

Re-Framing the Discussion: Commercial Genetic Testing in Canada

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A. Introduction

Private access to genetic services¹ must be viewed as a possibility in discussions about the provision of genetics services in Canada. The question of whether private access should be allowed (or whether it should be prohibited) is in some sense moot given that genetic tests can already be purchased by Canadians through U.S. and European sources (e.g. Myriad's Breast Cancer test² and University Diagnostics Ltd's cystic fibrosis test³). But more importantly, it is not obvious that private access should be restricted. While there are certainly concerns about the potential for social and psychological harm to Canadians, and the public health care system, these *potential* harms have not been fully explored or tested. Moreover, people use health care services such as genetic testing in ways that challenge the clinical view of how services should be used, and thus force us to reconsider where these services fit in our model of public health care. The discussion of whether private access should be permitted, i.e., whether it is "good" or "bad," must be re-framed – the focus must be on how best to integrate commercial genetic services with the Canadian health care system. This means asking questions about the nature of genetic services to determine what they are for and who should provide them to whom.

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¹Genetic services include a wide variety of services, ranging from prenatal testing, DNA fingerprinting, and carrier screening, to genetic counselling and gene therapy. For the purposes of this paper, "genetic services" will refer primarily to genetic testing and counselling. Further, by "genetic testing" I do not mean to include prenatal testing or diagnosis, DNA finger printing, or paternity testing; it will only refer to susceptibility testing, where an individual is tested for a specific gene or set of genes that incurs increased risk or susceptibility to disease.

²M. Wadman, "Ethical Terms Set for Breast Cancer Test" (1997) 390 Nature 324; M.J. Malinowski & R.J.R. Blatt, "Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards" (1997) 71:4 Tulane L. Rev. 1211 at 1214. See also Myriad Genetics' website <<http://www.myriad.com/gt.html>>.

³P.S. Harper, "Direct Marketing of Cystic Fibrosis Carrier Screening: Commercial Push or Population Need?" (1995) 32 J. Med. Genet. 249; S. Farrell, "Screen Yourself by Mail Order" *The Times* (24 September 1997) 6 at <<http://www.the-times.co.uk/news/pages/tim/97/09/24/timnwsnws01010.html?000999>>; M. Kirk, "Commercial Gene Testing: The Need for Professional and Public Debate" (1997) 6 British J. Nurs. 1043 at 1043. See also UDL's website <<http://www.udlgenetics.com/cf.html>>.

B. The Reality of Private Access

Currently, testing for genetic disease or susceptibility is provided through medical genetics departments in major teaching hospitals, cancer agencies, and research centres. While some genetic tests are covered through provincial health insurance (and thus available to the general public), many tests are still in the clinical research trial stage and access is limited. For example, until recently, the breast cancer testing programme at the B.C. Cancer Agency was largely funded through research grants although ongoing funding is now available to provide testing as a routine service. This means that testing for the two known breast cancer susceptibility genes (BRCA1 and BRCA2) has been, and will continue to be, restricted to individuals who meet certain criteria⁴ such that they are considered at high risk and for whom, therefore, the test would be medically indicated. Further, given the limited resources available and the need for pre- and post-test counselling,⁵ there has been an 8 to 12 month waiting list for testing and counselling. Inevitably, these restrictions mean that many women who seek testing will be refused because they do not meet the criteria for being at high risk; this may lead to feelings of frustration, rejection, anger, and increased anxiety.⁶ For example, while some women will feel relieved when told they are not at high risk and do not need testing, others may feel that their needs are not being met, their fears not allayed, and may thus have increased anxiety about developing cancer. If their

⁴For example, the Hereditary Cancer Program at the B.C. Cancer Agency has the following criteria for genetic testing, "Section 2.1, Criteria for Genetic Risk Assessment" *Cancer Management Manual* (Vancouver: BC Cancer Agency, 1999) <<http://www.bccancer.bc.ca/cmm/hereditary/01.shtml#2.1>>.

Genetic risk assessment may be appropriate for an individual who meets the following criteria:

a woman with breast cancer diagnosed at age 35 or younger; a woman with ovarian cancer diagnosed at age 50 or younger; an Ashkenazi Jewish woman with breast or ovarian cancer diagnosed at any age; a man or woman with colon cancer diagnosed at age 50 or younger, or

a blood relative with a confirmed mutation of a cancer susceptibility gene

Examples: BRCA1, BRCA2 for hereditary breast/ovary cancer; MLH1, MSH2 for hereditary non-polyposis colon cancer (HNPCC); APC for familial adenomatous polyposis (FAP), or

whose family history includes any *two* (2) of the following: cancer in two (2) or more closely related family members (parents, siblings, children, grandparents, aunts, uncles) on the same side of the family; cancers at an earlier age than expected in the general population (e.g. breast cancer before menopause or colon cancer before age 50); multiple primary cancers in one (1) individual; cancers associated with known hereditary syndromes (e.g. breast/ovary, colon/uterus); male breast cancer.

⁵Genetic counselling is considered a standard of care and must be provided (preferably by individuals well trained in dealing with genetic issues) prior to and following genetic testing. See N.F. Sharpe, "Genetic Screening and Testing in Canada: A Model Duty of Care" (1996) 4 H.L.J. 119; M. Sidarous & E. Lamoth, "Norms and Standards of Practice in Genetic Counselling" (1995) 3 H.L.J. 153.

⁶J. Bottorf & M. McCullum Address, "The Needs of Individuals and Families Ineligible for Genetic Testing for Breast Cancer" (B.C. Cancer Agency Presentation at Hereditary Cancer Progra Case Conference, 10 September 1999) [unpublished]. However, there is still little empirical evidence that waiting lists will necessarily increase anxiety.

demands are unmet by the public system, then some people may turn to the private sector, thereby creating a market for private genetic testing.

