cases involve testing for the genetic disorder sickle cell anemia. Sickle cell is not generally considered a late onset illness, but testing or screening for it does raise important parallels. Both late onset diabetes and sickle cell disease are more prevalent in particular ethnic communities than in the general population, for instance. Screening for the disease may thus target specific communities or populations, and so raises potential issues of stigmatization. There are, as will be shown, also parallels between genetic carriers of sickle cell and carriers of genes for some late onset illnesses. And the legal and bioethical principles raised by the sickle cell cases prove instructive for late onset situations.

C. Sample Cases

1. Case 1: Late Onset Testing for Health and Safety

The first case involves late onset genetic testing of employees on grounds of protecting health and safety. After examining three kinds of occupational screening initiatives that might flow from safety-based rationales, we explor occupational genetic testing for Huntington disease based on public safety.

Whose Safety?

Three scenarios illustrate three occupational and health safety interests that may implicate genetic information, genetic testing and human rights. First, initiatives might be undertaken to protect the employee. It may be prudent, for example, for a 35-year-old female who has recently recovered from hereditary breast cancer to minimize her exposure to non-

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135 See Table A, above.

136 Ibid.

therapeutic radiation.[137] To evaluate and manage the risk of returning to work in a nuclear power plant, she may need to evaluate her medical and occupational exposure with both her personal doctor and company occupational health professionals. Indeed, depending on the level of likely exposure to occupational radiation, federal law may require the company to measure and monitor her exposure.[138] If the company refuses to rehire her because of potential susceptibility to cancer, would her rights be violated? Reasonable minds may differ over how much employer paternalism based on employee safety is legitimate. But its lawfulness would diminish under the minimal impairment doctrine of human rights law, if it could be shown that rigorous monitoring or similar but less exclusionary options may both protect health and not infringe rights (see sections II.B.8 and III.B, above). Indeed, in a recent case, a high-level U.S. court found such paternalism unlawful. The court ruled that a petrochemical company had violated federal disability discrimination law when it refused to rehire a worker after a routine employment medical exam had revealed that the employee had a liver condition that the company feared might be aggravated by hazardous chemical work.[139] The ruling is consistent with an earlier U.S. ruling on the paternalistic exclusion of a building repairer with diabetes from the workplace.[140]

Second, initiatives might be undertaken to protect fellow employees from safety risks associated with late onset genetic disorders. If it were determined, on the basis of objective scientific evidence, that an employee's diabetes posed significant safety risks to co-workers, then the medical management of the worker's diabetes might be a legitimate legal concern to the employer and fellow workers.[141] Under such circumstances, Canadian disability case law indicates that the relatively diminished risks posed by generally less severe late onset diabetes — in contrast to insulin-dependent early onset diabetes — are germane to evaluating safety and fitness requirements.[142] An employer's duty to provide a safe workplace[143] may then justify narrow invasions of the privacy and equality interests of the worker. When a safety-sensitive worker's late onset diabetic symptoms and the associated risks may be controlled by oral medications and diet, as is typically the case, the employer's duty to accommodate the disability

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137 Goss PE, Sierra S. Current Perspectives on Radiation-Induced Breast Cancer. *J. Clin. Oncology* 1998;16:338-347.

138 Canadian Nuclear Safety Commission, *Radiation Protection Regulations,* s.8, adapted under the *Nuclear Safety & Control Act,* Stats. Can. 1997.

139 *Echazabal* v. *Chevron USA*, 213 F. 3d 1098 (9th Cir. 2000).

140 *Bentivegna* v. *United States Dept. of Labor*, 694 F. 2d 619 (9th Cir. 1982).

141 See *Canadian Pacific Ltd.* v. *Mahon* (1988) 1 F.C. 209 (Fed. CA) (insulin dependent worker poses safety risks).

142. See *Bahlsen* v. *Canada* [1997] 1 FC 801.

143 *Canadian Pacific Ltd.* v. *Canada* (1991) 1 F.C. 571 (Fed. CA) (HIV-infected rail cook not endanger fellow employees).

would likely require a "screen and monitor" or "screen and reassign" policy rather than a screen and exclude policy (see sections II.B.8 and III.B, above).

Third, occupational health initiatives might be undertaken to protect public safety. The employment discrimination case law is clear, for example, that medical examinations and standards that are imposed to protect public safety are lawful under particular circumstances. The precise workings of this public safety rationale may be seen in the following case involving occupational genetic testing for Huntington disease.

In turning to it, it should still be generally noted that the lawfulness of genetic testing or screening to advance any of these safety interests — to the worker, co-workers or the public — depends in part on how the nature of the test conforms to human rights standards. Whether the test is diagnostic, predictive or for predisposition proves important because of the specificity, accuracy and usefulness of the information revealed relative to the goal and impact of testing. For instance, a diagnostic test to determine whether one has diabetes now is directly relevant, more accurate and a more useful intervention for evaluating the risks that an employee currently poses, than a test that probes the risks associated with a future disabling illness. Comparing a situation in which a pilot with symptoms is compelled to submit to diagnostic testing for Huntington disease and one in which an asymptomatic pilot is compelled to submit to predictive testing for Huntington disease reveals the working of the standards.

Public Safety and Huntington Disease

Diagnostic and Predictive Testing. Huntington disease (HD) is a lethal inherited disorder that affects the central nervous system. According to the Huntington Disease Society of Canada, it affects roughly one in 10,000 Canadians. Its disabling effects are telling:

> Huntington disease is a progressive disorder of motor, cognitive, and psychiatric disturbances. About 2/3 of patients present with neurological manifestations, while others present with psychiatric changes. The mean age of onset is 35 to 44 years. In the early stage, manifestations include subtle changes in coordination, minor involuntary movements, difficulty in mental planning, and often a depressed or irritable mood... In the next stage, chorea becomes more prominent with increasing difficulty with voluntary activity and worsening.... Most patients are forced to give up their employment and become increasingly dependent on others for help, although they are still able to maintain a considerable degree of personal independence. The impairment is usually considerable, with intermittent outbursts of aggressive behaviors.... In late stages of HD, behavior problems are gradually lessened; motor disability becomes severe.... The median survival time after onset is 15 to 18 years. The average age at death is 54-55 years....

> Abnormalities of cognition. A global decline in cognitive capabilities occurs in all HD patients. Cognitive changes include forgetfulness, slowness of thought processes, impaired visuospatial abilities, and impaired ability to manipulate acquired knowledge....[144]

The discovery in the early 1990s of the gene for HD has thus far yielded mixed blessings. For diagnostic testing, the test adds another tool for assisting physicians in removing doubt over the diagnosis of HD.[145] For predictive testing, it offers difficult choices, largely because medical science currently offers neither a cure, nor effective medical treatment for HD. Predictive testing enables those at risk to know with virtual certainty whether they have the gene that causes HD.[146] A negative test enables those at risk to be free of the medical, psychological and social burden of the illness. Those who test positive may use the information to plan their lives. The deep implications of testing have prompted professional groups to specify the conditions under which predictive testing should optimally occur.[147] The potential implications for insurance have even driven some individuals to seek predictive testing safe havens in countries in which they do not reside.[148] Indeed, because of the broad social impact of a positive result, health professionals recommend that effective pre-test counselling and informed consent procedures require discussion of the potential stigmatization and impact on employment and insurance matters.[149]

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144 Huq Mahbubul AMH, Hayden MR. Huntington Disease (Sept. 1998) [www.geneclinics.org/profiles/huntington/details.html].

