Online Direct-to-Consumer Genetic Testing: Issues & Policy Options

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Editor's Preface

GPS: Where Genomics, Public Policy and Society Meet is an Ottawa GE^{3}LS Series led by Genome Canada, in collaboration with several partners, to bring together federal policymakers and leading researchers to explore options for addressing public policy issues at the interface of genomics and society. The resulting "Policy Directions Briefs" present the evidence base needed to support informed debate on a range of policy options, while deliberately stopping short of making any recommendations. Topics are selected on the basis of their broad societal importance, national interest, relevance to federal policymakers, and "ripeness" for policy uptake.

Co-authors of the Policy Briefs are renowned leaders in the field commissioned by Genome Canada to synthesize the current state of academic knowledge on a given topic and translate it into a format and language familiar to senior federal policy makers. Co-authors are asked to present a well-balanced range of feasible policy options, as neutrally as possible, without favoring any particular position.

The Policy Brief is not intended to reflect the authors' own views or opinions, nor those of Genome Canada. The co-authors have benefited from valuable commentary of national and international experts and relevant stakeholders convened at a half-day event in Ottawa organized by Genome Canada and its Core Advisory Partners. In order to assure excellent quality, practical relevance and suitability for its intended purpose, the draft brief was then submitted to a small review committee in accordance with an explicit peer review process. The intent of these Policy Briefs is to provide a neutral, credible and legitimate source of information for policy-makers on important societal questions at the rock face of emerging genomic technologies and their applications.

Patricia Kosseim

Executive Summary

Rapid growth of genetic testing companies and the number of tests they sell have been fuelled by much faster, more powerful and cheaper technologies. Increasing numbers of companies in the U.S., and now in Canada, are offering a wide variety of genetic tests directly to consumers (DTC) over the internet. Recent intervention by U.S. authorities has sparked considerable debate on how (and whether) these online DTC companies should be regulated and the implications for consumer choice and autonomy. Some see DTC access as the translation of genomic science with direct benefits to consumers while others say tests are of unproven value and may pose harm to consumers. Yet others say "the jury is still out" and more evidence and stakeholder input is needed to inform policy responses. This GPS Policy Brief reviews several options for addressing this policy issue: 1) adopt legislative measures to restrict or ban access to DTC genetic tests, particularly higher-risk tests for serious conditions; 2) allocate greater resources for effective oversight and enforcement action in this area; 3) enhance transparency and availability of information for consumers and health care professionals; and 4) continue to actively monitor, assess and study further developments on this issue.

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Genome Canada also thanks the co-sponsors of the June 29th event, Canadian Institutes of Health Research (CIHR) Institute of Genetics and the Public Health Agency of Canada, as well as our Core Advisory Partners of the GPS Year One Series: Office of the Privacy Commissioner of Canada, CIHR Institute of Genetics, CIHR Ethics Office, Council of Canadian Academies, Public Policy Forum, Policy Research Initiative of Canada, and Carleton University, School of Public Policy and Administration.

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I. The Context

With recent advances in genomic science, genetic tests are now available for over 1700 conditions (National Institutes of Health, 2010). Commercial enterprises have seized a new market opportunity to advertise and sell genetic tests directly to consumers. Indeed, Time magazine declared 23andMe's retail DNA test as "Invention of the Year" for 2008. To date, approximately forty (40) direct-to-consumer (DTC) genetic testing companies, most based in the United States, sell a range of tests for genetic susceptibility to disease (e.g. Alzheimer's disease, cancer, diabetes, and arthritis), nutritional and metabolic profiles, behavioural propensities and performance capacities.[1] Such tests vary widely in terms of quality and predictive value. Companies further vary in the extent to which they provide counselling and in how they communicate results (e.g. by mail, online access). The growth of DTC genetic testing companies and the number of tests they sell have been fuelled by rapid technological developments. DNA sequencing costs have dropped to a hundred thousandth of the cost of a decade ago (Carr, 2010) and sequencing can be done more quickly, making possible fast and more affordable testing services. In fact, some companies now offer whole-genome scans.