1. Ease of Access: The Internet

The advertising and sale of private medical services, products and pharmaceuticals on the internet⁷ has blossomed in the last few years, and genetic service laboratories and providers have been quick to follow. The results of a preliminary internet search found eight private companies offering adult genetic testing, two DNA test kit manufacturers (Genaco and Digene), one private clinic (David Drew Clinic), and one university laboratory (University of Utah). Moreover, seven of these companies were confirmed to be providing or in the process of developing marketing for services offered directly to the consumer (Table 1).

Table 1: Sample of Companies Offering Private (Adult Human) Genetic Testing⁸

Company/Laboratory	Direct to consumer	Via health care professional	Via third party	Tests offered
University Diagnostics Ltd (U.K.) <i>www.udlgenetics.com</i>	Yes	Yes		e.g. Cystic fibrosis and Osteoporosis
Interleuken Genetics (U.S.) <i>www.ilgenetics.com</i>		Yes	Yes	e.g. Periodontal disease, Diabetic retinopathy
Myriad Genetics, Inc (U.S.) <i>www.myriad.com</i>	Yes	Yes		e.g. Breast / ovarian cancer, Cardiovascular disease
Adnagen (Germany) <i>www.adnagen.com</i>		Unclear		Chemical / environmental susceptibilities

⁷See e.g. U-Save Pharmacy at <<http://www.capc.com/usave/>>; Click Pharmacy at <<http://www.clickpharmacy.com>>, and Priority Pharmacy at <<http://www.prioritypharmacy.com>>. These sites have not been without controversy. See Reuters Health, "Internet Pharmacy Site Under Fire" at <http://dailynews.yahoo.com/h/nm/19990929/hl/pha13_1.html> (Accessed 29 September 1999).

⁸The search was conducted via the Yahoo! search engine at <<http://www.yahoo.com>>, with keywords "commercial genetic testing". There were 94 listings in total as of 9 October 1999. Multiple listings, sites offering only paternity or DNA identity testing, agricultural genetic testing, etc. were then excluded, for a final total of 12 listings.

Genetic Consulting & Testing Services (Australia) <i>www.gcat.com.au</i>	Yes	Yes		Chemical / environmental susceptibilities
IMMD (Germany) <i>www.immd-ltd.com</i>	Yes	Yes		e.g. Sickle cell anaemia, Tay Sachs disease (27 tests)
Celtek (U.S.) <i>www.genetest.com</i>		Yes		e.g. Hemochromatosis, Hemophilia A (37 tests)
Helix Biotech (Canada) <i>www.helixbiotech.com</i>	Yes	Yes		Retinoblastoma
Genaco Biomedical Products (U.S.) <i>www.genaco.com</i>	Yes	Yes	Yes	DNA test kits
Digene Corporation (U.S.) <i>www.digene.com</i>	Yes	Yes	Yes	DNA test kits
David Drew Clinic (U.S.) <i>www.daviddrew.com</i>		Yes		e.g. Breast cancer, Alzheimer's disease
University of Utah DNA Diagnostics Laboratory (U.S.) <i>www-medlib.med.utah.edu/dnadx/</i>		Yes		e.g. Huntington disease, Myotonic dystrophy (17 tests)

This search was by no means exhaustive – a full search with multiple keywords, conducted through a number of different search engines, would likely find many more companies. Moreover, there may be private clinics or companies offering genetic testing who do not have a web presence or are not widely advertising these services. Thus any web search is likely to underestimate the actual number of companies offering private genetic testing.

For our purposes, the important point is that there are at least seven companies (one of which, Helix Biotech, is Canadian) that will provide genetic testing services directly to the consumer. When this is combined with the ever-increasing number

of people using the internet,⁹ it becomes clear that access to products and services is no longer restricted by national boundaries – the internet provides the framework for an international market in genetics products and services.

2. Sampling of Genetic Material

Obtaining genetic material for testing involves simple and largely non-invasive procedures. For example, with University Diagnostics' cystic fibrosis test, all that is required from the consumer is a mouth swab that is then sealed in an envelope and mailed to the company for analysis.¹⁰ At most, an individual may be required to provide a blood sample – a procedure that can be conducted at virtually any health clinic. By using saliva samples for analysis, University Diagnostics is able to guarantee their consumers' anonymity.¹¹ There is no need to involve personal physicians or the public health care system, although test results may be disclosed to a physician if the consumer wishes. Even where a blood sample is needed for analysis, as in the case of Myriad Genetics' BRCA 1/2 testing,¹² it is possible for individuals to obtain the service with some degree of ease and privacy;

⁹Internet usage is still highest in North America and Europe, but is rapidly expanding throughout the rest of the world. "Webtomorrow.com estimate that around 50 million people use the internet (although around 12 million have only casually tried it). Thirty million of these users live in U.S. alone, but the number is projected to grow to 100 million by 2002. Northerva.com estimate that over 50% of users are relatively new, having first accessed the internet within the past 12 months. Internet users are typically American men in their 20s or 30s, with a degree qualification, working in a professional or managerial position. The following data is from *realmarket.hypermart.net*:

- Place of residence: United States of America 76.4%; Canada 8.6%; United Kingdom 2.9%; Australia 1.8%; Germany 0.9%; The Netherlands 0.7%; Italy 0.7%; Sweden 0.6%; Japan 0.6%; other 6.2%.
- Gender: 83% male; 17% female (although other surveys suggest that the proportion of women is higher and rising)."

D. Shickle, "Cloning, God, Hitler and Mad Scientists: Arguments Used by the Public in the Cloning Debate on the Internet" in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) 157 at 159.

¹⁰*Supra* note 3.