145 Ibid.

146 Benjamin CM, Adam S, Wiggins S, Theilmann JL, et al. Proceed with Care: Directive Predictive Testing for Huntington Disease. *Am J Hum Gen*.1994;55:606-617.

147 International Huntington Association and World Federation of Neurology. Guidelines for the Molecular Genetic Predictive Test in Huntington's disease. *J Med Gen.* 1994;31:555-559.

148 See Burgess MM, Adam S, Bloch M, Hayden MR. Dilemmas of Anonymous Predictive Testing for Huntington Disease: Privacy vs. Optimal Care. *Am J. Med. Gen*.1997;71:197-201.

149 Benjamin, op cited. McKinnon WC, Baty BJ, Bennett RL et al. Predisposition Genetic Testing for Late-Onset Disorders in Adults. A Position Paper of the National Society of Genetic Counsellors. *JAMA* 1997 278(15);1217-1220.

In this context, a case of attempted genetic testing of an employee for HD has been noted in the literature. The test was requested to be undertaken at a university genetic testing clinic. The request came from the employee's company:

> We have had a request from a major air transportation company to do the predictive test on an employee without informing the latter — specifically, by obtaining a blood sample under false pretense. This at-risk employee is a pilot, and the company wished to learn whether he is likely to have HD in the future, because it could influence his continued employment as a pilot. This pilot, at the time of the company's request, did not wish to have predictive testing because he felt that the information could be detrimental to his future career plans.[150]

Though the report indicates that the clinic declined to do the testing, it does not specify the age of the pilot or the precise rationale that animated the genetic curiosity of the company. Such curiosity, as will be shown below in a legal case from the U.S., is generally insufficient to justify non-consensual testing. For our analysis, let us assume that it is a passenger airline company that wants to test for public safety purposes. Let us imagine that the pilot is 27 years old with a family history of HD, which he may have disclosed during one of his annual or periodic medical fitness examinations that are required of pilots under Canadian federal law.[151] If the test were to be conducted without the employee's knowledge or consent, would his rights be violated under federal law? If he were to suffer adverse employment opportunities by refusing to be tested, would his human rights be violated?

Federal and National Laws. Leaving aside the potential claims that the employee might have against the health professionals[152] or the clinic, the federal law issues require us to answer two questions: a) What human rights are implicated, based on what precise sources of law? And b) Assuming an infringement of human rights, is it reasonably justified? As to the first question, the implicated human rights include equality, privacy and autonomy, as protected by such sources of law as the *Canadian Charter*, the *Canadian Human Rights Act* and federal privacy law. Section II.A indicates that if the testing involves government action, then the *Canadian Charter* would apply. An example would be if a safety-based occupational standard in the Canadian Aviation Regulations were to disqualify those with, or at risk of, inheriting a late onset disease from becoming commercial pilots. In the latter instance, even if the direct employer were a private national airline, the hand of government would be clear and active in setting the standards under

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150 Higgins M, Bloch M, Kanani S et al. Ethical and Legal Dilemmas Arising During Predictive Testing for Adult Onset Disease: The Experience of Huntington Disease. *Am J Hum Gen.* 1990;47:4-12.

151 Transport Canada. *Canadian Aviation Regulations*, s. 424.04.

152 If surreptitious testing were undertaken, the medical team would be theoretically liable for non-consensual touching of one's person (battery), negligent informed consent, breach of confidentiality, invasion of privacy and fraud.

which private airlines choose their pilots. *Charter* protections of privacy, equality and autonomy would then apply, as well as the tests for balancing such human rights against pressing societal interests such as public safety (see sections II.B.3, 5 and 8, above). If the testing were imposed without government action, at the insistence of the airline, then the airline as a federally regulated enterprise would fall subject to applicable federal human rights, privacy and related laws. This seems to be the case here. In terms of privacy, then, section II.B.3 showed that that the federal *Privacy Act* only regulates government, so it is inapplicable to a private commercial airline. The health data provisions of the new federal legislation to govern the federally regulated private sector, the *Personal Information Protection and Electronic Documents Act*, do not take effect until 2002. As such, federal privacy law thus offers no current protection against such testing (see section II.B.3, above). To help to address this void, Part V proposes selected federal privacy law reforms.

Disability Discrimination? The most likely source of current protection is the *Canadian Human Rights Act* (CHRA). The threshold issue under the CHRA is whether the employee enjoys protection against "disability" discrimination.[153] Section 25 of the Act defines *disability* to include "any previous mental or physical disability." The case law that has interpreted such definitions indicates that those with clear illness, asymptomatic disorders,[154] predisposition[155] to illness or perceived[156] illness are likely to enjoy the disability discrimination protections of the CHRA. As such, a person diagnosed with HD will clearly be considered "disabled." A person genetically predisposed to develop HD is also likely to be considered disabled, though this is less clear. It would be consistent with the purposive approach of human rights law to give a full and broad interpretation of the word *disability* so as to extend the rights and corresponding duties that promote human dignity to the fullest reaches of the law.[157] Indeed, in recently noting that such terms are not to be rigidly confined to a narrow interpretation, the Supreme Court of Canada referred to genetic advances as a dynamic that weighs in favour of a broad and evolving legal definition of disability. In a case involving an employee's latent, asymptomatic spinal disorder, the Court noted that a disability "may be the result of a physical limitation, an ailment, a social construct, a perceived limitation...."[158] The attitudes, stereotypes and myths that define how we perceive a condition of biological status may, in short, be as disabling for the individual and society as any physiological impairment or genetic disability itself. As urged in Part V, technical

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153 See Section II.B.5, above. See generally, Gin BR. Genetic Discrimination: Huntington's Disease & the American with Disabilities Act. *Columbia L Rev.* 1997;97:1406-1434.

154 *Briggs & Cole v. Hudson (1988), 9 CHHR D/5391. See generally, Jones DJ, Sheppard NC. AIDS & Disability Discrimination in and Beyond the Classroom. Dalhousie L J. 1988;12:103-130.*

155 *Levac v. Canda* [1992], 3 F.C. 463 (T.D.) (healthy worker's predisposition to heart attack).

156 *Quebec v. Montreal* (2000) 1SCR 665 (hereinafter Boisbriand).

157 See Section II.B.8, above, citing *Action Travail des Femmes*.

158 *Boisbriand,* op cited, para 79.

amendments to the CHRA will heighten certainty, provide clearer legal standards, and remove ambiguity about the protection of equality rights of those with latent genetic disorders under federal anti-discrimination law in Canada.