In June 2009, the first annual Consumer Genetics Show was held in Boston, featuring the first public trade show for consumer genetic tests (Singer, 2009). In May 2010, Pathway Genomics announced plans to sell health-related genetic tests to consumers via the largest US drugstore chain, Walgreen's; the company suspended the plan after the Food and Drug Administration (FDA) questioned whether the company had regulatory approval to market these 'devices'. Also in May 2010, a US Congressional committee launched an investigation into the claims and practices of several DTC genetic testing companies and, in July 2010, the FDA held hearings to inform enhanced oversight of laboratory-developed tests, including DTC genetic tests (Federal Register, 2010; Shuren, 2010).

To build and expand communities around personal genomic information, some DTC companies facilitate social networking by permitting customers to share their genetic results online with family and friends and participate in company-sponsored blogs (Lee and Crawley, 2009). A US survey of Facebook users found almost two-thirds of respondents would consider using personal genetic testing services, with 'general curiosity about my genetic make-up' being the primary reason given, followed by interest in whether a disease runs in the family or is in the individual's DNA (McGuire et al, 2009).

Recent reviews of company websites and privacy policies have found wide variation in the amount and content of information companies make available about the scientific basis for their testing services (Einsiedel and Geransar, 2009; Geransar and Einsiedel, 2008) and about their privacy policies and practices (Ries, 2010). One study of ten websites found low adherence to best practices advocated by health professional associations (Goddard et al, 2009) and another study found that high literacy levels – typically, college-level reading skills – are required to understand information and navigate the sites (LaChance et al, 2010). Websites are more likely to present benefits rather than risks of genetic testing (LaChance et al, 2010; Berg and Fryer-Edwards, 2008).

[1] For a list of companies and conditions for which tests are available (current to 28 May 2010), see Genetics and Public Policy Center: http://www.dnapolicy.org/resources/AlphabetizedDTCGeneticTestingCompanies.pdf.

Several DTC companies are now based in Canada. Toronto's Medcan Clinic was the first, pairing up with California-based Navigenics, to test for a variety of disease markers. Inneova in Vancouver focuses on genetic tests for age-related predispositions and has also partnered with US-based Knome to offer whole-genome sequencing services. C2DNA, a new company in Edmonton, offers disease and drug sensitivity tests (e.g. predisposition to thrombophilia, type 2 diabetes, cancer). Geographic location of such companies, however, is largely superfluous as Canadians may access genetic tests online through companies based elsewhere. The growth in internet commerce generally and the rapid increase in household connectivity has made marketing directly to consumers a predictable outcome. Eighty percent (80%) of Canadians aged 16 and older (21.7M people) used the internet for personal reasons in 2009, up from 73% in 2007 (Statistics Canada, 2010).

Although there is a broad range of genetic tests currently available, this Policy Brief will focus on health-related genetic tests marketed and sold online directly to consumers.

II. The Issue

There has been much recent debate around the pros and cons of offering genetic tests directly to consumers over the internet. Some see DTC access as the translation of genomic science with direct benefits to consumers while others say tests are of unproven value and may pose harm to consumers. Yet others say more evidence and stakeholder input is needed to inform policy responses.

Proponents "support the continued growth of this nascent industry" (Ng et al, 2009; Collins et al, 2003), while sceptics contend these tests are "more hype than hope" (Begley, 2010). Proponents argue that DTC genetic testing is more 'democratic' as it eliminates the need for a doctor's visit and enables "consumer access to research knowledge" (Avey, 2008) where it may otherwise take years before research findings are translated to publicly insured genetic tests. Recent US focus group findings show that a majority of participants expressed interest in knowing information about their genetic disease risks (Kalb, 2010). Genetic information may allow for more informed decision-making and control over one's health and may educate the public about genetics and disease risk. Restricting DTC access to genetic tests is also criticized as paternalistic, especially if based on unsubstantiated concern that consumers 'can't handle' information about themselves. Available evidence indicates that learning about one's genetic predispositions does not provoke lingering psychological distress, even for conditions such as Alzheimer's disease or cancer (Green et al, 2009, Heshka et al, 2008). DTC genetic tests are believed to play an important translational role for the science of genetics (Helgason & Stefansson, 2010) and the collection of large-scale genomic datasets enables more research (Eriksson et al, 2010).