¹¹The issue of anonymity in genetic testing (and genetic information) is a major concern in the U.S., where fears of discrimination in access to health insurance seem to dominate the discussion. See Task Force on Genetic Insurance, *Genetic Information and Health Insurance: Report of the Task Force on Genetic Information and Health Insurance* (Washington, D.C.: National Institutes of Health, 1993); C.R. Naser, "High Speed Genetic Testing Technology and the Computerization of the Medical Record" *Ethics '97: The Second Annual Ethics and Technology Conference* (Chicago: Loyola Center for Ethics, Loyola University, 1997) <http://www.math.luc.edu/ethics97/papers/Naser.html>. Even in Canada, anonymity has been an important issue for some people, especially where life and extra health insurance are concerned. See T. Lemmens & P. Bahamin, "Genetics in Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis" in B.M. Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Cowansville, Québec: Les Éditions Yvon Blais, Inc., 1998) 115. Notwithstanding the insurance question, anonymous testing may also be desired for a host of other reasons, such as privacy, issues of family relations, and life planning. See M.M. Burgess *et al.*, "The Dilemmas of Anonymous Predictive Testing for Huntington Disease: Privacy vs. Optimal Care" (1997) 71 *Am. J. Med. Genet.* 197.

¹²*Supra* note 2.

a blood sample is drawn and sent to Myriad Genetics for analysis. The results are sent to the client's physician to ensure that genetic counselling is provided.

Acquiring tissue samples is therefore not a barrier for consumers seeking private genetic testing, and, in many cases, consumers will be able to avoid dealing with public health care providers. Private testing thus becomes a relatively convenient, albeit expensive (e.g. \$2,400US for BRCA 1/2 testing through Myriad Genetics), option that some may find preferable to access through a public system that will likely involve long waiting lists and restrictive entry criteria.

3. Patient Choice

Professional and patient attitudes about access to genetic services (and medical services in general) have increasingly emphasised patient choice and autonomy.¹³ Studies by Wertz¹⁴ have shown that both patients and genetics professionals place a high priority on patient choice. For example, in the United States,

Sixty percent of patients thought they were entitled to any service they requested and could pay for out-of-pocket; 69% thought withholding any requested service was a denial of patients' rights; 89% thought they were entitled to referrals...Most U.S. geneticists and primary care physicians agreed substantially with the patients' views.¹⁵

In Canada, significantly less genetics professionals (38%) thought that withholding requested services was paternalistic and a denial of patients rights. Yet 94% believed that they should refer for a procedure they were personally unwilling to conduct, and 53% would even refer out of province or out of Canada, if the procedure was forbidden by law.¹⁶ Further, while the Canadian public may be less demanding with respect to private access to services than their American neighbours, "unless Canadians are radically different from Americans in their views, the autonomy-oriented approach of patients...may well represent the wave of the future for both countries."¹⁷ Thus if a person does not qualify for genetic testing (e.g. for breast cancer testing¹⁸), they may demand and receive, from their physician, a referral to a clinic or private company that would be willing to provide the test.

¹³T.A. Caulfield & C. Feasby, "The Commercialisation of Human Genetics in Canada: An Overview of Policy and Legal Issues" in Knoppers, *supra* note 11, 343 at 383; T.A. Caulfield, "Reflections: The Practice of Human Genetics: Emerging Areas of Consensus?" (1995) 3 H.L.J. 307 at 314.

¹⁴D.C. Wertz, "Patients' and Professionals' Views on Autonomy, Disability, and 'Discrimination': Results of a 36-Nation Survey" in Caulfield & Williams-Jones, *supra* note 9, 171; D.C. Wertz, "Professional Perspectives: A Survey of Canadian Providers" (1995) 3 H.L.J. 59 at 77.

¹⁵Wertz (1999) *ibid.* at 173.

¹⁶*Ibid.* Table 2 at 174.

¹⁷*Ibid.* at 173.

¹⁸*Supra* note 4.

These statistics point towards the prevalence of a consumer attitude in the use of health care services. People are more willing to participate in health care decision making and choose between the variety of services or treatments that they are provided. But more importantly, there is a feeling (among patients and clinicians) that patients should have access to services they desire and feel they need. An obvious conflict arises between what a patient desires and the provision of services by a system with limited resources – not all services that patients want can be publicly provided. This may mean that some services should be purchased privately by patients, while others (e.g. if they are recommended by physicians) should be covered by public health insurance – the issue of where genetic tests fall in this range will be discussed below. But for the moment, an important point to consider is that people are choosing to have genetic testing and, while most access those services through medical genetics departments, an increasing number of people are likely to use private genetic service providers.

While it would certainly be possible to enact regulations to prohibit commercial genetic testing within Canada, as was proposed by the Royal Commission on New Reproductive Technologies¹⁹ and might have occurred with the now defunct Bill C-47 *Human Reproductive and Genetic Technologies Act*,²⁰ it should be clear that individuals who want, and can afford genetic testing, will have it regardless of whether the service is prohibited by provincial or federal legislation. The “global village” that has developed over the last few decades has led to a “global marketplace” – genetic services are only one of the many types of medical and non-medical services and products that are being made available to the growing international consumer market.

C. Re-Framing the Discussion

Why should we accept the reality of private access? It may well be argued that in focusing on this “reality”, we have missed or sidestepped the crucial moral issue of whether or not commercial genetic testing is “good” and should be allowed, or “harmful” or “bad” and should be prohibited. For example, there are important concerns raised about the social and economic effects of a two-tiered medical system and the potential injustices this may cause when the wealthy have better or quicker access to services.²¹ There are worries that private access will lead to misuse and abuse of services,²² and that individuals may be influenced by misleading marketing campaigns into purchasing products and services they do not

¹⁹Royal Commission on New Reproductive Technologies “Ch. 24: Commercial Interests and New Reproductive Technologies,” *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies 2* (Ottawa: Minister of Government Services Canada, 1993) 695.

²⁰Legislation of this sort might be considered a violation of individual rights protected under section 7 of the *Canadian Charter of Rights and Freedoms*. For discussion of the possible limits of regulation, see Caulfield & Feasby, *supra* note 13, at 397-399; A. Harvison Young & A. Wasunna, “Wrestling with the Limits of the Law: Regulating New Reproductive Technologies” (1998) 6 H.L.J. 239.