Assuming the pilot falls within the protections of the law, he must show that he has suffered employment discrimination. Typically, this would mean that because of genetic disposition the pilot has suffered an employment adversity, such as discharge, demotion or want of promotion. It might be argued that simply being targeted for medical examination and compelled to disclose genetic and medical information that is not required of other employees is discriminatory. A recent genetic testing case in the U.S., however, suggests that employee genetic testing that does not adversely affect an employee's opportunities is not discrimination (see section IV.C.3, below). Though beyond the scope of the public safety focus, such logic leaves open the possibility that employers might seek to screen and exclude those predisposed to HD on the grounds that they will impose an undue burden on employment disability or life insurance packages.[159]

Testing Justified? The answer to the question of whether the infringement of equality rights is justified underlines important differences between how diagnostic and predictive testing advance public safety relative to the infringement of human rights. Genetic testing may be authorized in narrow circumstances — that is, if it specifically qualifies as a "good faith and reasonable" justification. To do so, the airline must generally show that i) a legitimate goal is being advanced in good faith ii) by means or standards that are both iii) "rationally connected" and iv) "reasonably necessary" to accomplishing the goal. The reasonably necessary requirement includes a duty to "accommodate to the point of undue hardship." The CHRA refers to health and safety as factors in the analysis of "undue hardship" (see section II.B.5, above).

Public safety is, without doubt, a legitimate and compelling societal and institutional goal. Perhaps due in part to the high public value that society places on the protection of health and human life, the courts have recognized public safety as a "pressing and substantial" objective of pilot fitness standards in national and international civil aviation safety.[160] An argument that the HD testing requested in this instance meets the requirement of "good faith" testing would be undercut by the want of honesty that accompanies a request to test surreptitiously or under false pretenses.[161] Whether the genetic testing of pilots with or at risk of Huntington disease is "rationally related" and "reasonably necessary" to public safety depends on the information revealed by particular testing policies and the strength of the testing's relation to risk. In general, medical examinations that target the diagnosis of pilot fitness that pose imminent and significant risks to aviation safety are likely to be judged "rationally related" and "reasonably necessary" to ensure safe job performance. Applying that logic here, diagnostic genetic testing for Huntington

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159 See the brief discussion of insurance in Sections II.B.5 above & V.C.4, below.

160 *Bahlsen*, op. cited.

161 See Higgins et al, op cited.

disease is likely to relate rationally to the evaluation of safety risks of commercial airline pilots. The medical excerpt above indicates that HD typically impairs and disables motor coordination and cognitive functions, which are relevant to pilot fitness for maintaining public safety. Whether such testing is "reasonably necessary" depends partly on how narrowly drawn a particular policy is so as to advance public safety, and whether there are less invasive means that might advance public safety and accommodate the employee. This raises policy issues as to how "screen and exclude," "screen and monitor," "screen and reassign" and similar rationales and means of testing noted in Table B minimally impair human rights and improve the balance between the positive and injurious effects of testing. A policy of screening and excluding pilots diagnosed with Huntington disease does not satisfy the duty to accommodate the disabled employee when individual testing and medication can precisely target the degree of impairment, and so manage those who pose significant risks without imposing undue costs. The case law has not always required individual testing.[162] Still, under the duty to accommodate, the case law generally favours individual assessment over blanket exclusions.[163] The courts are thus likely to show deference to objective medical expertise and evidence-based testing standards targeted at imminent, clear and significant risks to public safety. In many respects, then, the validity of diagnostic genetic testing of Huntington disease in pilots seems, generally, likely to be judged favourably under established legal principles governing occupational medical conditions and employment discrimination case law.

By contrast, non-consensual predictive testing of pilots for HD on public safety grounds is unlikely to fare well under the CHRA. Such testing generally seems unlikely to be judged "rationally related" and "reasonably necessary" to safe job performance, unless the company were to show a strong relationship between public safety, the particular testing policy and future impairment. The information revealed by predictive genetic testing for HD provides, relative to other late onset illnesses, a highly accurate indication of future illness and disability. Under current medical science, a positive test for the 27-year-old pilot means that as a carrier of the HD gene he is condemned to develop the disease. Yet, the nature of the information revealed by predictive testing necessarily concerns health risks in the distant future. They are remote. They are not proximate to an evaluation of current risk. Arguably, the information is irrelevant to issues of imminent, significant and clear risks to public safety. Asymptomatic carriers of the HD gene may perform their jobs safely for many years. In short, a policy of predictive genetic testing of pilots for HD on public safety grounds seems unlikely to be judged rationally related to current public safety. The means relate poorly to the end. In a recent case, the failure of a mandatory occupational drug testing policy to relate rationally to the goal of safe and efficient job performance was a key factor in it being found unlawful.[164]

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[162] Compare *Bahlsen,* op cited, and *Hines* v. *Nova Scotia* (1990) 43 D.L.R. (4th) 491 (N.S.S.C.).

[163] *British Columbia v. British Columbia,* [1999] 3 SCR 868.

[164] *Canada v. Toronto Dominion Bank*, [1998] 4 F.C. 205 (FCA).

Nor is predictive genetic testing of pilots for HD likely to be judged "reasonably necessary" to ensuring public safety. It is not necessary, since other interventions may evaluate public safety risks in a manner more accommodating of human rights. Evaluating and monitoring pilot fitness through standard diagnostic testing during periodic medical exams, for instance, more directly reveals illness or disability that poses imminent risks to public safety. The same may be true for concerns about future safety. Diagnostic testing and medical monitoring are also more accommodating of at-risk employees and less invasive of human rights, because they require the disclosure, sharing and distribution of a narrower range of the employee's genetic or health information. The narrow range helps to minimize the risk of the information being used in a discriminatory or stigmatizing manner. Accordingly, consistent with the requirements for balancing human rights against other pressing societal goals, such means are more proportionate, less invasive and more beneficent (see sections II.B.8 and III.B, above). Such issues underscore the current limitations and concerns about resorting to predictive genetic testing in non-therapeutic contexts. Indeed, as indicated, the nature and potential abuse of the information received from predictive genetic testing in non-therapeutic contexts have prompted some in the international community to prohibit or strictly regulate non-therapeutic predictive testing. Norway has done so; moreover, some 30 European nations that have signed a treaty that aims to do so (see Table A).

2. Case 2: Genetic and Race Discrimination — Screen and Exclude or Monitor?

The second case arose decades ago amid national attention to address sickle cell anemia in the U.S.[165] Sickle cell anemia is a genetically caused blood disorder that affects a minority of blacks and others originally from the Mediterranean basin. Those who receive the sickle cell gene from both parents will have the chronic anemia and fragile, abnormal blood cells characteristic of the disease. Particular circumstances such as dehydration and acute oxygen deprivation can provoke these fragile blood cells to sickle. The sickling, in turn, prevents the transport of oxygen to tissues, and so may cause organ damage. Those who receive only one gene become carriers for the disease and are referred to as having sickle cell trait (SCT); they are generally without symptoms. In 1970, at about the time a test was developed to screen for sickle cell, the medical literature reported the deaths of four African-American army recruits who had collapsed during high-altitude combat training. Autopsies revealed that the deaths may have been attributable to sudden sickle cell crisis associated with SCT.[166] The finding of a potential relationship between carrier status and subsequent illness denotes a notable genetic and medical occurrence that parallels late onset disease. Often, carriers of genetic disorders only risk transmitting the genetic disorder. In such circumstances, carriers themselves are not at risk of developing illnesses related to the gene. Late onset disorders are notable in part because carriers of the defective gene are predisposed to developing genetic illness. Similarly, the 1970 report in the medical literature that some carriers of SCT might actually experience sickling of the blood cells from oxygen deprivation meant that one's carrier status might predispose one to genetically related illness.