Critics maintain that many genetic tests are being marketed prematurely and hardly provide 'actionable information' for consumers, particularly for complex conditions such as cancer, cardiovascular disease, or diabetes where genetic predisposition may play a relatively small role (Janssens et al, 2008). Whether genetic risk information motivates behaviour change remains uncertain (McBride et al, 2010), but people who act on advice provided by DTC companies are not necessarily better off than those who follow general public health advice such as not smoking, exercising regularly, eating a balanced diet, and maintaining a healthy body weight (Burke and Zimmern, 2004). Concern is also expressed about misleading marketing practices of some companies, including criticism that they encourage unnecessary genetic testing. For example, oncology experts say that a recent US DTC advertising campaign that urges all women to seek genetic testing for breast cancer is inappropriate, since only 2% of women benefit from such testing (University of Michigan, 2010).

Company practices regarding collection, use and retention of genetic samples and personal information also have important privacy and security implications. Genetic discrimination is a concern if third parties (e.g. employers, insurers) obtain access to test results. Proliferation of DTC tests could drive up costs in the public health care system if consumers, worried about genetic disease risks, go to their physicians seeking advice (Caulfield, 2009; McGuire and Burke, 2008). These physicians, in turn, may not be adequately trained to explain results to patients (Farrell, 2009).

In sum, the DTC marketing and sale of genetic tests online raise many policy issues, including, the accuracy, reliability and clinical utility of such tests, marketing/advertising practices of companies, consumer autonomy and protection issues, privacy and security of personal information in internet transactions, involvement of health professionals and resulting cost pressures on the health care system.

III. Legal – Policy Background

Given the broad span of issues canvassed above, a number of governmental and professional bodies in Canada have an interest in the nascent DTC genetic testing industry. For example, Health Canada regulates the manufacture and sale of genetic tests as in-vitro diagnostic devices (i.e. devices used in vitro for examination of biological specimens) under the Food and Drugs Act. However, whether DTC genetic tests fall within or outside the scope of existing provisions under the Medical Devices Regulations is debatable. The federal Competition Bureau enforces fair business practices under the Competition Act, including investigations of false or misleading marketing practices. The statute prohibits claims about a product's performance that cannot be substantiated with appropriate evidence and also forbids untrue or misleading testimonials. The Competition

Bureau periodically investigates health-related fraud concerning products sold over the internet. The Office of the Privacy Commissioner of Canada (OPCC) advocates for the privacy rights of Canadians and, under authority of federal privacy legislation, investigates complaints of alleged privacy breaches and oversees compliance with fair information handling principles in the public and private sectors. Genetic privacy is currently one of the four strategic policy priorities of the OPCC.

The role of Canadian federal regulators, law enforcement agencies, and other oversight bodies is complicated in the context of online commerce where enforcement against foreign companies raises jurisdictional uncertainties and practical challenges. In some situations, Canadian courts have enforced laws against companies based outside the country, but companies may attempt to deflect regulatory scrutiny by arguing they are not subject to Canadian legal requirements.

Health professional associations in Canada, including physicians and genetic counsellors, have an interest in DTC genetic testing. In May 2010, the Canadian Medical Association published recommendations for a national consultation on regulation of DTC genetic testing and professional associations outside Canada, such as the U.S. National Society of Genetic Counselors and the American College of Medical Genetics, have issued policy statements on DTC sale of genetic tests. These generally advocate for involvement of a knowledgeable professional in ordering and interpreting tests and for fully informed consent (that is, companies ought to disclose information about test purpose, accuracy, limitations, implications of results, and information handling practices).

IV. Policy Options

In view of current limitations of (or gaps in) existing regulatory and policy regimes, several policy options may be considered for addressing DTC genetic testing services online: (1) control access to genetic tests for more serious conditions; (2) allocate resources to enforce existing laws; (3) enhance information availability; and (4) actively monitor the situation. These options are not mutually exclusive and could be implemented concurrently. Industry self-regulation may be encouraged, especially in complying voluntarily with fair business practices and in being transparent and truthful in information disclosure to consumers.