²¹Caulfield & Feasby, *supra* note 13 at 358.

²²Malinowski & Blatt, *supra* note 2 at 1243.

need.²³ In particular, it is often maintained that private genetic testing will cause profound psychological harm to individuals and families, because the complexity of genetic information may not be properly understood,²⁴ especially if pre- and post-test counselling is not provided.²⁵

This argument goes to the heart of much of bioethics theory, and turns on the extent to which bioethics should be practical and applied and the place of moral ideals and theory in bioethics practice.²⁶ Without entering into this larger theoretical debate, I suggest that one of the primary reasons to accept private genetic testing as a reality (and work at integrating it instead of prohibiting it) is the complexity of the issues involved. The social and psychological harms that may be associated with private access are unclear, and the only way we are going to determine the extent to which these purported harms actually occur is to conduct limited trials of private genetic services.²⁷ There are many potential benefits to consumers (e.g. reduced waiting lists, quicker access, and better service) and the health care system (e.g. reduced costs, increased efficiency, and better allocation of current resources). Finally, it is not obvious that the consumer and the public health care system would necessarily be negatively affected by private access, or that regulating private genetic services would be impossible.²⁸

There is a need to re-frame the discussion, and by this I mean that the focus of the discussion must become more open, flexible, and practically oriented. The complexity of the situation is such that debating whether private genetic testing is

²³A. Clarke, "Population Screening for Genetic Susceptibility to Disease" (1995) 311 *British Med. J.* 35; D. Nelkin & M.S. Lindee, *The DNA Mystique: The Gene as a Cultural Icon* (New York: Freeman, 1995).

²⁴Clarke, *ibid.*; J. Stephenson, "Questions on Genetic Testing Services [News]" (1995) 274 *JAMA* 1661.

²⁵That private companies will have no interest in providing a service that may dissuade potential clients from purchasing tests is an important critique. Briefly, if a standard for counselling exists (*supra* note 5), a private genetic service provider would be at substantial risk for liability if a client suffered emotional or psychological harm from receiving genetic information without counselling support. See Caulfield and Feasby, *supra* note 13 at 369; J.N. Gibbs, "The Human Genome, FDA and Product Liability" (1996) 7 *Risk: Health, Safety & Enviro.* 267. This is probably one of the reasons that Myriad Genetics modified its initial marketing plan of selling direct to the consumer and now transmits all information resulting from its BRACAnalysis™ through the client's physician to ensure that counselling is provided. Moreover, Myriad Genetics has developed a detailed product information package and extensive internet resource. Myriad Genetics, *Genetic Testing for Hereditary Breast and Ovarian Cancer* (1999) <<http://www.myriad.com/labs.html>>. Thus it is at least conceivable that private genetic service providers could be encouraged (or induced) to provide appropriate genetic counselling. M.M. Burgess, "Marketing and Fear-Mongering: Is It Time for Commercialized Genetic Testing?" in Caulfield & Williams-Jones, *supra* note 9, 181 at 184-85.

²⁶See L.R. Kass, "Practicing Ethics: Where's the Action?" (1990) 20 *Hastings Cent. Rep.* 5.

²⁷Burgess, *supra* note 25 at 193.

²⁸An analogy that might be helpful is the legalization of heroin and other "hard drugs," a position based on the argument that de-criminalizing possession would eliminate the role of organized crime and allow the government to control and ensure a safe supply. Similarly, if there is concern about the quality of care provided by private genetic services, i.e., the use of internet or mail-order testing, then the government can better control distribution and ensure quality by making access legal; but in so doing, the government need in no way endorse the "product" to ensure a safe domestic supply.

“good” or “bad” is simply not particularly helpful in dealing with the present situation. Genetic technology is rapidly evolving,²⁹ and the next few years will likely see a plethora of new genetic tests coming on to the market that test for a wide range of inherited diseases and genetic susceptibilities.³⁰ Thus it is crucial to determine where genetic services fit in the current provision of health care and how they should be integrated. But first, we need to gain a better understanding of the role that genetic services play in the lives of patients: how are these services provided, what information do they produce, and how is that information used?

1. Nature of Genetic Services

i) Counselling

When a person seeks genetic testing through the public health care system, they usually receive a pre-test counselling session (given by a trained genetic counsellor or medical geneticist³¹) that can be up to three hours long. This time is needed to take the patient’s family history (e.g. in the case breast cancer, to determine which other family members have been affected, types of cancer, age of onset, etc.), to educate the patient about the nature of the test and the disease being tested for, and to present possible treatment options and the risk information that the test will provide. Individuals (and often their families) who are tested are also provided with a number of post-test counselling sessions to help them interpret the information and incorporate it into their personal and family lives. By contrast, counselling is usually only an option when a person obtains genetic testing through private service providers (although Myriad Genetics³² and Helix Biotech³³ have policies of only providing testing when counselling is assured).

Due to the fact that many of the diseases tested for are multifactorial (e.g. many cancers), and not inherited in a Mendelian fashion as dominant or recessive disorders (such as Huntington disease or cystic fibrosis), the test results will often not be definitive or diagnostic. At most, a genetic test for a multifactorial disease will tell the patient that he or she, and potentially family members, are at an

²⁹There are genetic technologies on the horizon, e.g. DNA chips, which may revolutionize the way genetic testing is performed. DNA chips can scan a sample with hundreds and potentially thousands of probes, and could allow for testing for a range of diseases; within one gene, DNA chips could test for all of the known disease mutations. I. Wickelgren, “Gene Readers” (1998) Nov. *Popular Science* 56; Naser, *supra* note 11; Reuters Health, “DNA Chips May Improve Cancer Diagnosis” *Yahoo! News* (October 15 1999) <http://www.dailynews.yahoo.com/h/nm/19991015/hl/can12_1.html>. See also Affymetrix <<http://www.affymetrix.com>> and Gene Logic <<http://www.genelogic.com>> web sites for examples of chips currently in development.