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[165] Reilly P. *Genetics, Law and Social Policy*. Cambridge, Massachusetts: Harvard Univ. Press, 1977:62-86.

[166] Jones SR, Binder RA, Donowho EM. Sudden Death in Sickle Cell Trait. *New Eng. J. Med*. 1970;282:323-325.

Under these particular circumstances, medical testing that revealed carrier status might thus precede on a logic similar to predisposition or susceptibility testing[167] — that is, carriers of the sickle cell gene who would be employed in settings where some oxygen deprivation was common might be screened for predisposition to disabling or lethal illness.

In 1972, two years after the report in the literature, the U.S. military requested the advice of the National Academy of Science (NAS). It was also a year during which two other military trainees with SCT collapsed.[168] In 1973, the military followed most of the NAS recommendations and instituted a policy of screening and excluding from military service those with sickle cell anemia; those with SCT were excluded from training and assignments as pilots and divers.[169] The policy thus operated on both diagnostic and predisposition and susceptibility testing analyses (see Table B and sections II.B, above). In 1979, six blacks with SCT were disenroled for medical reasons from the U.S. Air Force Military Academy. In 1980–81, one of the six blacks, who had been a star athlete in high school, instituted a lawsuit to challenge the exclusion.[170] Was the exclusion discriminatory? The courts seem not to have answered the question, because the case was apparently settled. In 1981, the restrictive policy of excluding those with SCT from flight status was modified.[171] The military thereafter moved towards gathering further data on the safety issues associated with SCT through research and by monitoring recruits with the condition. The change underlines a shift from a screen and exclude rationale to a screen and monitor or research rationale for the genetic testing.

It should be noted that, to the extent the lawsuit partly prompted the revised policy, the law played an active role in re-allocating the risks of discrimination and risks to health. The lawsuit apparently left unchallenged the screen and exclude rationale for those with sickle cell disease. It likely did so on important safety grounds — evident risks to recruits, co-workers or the public. Such exclusion might be authorized under the legal standards relied on to determine when an infringement of human rights is justified: namely, given a compelling societal interest in public safety, diagnostic testing for sickle cell disease is "rationally related" and a "reasonably necessary" means of furthering safety; whether the policy "minimally impairs" equality would seem to depend on whether the exclusion is narrowly or broadly drawn, such as ineligibility from all positions or only from safety-sensitive ones.[172] The same legal standards would apply to

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167 See section III.A, above.

168 Brodine CE, Uddin, DE. Medical Aspects of Sickle Hemoglobin in Military Personnel. *J National Med. Assoc.* 1977;69:29-32.

169 Diggs LW. The Sickle Cell Trait in Relation to Training and Assignment Duties in the Armed Forces. *Aviation, Space & Envt'l Med.* Mar.1984:180-185.

170 Holden C. Air Force Challenged on Sickle Trait Policy. *Science* 1981; 211:257.

171 Severo R. Air Academy To Drop Its Ban On Applicants With Sickle-Cell Gene. *N. Y. Times*. 4 Feb.1981: A1.

172 See Sections II.B. 8 and III.B, above.

justifying testing applicants for SCT. The original screen and exclude rationale for SCT may have advanced the health and safety interests of new recruits and implicated third parties. But it did so at the risk of being unlawfully overexclusive and thus not minimally impairing of affected human rights by restricting the employment opportunities of those with SCT who do not present significant safety risks. The revised screen and monitor rationale may still advance safety interests by individual testing and periodic monitoring, while not limiting the employment opportunities of all would-be recruits with SCT.

The considerations in this historic case raise concerns, even internationally. Under the norms of the International Civil Aviation Organization (ICAO), which sets minimum standards and recommended practices in civil aviation for some 185 countries, pilots with sickle cell anemia would be deemed unfit for flying.[173] Canada has been a member of this specialized United Nations agency since its creation under an international treaty in the 1940s. Indeed, in a recent Canadian case that upheld the regulatory exclusion of those with early onset insulin-dependent diabetes from some pilot licences, ICAO medical fitness standards were acknowledged as creating international legal obligations that play an instrumental role in international airline safety. [174] The differing rationales for screening have also prompted reflection within the ICAO on sickle cell trait. In a resolution, the ICAO has declared that "the mere possession of the sickle cell trait should not be a reason for disqualifying him for flying duties in civil aviation, unless there is positive medical evidence to the contrary."[175] The gathering of empirical data[176] on safety matters over time, through the functioning of a screen, monitor and research approach, may allow for refinement, and safe and just implementation, of such policies.

3. Case 3: Genetic Privacy: Screen and Inquire?

> ... One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.... The carrying of sickle cell trait can pertain to sensitive information about family history and reproductive decision making. Thus, conditions tested for were aspects of one's health in which one enjoys the highest expectations of privacy. U.S. 9th Circuit Court of Appeals, 1998.[177]

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[173] Personal communication with ICAO, Aug. 2000, discussing paragraph 6.3.2.18 of Annex 1 to the *Convention on International Civil Aviation.*

[174] *Bahlsen* , op cited.

[175] International Civil Aviation Organization. *Resolution A21-24: Sickle Cell Trait in Civil Aviation*, 1974 .

[176] Drechner DM, Neuhauser KM, Neuhauser TS et al. Death Among US Air Force Basic Trainees, 1956 to1996. *Military Med*. 1999;164:841-47.

[177] *Norman Bloodsaw* v. *Lawrence Berkely Laboratory*, 135 F. 3d 1260(9th Cir. 1998).

The third case involves a recent U.S. court ruling that unjustified routine genetic testing of employees may discriminate and invade personal privacy. The case arose when seven former and current clerical and administrative workers at a government research laboratory claimed that they had been subjected to non-consensual pregnancy, sexually transmitted disease (STD) and sickle cell trait screening as part of a preplacement employment medical examination. The testing was done on urine and blood samples collected as part of an occupational health program from the 1970s to the mid-1990s. Employees were hired on the condition that they submit to a medical questionnaire and medical examination. They claimed they had no knowledge of, or did not consent to, the performance of the pregnancy, STD and sickle cell tests. A major issue contested in the case was whether such tests are a standard part of occupational medical examinations for such employees. A lower court ruled in favour of the laboratory and dismissed the suit. The U.S. Court of Appeals reinstated the case for trial and enjoined the laboratory from conducting further such tests. After the appeals court ruling, the laboratory agreed to settle the case for $2.2 million.

The appeals court ruling is noteworthy in several respects. First, it gives legal authority to the public policy and common sense perception that non-consensual genetic testing in the workplace may violate fundamental human rights. It is important to note that the court was moved by the sensitive nature of both genetic and non-genetic health information. Second, the ruling made clear that equality and anti-discrimination laws offer important but limited standards for evaluating the lawfulness of non-consensual genetic testing. The court found, on the one hand, that genetic testing may racially discriminate: the employment of blacks was conditioned on invasions of health privacy to which non-black employees were not subjected. On the other hand, the court found that the applicable federal disability discrimination law had not been violated, partly because no employee had suffered an adverse employment decision as a result of the testing, and partly because the court interpreted the law in question as not restricting the nature and scope of pre-employment medical examinations. Third, the ruling indicates that privacy law standards will challenge the legality of non-consensual genetic testing based in part on the nature of the test, the sensitivity of the health information revealed and the precise justification or rationale for the testing. While the court seemed to accept the notion that bona fide occupational health programs have a role to play in the workplace, the court made clear that institutions have the onus of justifying a significant invasion of intimate, personal health information. It found that the laboratory had asserted no precise testing rationale other than including the genetic testing as a normal part of a general preplacement medical examination. This echoes the importance of precise testing rationales for human rights law as outlined in section III.B above.