Option 1 - Control access to genetic tests for more serious conditions

Legislative measures could be put in place to restrict or ban access to DTC genetic tests, especially tests for conditions that are more likely to have serious health implications. A legislative review in the US found that 13 states had laws prohibiting direct consumer access to laboratory services, including genetic tests, and 12 had restrictions (Hogarth et al, 2008). Germany passed a law in 2009 banning DTC sale (Wright, 2009) and a 2008 Council of Europe protocol states that genetic testing for health purposes must be conducted under medical supervision (Council of Europe, 2008). Although a ban on DTC genetic tests would not preclude access to testing in a clinical context, some commentators describe such prohibitions as "misdirected precaution" (Prainsack et al, 2008) and a "regressive and paternalistic approach" (Wright 2009) that "cannot keep pace with the reality of a dynamic science" (Brand, 2009). Some government bodies and professional associations have acknowledged that the wide range of DTC genetic tests – with varying risks and potential benefits – precludes a 'one-size-fits-all' regulatory approach, and that regulation according to risk is therefore desirable (American Society of Human Genetics, 2007; Secretary's Advisory Committee on Genetics, Health and Society, 2007; Human Genetics Commission, 2007).

How is the 'risk' of a genetic test to be determined? The physical risk of collecting a buccal swab is negligible, thus risk assessment must centre on potential harms associated with learning genetic information. Relevant questions may include: (1) what is the nature of the genetic trait/condition for which the test is offered; (2) how accurate/useful is the test in identifying genetic predispositions; and (3) what are the implications for clinical management of a condition? (Melzer et al, 2008; Burke et al, 2001) A test for predisposition to a particular type of ear wax (a test that some companies offer) is arguably less serious than a test for predisposition to a disease such as cancer or Alzheimer's disease. Genetic tests that offer diagnostic information or assess predisposition to a higher-penetrance, serious condition may warrant higher risk categorisation and tighter regulatory controls - especially if pre- and post-test counselling by an independent health professional (e.g. physician or genetic counsellor) may be needed to aid health care and reproductive decisions. A legislative approach could enhance consumer protection, protect the industry from the less scrupulous companies, and provide greater certainty and a more predictable business environment. Potential downsides include difficulty assigning risk categories in the absence of clear evidence of the harms and benefits of DTC access to information about genetic predispositions (see e.g. Heshka et al, 2008; Caulfield et al, 2010), as well as significant costs associated with regulatory enforcement.

Option 2 - Allocate resources to enforce existing laws

While existing laws may already govern some aspects of DTC genetic testing, the decision to allocate resources for effective oversight and enforcement action in this area requires a deliberate choice. Existing best practice statements (e.g. OECD Guidelines for Quality Assurance in Molecular Genetic Testing) may help guide allocation of regulatory resources.

Trade and advertising regulators have taken action against online companies in the US and the UK for making false or misleading claims about health-related services. The UK Advertising Standards Authority and the Trading Standards Office have both pursued complaints against companies making misleading genetic testing claims, resulting in changes to advertisements (Ries, 2009). The US Federal Trade Commission (FTC) periodically conducts web searches for companies that promote unfounded cures or therapies for conditions like cancer, multiple sclerosis and AIDS, and sends email warnings that, in some cases, motivate voluntary compliance without further regulatory action (Ries, 2009). The US Government Accountability Office investigated four online DTC genetic testing companies in 2006, which resulted in FDA follow-up (Hogarth et al, 2008). The FTC also publicises a consumer information sheet that provides a brief explanation of genetic testing, advises that "[n]o standards govern the reliability or quality of at-home genetic tests" and recommends that "[i]f you decide to use an at-home genetic test, talk to your doctor or health care provider about which test might be best, and discuss the results with your provider afterward."
(See www.ftc.gov/bcp/edu/microsites/whocares/genetictests.shtm).

As noted above, enforcing existing laws against companies based in another jurisdiction may be challenging. Short of costly and time-consuming legal action, however, Canadian officials may send warnings to companies that appear to violate domestic standards thereby prompting voluntary compliance.