³⁰P.H. Silverman, “Commerce and Genetic Diagnostics” (1995) 25:3 *Hastings Cent. Rep.* S15.

³¹Although with increased demand and a shortage of trained counselling staff, general practitioners are being more relied on to provide this service, and it is unclear that they are receiving sufficient training for the task. M.M. Burgess *et al.*, “Bioethics for Clinicians:14. Ethics and Genetics in Medicine” (1998) 158 *C.M.A.J.* 1309.

³²Myriad Genetics, *supra* note 25.

³³Personal communication with Dr. Terrance Owen, President of Helix Biotech (Oct. 1998).

increased or decreased risk of developing the disease.³⁴ The complex nature of risk assessment,³⁵ the difficulty that many people (and clinicians) have in understanding this information, and the profound social and psychological ramifications for the people and families being tested³⁶ make counselling and psychosocial support extremely important. To offer testing without counselling would be to offer unprofessional service that violates the existing standard of care,³⁷ because the risks and benefits associated with genetic information are so complex and not easily understood.

ii) Genetic Information

The information that is derived from genetic testing is complex for a number of reasons. It may be very helpful, for example, if knowing a person's risk of developing a disease will give them an opportunity to evaluate whether they should undergo prophylactic surgery to reduce their risk (e.g. for breast, ovarian, or colon cancer). Or, it may help them make planning decisions for the future, for example, whether they need more life insurance, or whether increased or decreased surveillance is required. But this information may be very confusing and ambiguous. For example, if a person is tested for the two known breast cancer genes and receives a negative result, they may interpret this to mean that they are not at risk or will never develop breast cancer – this may lead women to stop performing routine self-examinations or obtaining regular mammographies, thereby increasing their risk. In fact, all that the test has determined is that they do not have any of the mutations in either of the two known breast cancer genes. A negative result does not mean that the individual will never develop breast cancer – it simply means that they are at the same background risk as the general population for developing the disease.

If the woman receiving the result is a member of a “breast cancer family,” then a negative result will mean that she has likely not inherited either the BRCA1 or BRCA2 mutations associated with the familial occurrence of cancer. Such information can be extremely important for the individual as it may alleviate a substantial amount of anxiety and reduce the need for extensive surveillance – such that he or she need only take the precautions commonly suggested for the general public. Yet if the individual receiving the negative result has no family history of breast or ovarian cancer, then having the test does not aid clinical management,

³⁴That is, this type of testing is for genetic susceptibility (risk of developing the disorder), compared to the less common diagnostic testing (test confirms/explains a condition).

³⁵L. Stranc & J. Evans, “Issues Relating to the Implementation of Genetic Screening Programs” in Knoppers, *supra* note 11 at 49.

³⁶See Burgess *et al.*, *supra* note 11; C. Benjamin *et al.*, “Proceed with Care: Direct Predictive Testing for Huntington Disease” (1994) 55 Am. J. Med. Genet. 606; A.-M. Codori & J. Brandt, “Psychological Costs and Benefits of Predictive Testing for Huntington’s Disease” (1994) 54 Am. J. Med. Genet. 174.

³⁷*Supra* note 5.

does not reduce (objective) risk, and may in fact produce more harm in the form of anxiety by making the person worry about risks they do not have.³⁸

But simply because a test may provide no relevant clinical information or does not change objective risk status, does not mean that it is useless and should not be accessible. Regardless of whether the test will change a person's objective risk status or be clinically relevant, it is important to ask why a person seeks testing. As with many other forms of information (e.g. information about one's financial status), there are numerous possible uses and reasons for obtaining it; using information to resolve anxiety or psychological distress may be only one of many valued uses. For example, non-clinically valuable genetic information may be important in addressing particular life circumstances, such as aiding a person in planning for the future, organizing and dealing with family commitments,³⁹ or addressing concerns about discrimination (e.g. on insurance coverage or job opportunities) or stigmatization. Moreover, genetic information may serve as a means for provoking and facilitating open family discussion on difficult and painful issues, such as who wants the information, who does not, and who is willing to provide samples for analysis.⁴⁰ As will be discussed below, these different uses may be sufficient grounds for arguing that tests that only meet these needs (and are not medically indicated), should not be covered by public health insurance – but this does not mean that these uses of genetic information are any less valuable to the patient.

2. What Makes Commercial Genetic Testing So Different?

Given the variety of uses that people have for genetic testing, we now need to ask: what is it about the commercialization of genetic services that makes it so unacceptable? There are obviously commercially available tests that have beneficial effects and are considered useful by the consumer, but the reason a product or service is considered useful may not align with existing standards of medical or clinical relevance. Nonetheless, if the decision to obtain a specific product or service is primarily in the hands of the consumer, then the reasons for accessing that service or product should arguably be those of the consumer.

Moving control and access to a genetic test out of the medical environment and into the market will increase individual freedom of access and privacy, as well as allow a person to use the technology in an environment in which they are comfortable, (i.e., their homes). For example, commercial pregnancy tests, first developed more than twenty years ago, give some of the power to assess and

³⁸This is an important argument against commercial testing, i.e., that people will be sold a test they do not need and that may be harmful. Malinowski & Blatt, *supra* note 2.

³⁹See S.M. Cox & W. McKellin, "'There's This Thing in our Family': Predictive Testing and the Construction of Risk for Huntington Disease" (1999) 21 *Sociology of Health & Illness* 622.