D. Lessons and Resolution

The foregoing cases offer important guidance on how society should begin to reconcile the competing interests related to genetic screening in the workplace. The cases and the chronology suggest that an interdisciplinary perspective provides insights from several sources. From North American and international legal history, for example, it is relevant that the presumed neutrality of science and the social power of medical diagnosis have sometimes been usurped in both non-employment and employment settings to stigmatize, label and infringe the basic human rights of those with genetic disorders. In the job setting, as the above cases suggest, persons with such diverse genetically related conditions as diabetes, sickle cell trait, cancer, short stature and mental disorder have been wrongfully excluded. In other words, the interaction of the law with issues of genetic testing is not ahistoric. Indeed, some may argue that such history should now shape a more nurturant, preventive and modern role for law in our biotechnology era. The new role is activated when jurisdictions such as the Norway, France and the U.S. enact genetic-specific laws with clear legal standards that protect genetic privacy and generally prohibit genetic discrimination and non-consensual genetic testing in employment.[178] A parallel legal role is played by adopting the purposive approach to human rights law. It proves especially instructive in jurisdictions that have not enacted genetic-specific laws (e.g. Canada). A purposive approach to disability discrimination laws means, for instance, that predisposition towards disability (e.g. abnormal genotype) generally is not a lawful basis for excluding, demoting or discharging workers. Rather, such exclusion tends to discriminate on grounds of perceived or actual disability. Thus, construing equality statutes to curb genetic discrimination a) gives effect to the egalitarian purposes behind anti-discrimination laws, b) so protects those with latent or patent genetic disorders, and c) yields a narrow range of exceptional circumstances that must be shown to justify genetic testing or the use of genetic information in the workplace. Such justifications are likely to depend in part on the testing rationales outlined in Table B, above.

A nurturant, purposive approach also means that privacy and equality laws share complementary roles in this domain. In an age when the revolution in genetics has begun to merge with the revolution in data storage and computer technologies, a modern and nurturant role for the law is to advance more fully and coherently the autonomy, bodily integrity and information integrity interests implicated by testing. While equality law should bar discriminatory employment practices based on the use of such information, privacy law should, in the first instance, protect against unjustified invasions of one's person or personal genetic information (see cases 1 and 3, above). Privacy and equality law thus work in tandem to protect against illegitimate screening initiatives.

These roles of the law are consistent with both the historical evolution of international human rights instruments and modern bioethics thought (see section II.B.1, above). Both remind us that privacy and equality concerns emanate from a core concept that inspires and unifies

[178] See Table A, above.

human rights law: respect for human dignity. Finally, from preventive medicine, we are reminded that the goal of occupational and environmental health is to promote the establishment of a safe and healthy work environment.[179] Accordingly, basic occupational health principles hold that the first priority should be to employ environmental, engineering and technological controls to clean a hazardous work site before resorting to excluding potentially susceptible workers.[180, 181, 182] The minimal impairment doctrine of human rights law helps to transform this principle into an affirmative legal duty. This approach protects and promotes the health of all workers, and has already influenced leading employment screening law cases.[183] When this is so, the law helps to prod institutions and technology to innovate technical solutions for a healthy and just workplace.

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[179] See International Commission on Occupational Health. *International Code of Ethics for Occupational Health Professionals.* 1996, discussed in, Soskolne, CL. Ethical, Social, and Legal Issues Surrounding Studies of Susceptible Populations and Individuals. *Environ Health Perspect*. 1997;105 (Suppl 4):837-41. See also, United Nations, International Labour Organization. *Occupational Health & Safety Convention*, No. 155, arts. 4-5 (1981).

[180] Health & Welfare Canada, Task Force on the Periodic Health Examination. Report of the Task Force on Health Surveillance of Workers. *Can. J. Pub. Hlth.* 1986; 77:91-99.

[181] Ashford et al, op cited, pp.109-122.

[182] Royal Commission, op cited under Canada in Table A, above.

[183] See Jones DJ. Reproductive Hazards and the Workplace. *Can. Med. Assoc. J.* 1992; 147:1412-1413 (letter).

V. Conclusion: Working Recommendations

A. Guidance From Human Rights

Before turning to some of the recommendations that flow from the foregoing analysis, a concluding observation about guidance from human rights is offered. It is fitting to do so for the interdisciplinary endeavour of developing national genetic testing policy.

Modern human rights is a heritage bequeathed to us as part of the restructuring of international relations, national constitutions and laws, and even science and medicine in the post-World War II era. Lest it be forgotten, it bears repeating that human rights are not simply abstract ideals. They do influence how we think. But human rights also influence daily deeds and behaviour, in part because they impose enforceable legal duties that govern conduct (see section II.A, above). As such, they most fundamentally concern human relations. The rights-duty dynamic structures how we relate to government, hospitals and health professionals, employers, genetic technology and each other. As part of this continuing revolution, the law helps to nuance, enrich and shape many of the relationships that define modern culture.

It will sometimes be said that respect for human rights may unduly restrain the reach of government, of scientific pursuit and of professional discretion. To sort out such claims, the human rights issues, applicable standards and associated values must be studied in their particular context. Some facets of the claim are clear, however. Humans rights do sometimes work to check and even balance power. They do so for the preservation and promotion of the dignity of humans. This purpose will sometimes function to constrain the exercise of authority. But it will also sometimes work to clarify government responsibilities and sharpen its role(s), as in the pursuit of public health and safety. This function also heightens accountability to citizens. At other times, human rights will protect the intellectual freedom of the genetic researcher. The protection may, in turn, help to advance scientific knowledge, and beget clinical advances that save lives. At still other times, the application of human rights principles will identify standards and workable norms to ensure that communities with unique genes maintain control of access to their genetic material, its uses and the associated genetic information. This is not to say that human rights will ever come close to addressing, let alone resolving, the many societal issues that arise. The argument is more simple: the law of human rights offers principles, standards and processes that may meaningfully guide the development of genetic testing policy.

Within this context, the following recommendations focus on the federal government, for its policies, laws and initiatives may foster coherent genetics testing policy across the nation. The recommendations essentially urge the Government of Canada to adopt a principled framework of public policy and to harness the promise and minimize perils of the modern biotechnology of genetic testing. The framework should be informed by guiding principles that generate specific policy initiatives. Many of the genetic testing laws and guidelines adopted in the international community in the past five years have been inspired by fundamental human rights principles. Canada should draw on and contribute to this evolving initiative.

B. Sample Guiding Principles for Genetic Testing Policy

To ensure that specific applications of biotechnology unfold in a manner consistent with evolving public values, Canada needs guiding principles to help frame the application of genetic testing technologies over the coming years. Because the applications of genetic testing transcend science, such principles should be drawn from interdisciplinary sources and common grounds shared by law, medicine and ethics. The foregoing analysis reveals a number of relevant principles, including the following:

- respect of human dignity;
- protection and promotion of human health;
- equality and non-discrimination;
- privacy and confidentiality;
- autonomy;
- justice, and
- public participation.

Four features should be noted about such principles. First, this sampling is not exhaustive; it is simply illustrative of leading public values that have emerged in law in recent decades, but also in ethics and medicine. Such principles continue to guide the development of public policy on biotechnology in various nations. Second, then, the adoption of such principles is consistent with both leading national and international norms. Thus, conforming with such principles furthers the international legal obligations to which Canada adheres in human rights. It is also consonant with standards that have been articulated by such international organizations as UNESCO and the WHO (see Table A, above).

Third, the guiding principles of such frameworks should espouse both substantive and process values. Clear process and fair procedures are essential, in part because substantive principles alone are seldom determinative of policy outcomes, and in part because some policy contexts may provoke conflicts between principles. Society needs clear process and fair procedures for addressing, deliberating and mediating such conflicts. Indeed, the commitment to equality, privacy and autonomy is critical when defining social applications of genetic testing. But such commitments need processes such as informed consent to further autonomy, and open governance, institutional transparency and inclusive proceedings to advance informed public participation. Finally, the application of guiding principles to particular genetic policies should be informed by leading human rights standards and processes for balancing fundamental principles with other competing societal interests. These include the “purposive approach,” the‘‘rationally connected and reasonably necessary means” test, the “minimal impairment doctrine” and the “proportionality standard” discussed in sections II.B.8 and III.B and Table B, above.

C. Policy Implications and Legal Initiatives

Applying such guiding principles to leading issues of genetic testing generates specific policy implications and legal initiatives.

1. Health Protection and Promotion

A commitment to protecting and promoting human health expresses long cherished values that society holds about human life. Coherent national policy to protect and promote health regarding genetic testing requires minimum standards regarding genetic tests, testing laboratories and the professionals that use them. Consistent with this need is the role that the federal government plays in fostering safe and effective genetic testing technologies (see section II.B.7, above). As noted above, Canadian citizens have, through public law, formally delegated to the Government of Canada national responsibility for regulating new in vitro diagnostic medical device technologies. Indeed, these duties and roles parallel the public health duties of national or federal governments in other countries. Like them, the Government of Canada has unique responsibilities to ensure that emerging genetic testing technologies are safe and effective for their intended purposes. This important responsibility is unlikely to be exercised effectively alone, however. It will require effective collaboration with professional bodies, provincial governments and international harmonizing authorities. It is also likely to require significant educational initiatives for professionals, institutions and the public.

2. Genetic Privacy and Confidentiality

A commitment to respecting confidentiality and privacy in genetic testing is consistent with leading legal and ethical principles in Canada and the international community. Taken together, these principles generally indicate that infringements of human privacy should be strictly limited to a narrow set of compelling societal needs and circumstances. The foregoing analysis has shown that existing federal law offers some privacy protection, but suffers important limitations. Privacy principles under the *Charter* suggest strong protection of the autonomy, bodily integrity and information privacy interests implicated by genetic testing (see section II.B.3). *Charter* principles also indicate that factors such as the precise rationales, means and distributive impact of genetic testing are critical to structuring lawful testing statutes and policy (see section II.B, Part III and Table B). While such guidance is helpful, its limitation to government conduct, the predominantly reactive nature of *Charter* litigation, and standard interpretive divergences are major limitations of effective *Charter* protection. Beyond the *Charter*, no federal law explicitly prohibits genetic testing or the general invasion of "genetic privacy." Nor does existing law specifically, clearly and authoritatively address the collection and use of genetic information. Such fluidity or voids contrast starkly with leading norms in Europe, the U.S. and the international community, where a growing number of jurisdictions provide explicit and often stringent statutory protection of genetic and health privacy (see Table A, above). Canadians would seem to enjoy less clear, less rigorous and, likely, fewer protections of genetic privacy than do many citizens of Europe and the U.S.

Such limitations suggest several avenues that the federal government may pursue to advance genetic privacy policy.

First and foremost, privacy should be recognized in federal policy and law as a fundamental human right that is put at risk by untoward genetic testing initiatives. To minimize the risk, the strengths of existing legal protections in the *Canadian Charter* and federal *Privacy Act*, as well as helpful standards from abroad, should be harnessed to strengthen federal regulation of medical testing and the collection and use of genetic and health information in both the public and private sectors.

Second, in the public employment sector, serious and prompt consideration should be given to drafting a federal directive that generally prohibits and otherwise strictly regulates genetic testing of federal employees. This would parallel prior statements from the Treasury Board of Canada on HIV/AIDS testing,[184] and recently adopted genetic testing policy for U.S. federal employees (see Table A, above).

Third, for the federally regulated private sector, the new federal *Personal Information Protection and Electronic Documents Act* should be strengthened to accord special protections and *explicit* standards for sensitive personal data such as health and genetic information. The standards should be consistent with the privacy norms under the *Charter* (see section II.B.3, above). Because the health data provision of the Act becomes effective in 2002, an opportunity remains to strengthen its health and genetic data applications, perhaps through statutory refinement or regulation. The health or genetic data provisions of the European Union Privacy Directive, Council of Europe *Convention on the Protection of Individuals with Regard to the Automatic Processing of Information* and related Council of Europe policy recommendations, are apt models (see Table A, above). Moreover, to avoid pre-empting and to harmonize with rigorous privacy protections under provincial law, it should be made clear that the *Personal Information Protection and Electronic Documents Act* establishes minimal national privacy norms for federally regulated matters. This would allow the provinces to offer more stringent genetic privacy protections and allow courts to construe provincial and federal law harmoniously (see section II.B.3). Consistent with the need for effective processes to implement substantive rights, the Privacy Commissioner should have clear authority under the Act to seek expedited court orders to suspend and enjoin genetic testing deemed likely to cause irreparable harm.

Fourth, to overcome the limitations of such data collection statutes, prompt and serious consideration should be given to amending the *Canadian Human Rights Act* (CHRA) so that it prohibits "arbitrary or unlawful interference with private life." *Private life* should be defined to include "identifiable health and genetic information," meaning that medical examinations or tests that generate such information would be bound by the law. Regulations adopted under a revised CHRA may detail and define provisions regarding genetic privacy. The language and experience

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[184] Government of Canada. Treasury Board Occupational Health Policy: HIV and AIDS in the Workplace. *Treasury Board Manual, Occupational Safety and Health (OSH) vol., chap.* 1-6. (Revised 1994).

of jurisdictions with specific privacy protections in their human rights and medical testing statutes may guide the precise language and standards. Consistent with the purposive approach and general principles of human rights law, justified exceptions or infringements to the right to genetic privacy should be narrow, precisely defined and based on grounds of objective necessity (see sections II.B.3 and 8). Typical exceptions might include i) informed consent or waiver, ii) protection of public safety on grounds of clear, imminent and serious risk of danger, iii) varying classes of narrow and compelling public interests (e.g. non-identifying epidemiological research), and iv) infringements authorized by law (e.g. court order and statutory or regulatory provisions consistent with the *Charter*). The onus for proving that a testing proposal falls within a justified exception should fall on the one claiming the exception. Consistent with the need for effective processes to implement substantive rights, the Canadian Human Rights Commission should have clear authority under the CHRA to seek expedited court orders to suspend and enjoin genetic testing deemed likely to cause irreparable harm. Thus, including an explicit privacy protection in the CHRA would make clear that human privacy enjoys quasi-constitutional status within federally regulated matters. It would enhance the protection of genetic and health privacy. It would also advance within Canada the principles of the *Universal Declaration of Human Rights*, the *International Covenant on Civil and Political Rights*, and the UNESCO *Declaration*. It would begin to transform the CHRA from a strictly non-discrimination statute towards a full human rights law. Modernization of the CHRA is consistent with human privacy needs in the face of the unfolding revolutions in genetic and information technology.