⁴⁰Burgess *et al.*, *supra* note 11.

control fertility and reproduction back to women.⁴¹ A woman can learn as early as seven to ten days after a missed period whether she is pregnant or not. This test gives a woman, in the privacy of her own home, time to consider whether she wishes to continue with the pregnancy and, if so, allows her to plan changes in diet, to manage social responsibilities, etc.⁴² Other commercially available tests include kits for cholesterol, HIV-1, blood pressure, and blood glucose levels.⁴³

Perhaps a more controversial example of commercially available genetic testing is DNA paternity test kits. There are many private corporations around the world currently offering genetic paternity testing (e.g., Helix Biotech in Canada and University Diagnostics Ltd. in the U.K.).⁴⁴ These services are often provided through a clinic to ensure accuracy, but there are also over-the-counter test kits available directly to the consumer.⁴⁵ There have been some legal concerns about informed consent, accuracy, liability, and controlling rights over the genetic material being tested (in particular whether an article of clothing can be tested without the consent of the owner), but the general legal opinion has been that the onus to obtain consent rests with the individual bringing in the material to be tested.⁴⁶ Yet there has been relatively little public debate about the psychological, social, or familial impact of such testing; there has certainly been no widespread demand (from professionals, as there is in the case of genetic testing⁴⁷) for counselling to accompany such testing. So why do people worry so much more about genetic testing?

Is this difference simply based on the assumption that information resulting from genetic testing is more complex than the information derived from a paternity test? Moreover, are the harms associated with genetic information likely to be more severe and difficult to deal with than those associated with paternity testing – can we even tell the difference? Information resulting from genetic testing may be more difficult for a person and family to deal with than information about paternity, as the former clearly has far reaching implications for the individual's health, conception of self, future opportunities, and family relations. While information about paternity may also affect one's identity and certainly one's family relations, it might appear not to pose a threat to one's sense of being ill or healthy, as it does

⁴¹A. Bargiel, "Pregnancy Tests: From Piss-Prophets to Radioreceptorassay" (1980) 3:1 WomenWise 10.

⁴²J. Hunt, *How to Use Home Pregnancy Test Kits* (1997) Queen's/HMSA Premier Plan, Woman Health Archive, <http://www.premierplan.org/whealth/1997/12/preg_test.html>.

⁴³R. Geraci, "New Kits on the Block" (1998) Oct. Men's Health 78.

⁴⁴*Supra* note 8. The majority of web sites found in the brief internet search through Yahoo! (Table 1) were for companies offering paternity and DNA identity testing.

⁴⁵See P. Belluck, "Everybody's Doing It: Paternity Testing for Fun and Profit" *The New York Times* (1999) <<http://search.nytimes.com/search/daily/bin/fastweb?getdoc+site+site+78657+0+wAAA+paternity%7Etesting%7Efor%7Efun>>; C. Hall, "Call for Curbs on DIY Paternity Test DNA Kits" *Electronic Telegraph* (14 July 1998) <<http://www.telegraph.co.uk:80/et?ac=002018315849935&rtmo=Lbt7tNKd&atmo=FFFFSkEX&pg=/et/98/7/14/ndna14.html>>.

⁴⁶This is also an issue for DNA fingerprinting, as was seen in the media spectacle involving Monica Lewinsky and President Clinton.

⁴⁷*Supra* note 5.

not force the individual to come to terms, for example, with what it means to be “at risk” for a disease.⁴⁸ There is likely also greater consumer knowledge of the implications of pregnancy and non-paternity than there is of genetic testing.

Yet if we return again to the varied use of personal information and the reasons people have for seeking testing of whatever sort, it becomes much less obvious that genetic testing is significantly different with respect to the nature and level of harms from paternity testing. For example, a man finding himself not to be the genetic father of his child as a result of a paternity test may lose his presumed link to the future (e.g. the idea that parents live on through their biological children), and thus might suffer a greater negative psychological impact than his discovering as a result of a genetic test that he is at significantly increased risk of developing prostate cancer.⁴⁹

I would agree that consumers probably know less about the full implications of genetic testing than they do about paternity or pregnancy testing. Most medical services involve some minimal level of counselling, but it is unlikely that women having abortions, for example, would receive as much counselling as is currently provided to women undergoing testing for BRCA 1/2. And the implications of pregnancy, abortion, or non-paternity may be equally if not more difficult for a person to grapple with than the information resulting from genetic testing; the perception of risk and anxiety caused by the genetic (e.g. prostate cancer) and paternity information likely constitute two (among many) overlapping ranges of experience. One type of information may be of a more severe or pressing nature, but that situation will likely change depending on a variety of other factors in a person’s life. Of course individual experience will vary, but to focus exclusively on the problems caused by genetic testing (while ignoring the issues raised by paternity testing, for example), misses the point that genetic testing is not categorically or dramatically more harmful than other types of testing.

Prohibiting private genetic testing (or requiring strict regulation, provision of counselling, etc.), while rejecting or simply failing to provide counselling for paternity testing, seems incongruous. Clear and helpful information should be available regardless of the test being provided. Such information should be accompanied by professional counselling, but this could equally be true for a young teenager seeking pregnancy testing as for an adult seeking testing for paternity or prostate cancer susceptibility.

⁴⁸*Supra* note 39.

⁴⁹I am indebted to Dr. Peter Danielson for this clear and helpful example.

3. “Medically Necessary” and the Provision of Services

It is probably reasonable to maintain that any test that does not provide clinically relevant information should not be publicly provided – a just distribution of limited government resources would support only medically necessary⁵⁰ or clinically relevant services. For example, population wide genetic screening for multifactorial diseases, at present, would be inefficient, prohibitively expensive, and unlikely to identify significant numbers of people for whom the information would be of clinical benefit.⁵¹ One can even argue that for more closely targeted genetic testing, it is reasonable for the public system to withhold testing from individuals who do not meet certain criteria that would place them at higher than average risk and thus in need of genetic testing (as is presently the case for breast, ovarian, or colon cancer testing⁵²). But it clearly does not follow that if the public health care system is not providing a service, then the private sector should be constrained from offering that service.

There are many medical services that are not covered under the public health care system but are nonetheless permitted and accessible through the market. For example, while most (but not all) cosmetic surgery is not considered medically necessary and thus not provided by the public health care system, consumers are still at liberty to purchase such services from private clinics. There is also a growing market in alternative medicines and, while there have been attempts to regulate these products (and determine which are medically effective according to the Western scientific model), they are still available to consumers even though they are not part of the public health care system. But probably the most compelling example is dental care, as this service is not covered under provincial health insurance plans (although some provinces, e.g. Québec, do provide limited access for children), but it is still widely accessible to the general public.