Fifth, and in a similar vein, a parallel approach may be used to heighten protection of genetic and health data under the federal *Privacy Act*. This should be made part of a proposed review of the *Privacy Act.*

Finally, to develop effective national norms on genetic privacy protection in such areas as the workplace and insurance, such departments as Health Canada, the Department of Justice Canada, the Canadian Institutes of Health Research, and the Privacy Commission of Canada should begin formal collaboration to do so. As part of such collaboration and to further substantive privacy norms, federal government departments should be asked to review applicable medical testing and confidentiality laws. Laws that are insufficient to meet modern privacy norms and the requirements of the *Charter* warrant reform. Government of Canada advisory committees on genetic testing may play an important role in sensitizing and educating the public and government about these needs and priorities.

3. Genetic Equality: Discrimination and Stigmatization

Though nature may not endow us equally, the law should ensure that we are treated equally, despite our rich and vibrant genetic differences. Accordingly, the Canadian commitment under international and national law to equality defines a founding principle of federal genetic testing policy: individuals should not be discriminated against on the basis of genetic composition, heritage or information (see section II.B.5). Recent case law, persuasive analysis from the literature and analogous legal authorities from other jurisdictions suggest that genetic discrimination should be legally intolerable in Canada. Still, the societal commitment to the

protection and promotion of human dignity weighs strongly in favour of minimizing legal doubt or uncertainty about protection against genetic discrimination.

Three initiatives help to advance this need.

First, the *Canadian Human Rights Act* or its implementing regulations should be amended to make clear that the Act i) explicitly prohibits "health" and "genetic" discrimination, or ii) explicitly includes within the definition of *disability* "predisposition to being disabled" and iii) explicitly prohibits discrimination on the basis of "perceived or actual disability." The first option would add new, explicit grounds that would prohibit discrimination on the basis of one's health or genetic status. This is the approach adopted in many foreign jurisdictions. Option two would similarly address genetic discrimination by expanding the legal definition of *disability* to include latent predisposing conditions, such as genetic or physical disorder. This would be consistent with leading cases and with the recommendations of a special review panel that recently urged recommendations to modernize the CHRA.[185] Option three should be pursued in addition to options one or two. It would extend leading statutory approaches in Australia, the U.S. and Ontario, as well as Canadian cases on disability discrimination law, to make explicit that the definition of *disability* includes both actual and perceived disability. The latter would protect against discriminatory treatment though one is not disabled: for example, when an employee is demoted or discharged on the mistaken belief that the employee has the Huntington gene, when in fact the employee does not. The time required for society to deliberate and act on the full ambit of such issues may require interim initiatives.

Second, the Canadian Human Rights Commission should promptly begin deliberations to develop a policy statement on genetic testing in applications such as the workplace. An interim statement might be developed for public commentary before the end of 2001. A final statement should be targeted for 2002. A policy statement on genetic testing and discrimination would be consistent with prior statements from the Canadian Human Rights Commission on HIV/AIDS testing[186] and drug testing.[187] As with these statements, a formal statement on genetic testing would help to educate society. It would provide legal standards and guidance to individuals, employers and institutions on the use of genetic testing technology from a human rights perspective. Sample provisions of the proposed policy statement for employment matters are outlined below.

Third, the development of such norms may be furthered by leadership and partnership among Health Canada, the Canadian Human Rights Commission, the Department of Justice

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[185]La Forest G et al. *Promoting Equality: A New Vision -- The Report of the Canadian Human Rights Act Review Panel*. Ottawa, 2000:101-102.

[186]Canadian Human Right Commission. *Policy on HIV/AIDS*. Ottawa: 1988, revised 1996, www.chrc-ccdp.ca/Legis&Poli/Index.asp?l=e.

[187]Canadian Human Right Commission. *Policy on Drug Testing*. Ottawa, 1999.

Canada, the Privacy Commission of Canada, analogous provincial authorities and professional associations. The Health Canada Advisory Committee on Genetic Testing for Late Onset Diseases may play a critical role in such an initiative by i) inviting the Canadian Human Rights Commission to begin deliberations and collaboration on such a policy statement, and ii) by sharing its interdisciplinary expertise and assisting in shaping the substantive provisions of a genetic testing policy statement.

4. Employment and Insurance Testing: A Nexus

The adoption and implementation of the foregoing recommendations will significantly advance the protection of genetic privacy and genetic equality in federally regulated domains in Canada. They will make clear that both the Canadian Human Rights Commission and the Privacy Commissioner of Canada have authority to seek expedited court orders to enjoin genetic testing that is likely to cause irreparable harms. Consistent with international norms, the recommendations would strengthen the health (and genetic) data collection standards and genetic standards of the new legislation that applies to the federally regulated private sector. The inclusion of an explicit and well-defined privacy protection in the *Canadian Human Rights Act* would provide clearer, more precise and more rigorous standards on both genetic/medical testing and genetic and health information for the federally regulated workplace. The collaborative development of a policy statement on genetic testing by the above-noted players will educate society, specify standards and offer important guidance.

The latter recommendation and its broader context warrant two additional comments.

First, as with the existing Human Rights Commission policy statement on HIV and drug testing, the proposed genetic testing policy statement should specifically address employment matters. Indeed, it is recommended that, among other things, the policy statement i) generally prohibit and otherwise strictly regulate genetic testing in employment contexts, ii) generally prohibit and otherwise strictly regulate pre- and post-medical questionnaires or employment inquiries about whether one or one's family has been genetically tested, and iii) generally prohibit or otherwise strictly regulate presymptomatic, predictive and carrier testing in employment. As noted above, presymptomatic and predictive testing for late onset conditions in non-therapeutic contexts has been prohibited or strictly regulated by some laws in the international community.[188] Consistent with the protection of human dignity, those exceptional circumstances thought to justify either testing or the gathering of genetic information should conform to the purposes and standards of human rights law. That is, the exceptions should be justified by a compelling goal, be precise, narrow, rationally related and reasonably necessary to the goal, minimally impair human rights, and so be limited to strict instances of objective necessity (see sections II.B.8 and III.B).

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[188] See, e.g., Norway & the Council of Europe *Convention* in Table A, above. See also sections IIB.8 and III.B, above.

Second, the policy statement or revised regulations under the CHRA should address genetic testing and information with regard to disability, life and related insurance benefits that are typically included in modern employment benefit packages. The panel that recently reviewed the CHRA has noted the complexity of the intersection of human rights law, insurance law and disability-based discrimination. It convincingly argued that individuals should not be deprived of employment opportunities due to likely exclusion from an employer's pension or insurance plan.[189] If the law were to provide otherwise, it would give licence to genetic-based employment discrimination. This still leaves open the question of equal access to employment-based insurance benefits. The review also called for scrutiny and public study of these matters. Such study should include the arguments for and against genetic testing and use of genetic information in insurance, and the insights and standards on these issues from other countries. Given the diversity of, and evolving views on, insurance in Canadian society, such study and the development of modern and coherent legal norms will require focussed public debate, education and public process.

5. Public Participation, Education and Process

Citizen participation in defining our genetic future is, some would argue, a fundamental human right. Indeed, the public has a right to participate in developing national public policy on genetic testing. Government has a corresponding duty to engage it in the process. The duty derives from the fiduciary responsibilities of government (see section II.B.9). Each ministry implicated by genetic testing derives its public responsibilities from a formal Act of Parliament. Through such Acts, citizens have delegated to the Government of Canada public powers, responsibilities and monies. The monies, powers and responsibilities are held in trust for the benefit for the public.

These responsibilities bespeak important roles and challenges for government. Sometimes, government will exercise its public law responsibilities as regulator, sometimes as defender of human rights, as reformer of law and policy or as facilitator of public process. The development and implementation of national genetic testing policy implicates rights and interests cherished deeply in Canadian society. It raises legal and moral uncertainties and associated value conflicts. Many of these issues — genetic testing and insurance, public health screening of disorders, investing monies for research on new genetic tests — will require the best of deliberative democratic process to debate and advance coherent policy.

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[189] La Forest, op cited, pp. 122-126 & recommendation 135.

Government should discharge its unique responsibilities by engaging the public in the task of building its genetic future. It should do so with a commitment to a range of process norms and values that aim to foster pluralistic debate, education, citizen participation and public oversight. These include a commitment to the following:

- transparency and open governance (e.g. sharing information, documentation and deliberations);
- inclusive problem solving;
- formal and informal public forums;
- meaningful opportunities to be heard;
- accountable, effective deliberative entities, and
- shared decision making.

Three particular tasks warrant special attention.

Defining a Principled Framework. Government should begin a creative campaign to engage the public in the challenges and opportunities of developing national genetic testing policy. It might begin by seeking public participation, comment and input into developing guiding principles for a framework for genetic testing.

Transparency Via the Web. Consistent with the practices of other genetics advisory committees in the international community,[190] the mandate, membership, work agenda, minutes and work products of government advisory committees on genetic testing ought to be made readily accessible to the public. To do so, they should be placed on the Internet in a timely and regular fashion. The creation of a Health Canada website dedicated to the work of its committees would be an important first step in this regard. Government transparency via the Internet requires time, technical support and human investment. It flows from a fundamental commitment to public education, debate and inclusion, and from a judgment to make prudent use of public resources for advancing citizen involvement in scientific and health policy. Such transparency enables scholars, students, voters and government analysts to remain abreast of, and then help to define, the emerging legal issues, ethical questions, policy dilemmas and interdisciplinary challenges of genetic testing. It is consistent with the fiduciary responsibilities of government.

Signing the International Bioethics Convention. Canada should give serious consideration to signing the Council of Europe (COE) *Convention on Biomedicine*. Nations who are not official members of the COE may sign this treaty, which, as noted above, contains provisions on privacy, genetic discrimination and predictive genetic testing. Furthermore, the COE is in the process of developing a protocol to the Convention on genetics. Government should begin a more public process of deliberation and debate on this policy option. Fruitful deliberation on it demands

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[190] See e.g., US Department of Health & Human Services, Secretaries Advisory Committee on Genetic Testing, www4.od.nih.gov/oba/sacx.htm; United Kingdom, Human Genetics Commission, www.hgc.gov.uk.

broad public input, consultation with the provinces, and concerted collaboration among such government entities as Health Canada, the Department of Justice Canada, the Privacy Commissioner, Industry Canada and the Canadian Human Rights Commission. Government genetic advisory committees should study the merits of this option and help to educate both government and the public of its advantages and disadvantages.

Appendix A

Personal Information Protection & Electronic Documents Act
Statutes of Canada 2000, c. 5
(Excerpts)

Entry into force: 2001, application to health data effective 2002

Division I: Protection of Personal Information

Interpretation (s.2)
2. (1) The definitions in this subsection apply in this Part. ...

"personal health information"', with respect to an individual, whether living or deceased, means

(a) information concerning the physical or mental health of the individual;
(b) information concerning any health service provided to the individual;
(c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily
substance of the individual;
(d) information that is collected in the course of providing health services to the individual; or
(e) information that is collected incidentally to the provision of health services to the individual.....

Purpose: (s. 3)
The purpose of this Part is to establish, in an era in which technology increasingly facilitates the circulation and exchange of information, rules to govern the collection, use and disclosure of personal information in a manner that recognizes the right of privacy of individuals with respect to their personal information and the need of organizations to collect, use or disclose personal information for purposes that a reasonable person would consider appropriate in the circumstances.

Application: (s. 4.1)
This Part applies to every organization in respect of personal information that
(a) the organization collects, uses or discloses in the course of commercial activities; or
(b) is about an employee of the organization and that the organization collects, uses or discloses in connection with the operation of a federal work, undertaking or business.

> [Federal "work, undertaking or business" includes airlines, banks, telecommunications, etc., as per s. 2(1). The Act does not apply to government institutions governed by the federal *Privacy Act*.]

Workings

Collection: (s. 5(3): An organization may collect, use or disclose personal information only for purposes that a reasonable person would consider are appropriate in the circumstances.

Consent: (Schedule I, s. 4.3) The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information, except where inappropriate.

... In certain circumstances personal information can be collected, used, or disclosed without the knowledge and consent of the individual. For example, legal, medical, or security reasons may make it impossible or impractical to seek consent. When information is being collected for the detection and prevention of fraud or for law enforcement, seeking the consent of the individual might defeat the purpose of collecting the information. Seeking consent may be impossible or inappropriate when the individual is a minor, seriously ill, or mentally incapacitated. In addition, organizations that do not have a direct relationship with the individual may not always be able to seek consent.

Exceptions: (s. 7)...

s. 7(1)): ... an organization may collect personal information without the knowledge or consent of the individual only if
(a) the collection is clearly in the interests of the individual and consent cannot be obtained in a timely way;
(b) it is reasonable to expect that the collection with the knowledge or consent of the individual would compromise the availability or the accuracy of the information and the collection is reasonable for purposes related to investigating a breach of an agreement or a contravention of the laws of Canada or a province;
(c) the collection is solely for journalistic, artistic or literary purposes; or
(d) the information is publicly available and is specified by the regulations ...

Remedies: (ss. 11-16)

-Individuals may file written complaints to the Privacy Commissioner (ss. 11, 12)
-Privacy Commissioner Investigation & Reports (s. 13)
-Complainant Remedy in Court (s. 14)
-Privacy Commissioner to Court (s. 15)
-Court Hearings & Orders: Retraction, Correction, Damages (ss. 14-16)
-Audit, if Commissioner has reason to believe a failure to respect norms (Division 3).

Appendix B

Bibliography on Ethico-Legal Issues in Genetic Testing

This bibliography largely consolidates selected articles from the legal and ethical literatures. Some pertinent medical articles are also included. Government reports and documents from selected countries are listed separately, after the general literature. They should be considered in conjunction with Table A, above.

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