Genetic testing that is not medically indicated (e.g. because the person does not have a family history of disease and is unlikely to receive clinically relevant information) may be like dentistry, cosmetic surgery or alternative medicines, in the

⁵⁰Unfortunately, while this term is widely used (for example, in the *Canada Health Act*), it is rarely defined. Most often, what is considered “medically necessary” is that which a physician deems to be required by the patient. This definition obviously becomes problematic when it is used as a means of determining what services should be covered by public health insurance, as strictly speaking, any service a physician recommends should be covered. Yet it can still be useful “as a broad concept that symbolizes our society’s values, beliefs and goals for the health care system.” T.A. Caulfield, “Wishful Thinking: Defining ‘Medically Necessary’ in Canada” (1996) 4 H.L.J. 63. For the purposes of this discussion, I will use “medically necessary” in this broader sense, and thus as something to point towards for consideration – as Caulfield observes, it is obviously a concept that requires further deliberation.

⁵¹Efficiency may improve, however, if there are significant breakthroughs and cost reductions in testing technology, e.g. DNA chips, *supra* note 29.

⁵²*Supra* note 4.

sense that many people do not need it to maintain their health,⁵³ and therefore it should not be covered by public health insurance. But to return to the example of dentistry, the extent to which there is a connection between a service being “medically necessary” and it being publicly provided is, at best, tenuous. Basic dental care is arguably medically necessary (although there is no agreement about what constitutes “basic care”) because poor dental hygiene can lead to a variety of potentially serious medical conditions. Nonetheless, dental care is only available to those Canadians who can afford to purchase it or have extended private health and dental insurance; there are also free or charity based dental programmes for the poor (e.g. supported by subsidies through social assistance programmes), but they can only provide “basic” sporadic service. This situation leads to grossly unequal access among Canadians, and highlights the inconsistency (and historical contingency) of how medical services are currently provided and which are deemed worthy of public support.⁵⁴ Thus even if concepts of “normal health” or “medically necessary” are refined to the point of being useful in practice, the actual process by which services come to be funded is much more complicated – history of provision of the service, lobbying efforts from special interest groups, and political expediency are likely to have a greater impact on decisions over what services are covered by public health insurance.⁵⁵

D. Integrating Commercial Genetic Services in the Canadian Context

Given the somewhat arbitrary way that services have been incorporated into or left outside of public health insurance, explicit discussion about where genetic testing fits is necessary.⁵⁶ Some genetic tests, such as those for breast, ovarian, or colon cancer, will continue to be provided by the public system; there is sufficient demand, as well as strong clinical and public support. As other tests become technologically feasible (and affordable to public genetic laboratories), they will be evaluated for support under public health insurance. But there will also continue to be many tests offered by private service providers that either are not covered by

⁵³An alternate approach to determining what should be covered by government sponsored medical care has been to argue for criteria of “normal health,” a concept that would also help work towards “equality of opportunity” in the population. See N. Daniels, *Just Health Care* (Cambridge: Cambridge University Press 1985).

⁵⁴For discussions of justice in access to health care, and genetics in particular, see Burgess, *supra* note 25 at 186.

⁵⁵C. Abraham, “Tenacious Woman Scores Medical Victory” *The Globe & Mail* (27 August 1999) A1. For example, a recent appeal to the Ontario Health Insurance Plan (OHIP) resulted in the province covering the \$3,600 CDN fee for private BRCA 1/2 testing (through Myriad Genetics) to facilitate quick results for women at high risk for breast cancer. “This decision is expected to have implications for women throughout Canada and for provincial governments, which must confront the fact that costly new genetic tests for a wide range of disease are popping up every month.”

⁵⁶I have briefly touched upon the issue in this essay, but for more detailed discussion, see Burgess *supra* note 25.

public health care, or are only available to a limited number of people who meet certain strict criteria for testing.⁵⁷

With any new technology, there will be costs and benefits associated with genetic testing. As discussed previously, concerns about emotional and psychological harms to consumers and the impact of private access on the public health care system, are important issues for consideration. Ideally, these costs and benefits would be evaluated in advance of integrating the technology into the market, but once the technology is available, as is currently the case with commercial genetic testing, what is needed is close monitoring and empirical research to determine the level and extent of access to be permitted.

Thus the question is: how should public policy go about integrating private genetic testing into the Canadian health care system? Should companies be left to decide how to market their services and what support to provide, or should the scientific and medical community be involved in pressuring corporations to self-regulate and governments to legislate the way these technologies are made available? I favour the latter position, and argue that what is needed is constructive dialogue between public and private genetic service providers, and the general public.

This integration process will by no means be an easy one. A coherent decision making framework must be established to decide what services are medically necessary and to be covered by public health insurance.⁵⁸ The professional standards of care that currently govern genetic testing and counselling must be evaluated to determine whether they are adequate for protecting the public, and more importantly, how these standards can be translated into the private arena. Finally, there must be further in-depth discussion over what sort of regulatory methods will be most appropriate for controlling private genetic services.

Governments have many ways of dealing with new products and services, and prohibition (or criminalization) is only one way. For example, a government might enact strict legislation similar to Bill C-47, or something resembling the way pharmaceuticals and other medical products are regulated, with advisory bodies and

⁵⁷*Supra* note 4.

⁵⁸*Supra* note 50.

regular oversight procedures.⁵⁹ They might also opt for a loose self-regulatory⁶⁰ and public oversight approach, or rely on taxation, grant-giving and public education. While determining how policy should be developed will require significant effort and attention to detail, there are a wide range of tools available to ensure the safe distribution of products and services.

As an example, I will focus on one particular problem, ensuring appropriate access to genetic counselling, and suggest some constructive ways that public and private services can be integrated to maintain the current standard of care in genetic counselling.

1. The Problem of Counselling

As discussed above, genetic counselling is considered a standard of care in the medical community,⁶¹ and, without extensive empirical studies demonstrating that it is unnecessary, pre- and post-test counselling will continue to be provided through the public system. The difficult, but not insurmountable, problem will be figuring out how to continue providing adequate counselling for patients of public and private testing.

When genetic test kits are available in every doctor's office, or over-the-counter at every pharmacy, the level of counselling received by patients will be entirely dependent on the level of knowledge that physicians or pharmacists have about the social and psychological implications of genetic information. Currently, this understanding is minimal⁶² but given what is likely to be the reality and not the ideal (i.e., physicians and pharmacists providing counselling instead of trained genetic counsellors), the solution is education of physicians and the public.⁶³ More importantly, if physicians are going to bear the brunt of the counselling, they must have community support and funding for increased time to spend with patients. Yet given the rapidly evolving nature of genetic technologies, the complexity of risk information, and the difficulty of addressing the various psychological and emotional issues, a better approach might be to have doctors refer patients directly

⁵⁹For example, in the U.K. there have been demands for a code of practice to regulate private genetic testing. N. Hawkes, "Code of Practice to Regulate Sale of DIY Gene Tests" *The Times* (24 September 1997) <<http://www.the-times.co.uk/news/pages/tim/97/09/24/timnwnws01011.html?000999>>. There have also been concerns raised about the quality and accuracy of information from private companies which remain unregulated and free of government oversight. See R. Weiss, "Genetic Testing's Human Toll: In Unregulated Field, Errors Can Upend Lives and Mean Unneeded Surgery" *Washington Post* (21 July 1999) A01.

⁶⁰See Associated Press, "Web Health Cos. Seek Ethics Policy" *NewsEdge* (14 October 1999) <<http://www.newspage.com/cgi-bin/pnp.GetStory?story=h1013165.502&topic=61443&date=19991014&inIssue=TRUE&mode=topics>>.

⁶¹*Supra* note 5.

⁶²Burgess, *supra* note 31.

⁶³G. McGee, "Ethical Issues in Genetics in the Next 100 Years" (1997) *Web Discussion Forum, Ethics & Genetics: A Global Conversation*, (Center for Bioethics, University of Pennsylvania) <<http://www.med.upenn.edu/~bioethic/genetics/articles/3.mcgee.kobe.html>>; Naser, *supra* note 11.

to trained genetic counsellors. This would obviously require a substantial investment of human and financial resources, but given the ever increasing demands being placed on the time and skills of general practitioners, such a move might well be cost-effective and a more efficient use of professional resources.

Whatever method is used to ensure adequate counselling for patients accessing genetic testing through the public system, it will not ensure that those people using private genetic services will receive equal support, especially if private genetic testing is unregulated and counselling is not in the corporate interests.⁶⁴

2. A Possible Solution

Developing the structures to allow for the provision of counselling for private genetic testing may be difficult. However, given the quite substantial potential for profit on the part of private corporations offering genetic testing, and the strong feelings on the part of much of the medical community that genetic counselling is essential, some mutually beneficial agreement should be feasible.⁶⁵ For example, it might be possible to set up private genetic counselling services that exist at arm's length from the genetic testing companies (to prevent conflict of interest), such that consumers seeking testing would first have to be seen through one of the counselling programmes. Another possibility would be to organize counselling through the existing services offered by the public system (although this would leave the public system paying for private patients, and raise a host of concerns about unfair access to services and misallocation of resources). A more complementary arrangement might be to encourage private testing companies to enter into licensing agreements with genetic counselling programmes at various public institutions; more counsellors could be hired with a percentage of their salaries covered by the private service companies. Such an arrangement would likely raise serious concerns about justice in access (e.g. if private patients move ahead in line for genetic counselling), but these worries can be addressed.⁶⁶

Currently, many genetic counsellors allocate part of their time to research projects; so it seems reasonable that if their salaries were partially paid by private corporations, they could agree to set aside a percentage of their time to counsel private patients, much in the way that physicians allocate time for research and are paid for consulting with private industry. Moreover, if such an arrangement led to more counsellors being hired to fill the demand for private access to testing, the public system would be able to significantly reduce the current backlog of people waiting for counselling and testing. Connecting private genetic testing to genetic counselling is primarily a matter of co-ordinating expectations and funding arrangements, and is not necessarily a major ethical problem. If organized well, private genetic services may actually improve access for all.

⁶⁴*Supra* note 25.

⁶⁵Burgess, *ibid.*

⁶⁶*Ibid.*

E. Conclusion

I began this paper by arguing that private access to genetic services is a reality in Canada. Whether or not private access is prohibited, the rapid development of the internet and the creation of a “global marketplace” will ensure that Canadians who can afford genetic testing will continue to have access through international sources. Thus, as a society, we should face this fact and work towards integrating these services into or alongside the public health care system. Yet I do not mean to take a defeatist “if we can’t beat ‘em, join ‘em” attitude towards commercial testing. If there were convincing arguments for completely prohibiting private genetic testing in Canada, then I would support that position. But as I have demonstrated, while the concerns commonly raised against private genetic testing are valid, they by no means necessarily lead to the conclusion that private access must be restricted. The nature of genetic services, and the uses that people have for genetic information, are simply too complex. Further, it remains unclear where genetic services fit in the provision of health care – some tests will be “medically necessary” and clinically indicated, but others will more likely be optional services that are not, strictly speaking, “health services,” much like alternative medicine or cosmetic surgery.

There are a variety of regulatory tools available to design effective regulations to address the concerns raised about private genetic testing. What is required is the willingness to move forward and tackle this issue. It is only by re-framing the issue, from a debate over whether private genetic testing is “good” or “bad,” to an open and pragmatic discussion about the nature of genetic services and their role in health care, that it will be possible to ensure that genetic testing is provided in a safe, respectful, and equitable manner.