Option 3 - Enhance information availability

To make knowledgeable choices about doing business with a DTC genetic testing company, consumers require, at a minimum, clear, evidence-based information about the predictive value of the test and the meaningfulness of test results, as well as information about companies' policies and practices for handling genetic samples and personal information. Codes of practice have been proposed to set out minimum standards to ensure transparent communication and thorough explanations about company services, policies and practices (Human Genetics Commission, 2010). To date, however, no industry-wide code of practice, either mandatory or voluntary, has been developed. It should also be noted that, absent independent oversight, a claim of adherence to a code of conduct may become another source of misleading marketing.

Genetic test registries have been proposed as a means to provide consumers and health professionals with access to up-to-date information about availability, validity and clinical utility of genetic tests (Javitt, et al, 2010; Melzer et al, 2008; US Secretary's Advisory Committee on Genetics, Health & Society, 2008). In the UK, a 2009 House of Lords report noted a proposed Department of Health website that would provide information on DTC genetic testing companies, including details about laboratory accreditation and validity and utility of tests (House of Lords, 2009). In March 2010, the US National Institutes of Health (NIH) announced it would establish a voluntary, publicly accessible genetic test database anticipated to be operational in 2011. This registry will be freely available to consumers and health professionals and has promise as a useful information source – provided people are aware of its existence. The US National Center for Biotechnology Information also hosts Genetests, a medical genetics information resource developed for healthcare professionals and researchers (see www.ncbi.nlm.nih.gov/sites/GeneTests/?db=GeneTests).

Canadian government and health professional organisations could collaborate on a public information campaign about DTC genetic testing, perhaps similar to fact sheets available on FTC and CDC (www.cdc.gov/genomics/gtesting/index.htm) websites in the US. An information campaign could achieve two key objectives: (1) publicise up-to-date and reliable sources of information about genetic tests (such as the NIH test registry) and (2) provide consumers with guidance on questions they need to have answered before doing business with genetic testing companies. For instance, a recent analysis of DTC company privacy policies includes a list of questions, based on ten fair information principles that consumers should ask to ensure they are fully informed about how companies handle genetic samples and personal information (Ries, 2010). Pursuing this type of option is relatively low-cost, meets consumer education goals, and counters less reliable sources of information on the internet. Downsides of the educational approach are that it places consumer protection responsibility largely on consumers themselves and it only reaches those who are motivated to look up government websites for information on genetic testing.

Option 4: Actively monitor the situation

Governmental and professional bodies with an interest in DTC genetic testing could continue to monitor developments in the DTC genetic testing marketplace. An advantage of this approach is that it would give more time to see how the science and commercialisation of genetic testing advances, whether industry best practices begin to emerge organically, what new research reveals about the benefits and harms of DTC access, and how regulatory initiatives elsewhere might benefit Canadians. A disadvantage of delaying more concerted regulatory action is that it can become 'too-little-too-late.' Indeed, some commentators already suggest that the genomics "genie is out of the bottle" (Khoury, 2009) and that governmental oversight bodies have been uncoordinated and inconsistent in addressing DTC services (Lakhman, 2010).

V. Practical considerations

As a practical matter, the inherent challenges of monitoring, enforcement and defining appropriate regulatory authority and control in cyberspace (Murray, 2007) will apply to online DTC genetic testing. Moreover, as noted by some scholars, "[t]he Canadian regulatory framework governing genetic tests is fragmented as a result of the constitutional division of powers between the federal and provincial levels of government." (Petit et al, 2008) Any regulatory or policy initiative will have to consider these complex jurisdictional issues.

VI. Future Research Questions

Given the uncertainty of existing legislative coverage in this area, a 'gap analysis' would be useful to clarify the applicability of existing laws to DTC genetic testing companies (including companies based outside Canada) and would help identify priorities for resource allocation.

Some existing research (e.g. Janssens et al, 2008) has examined the scientific basis for a sample of DTC genetic tests and current FDA and GAO regulatory scrutiny in the US is also probing evidence for some companies' claims (GAO, 2010). Further research into the reliability, clinical validity and utility of such tests will continue to be important as science evolves and new tests develop.

There is also a need to examine the evolving market around DTC genetic tests, including: Canadians' awareness of and views on these tests; how consumers may use test results and share them with others through social media; the perception and perspectives of health care providers; how industry practices evolve– from privacy and consent to information provision, advertising and promotion; and the economics of business models (e.g. cost-benefit analyses and impacts of pricing structures on consumer purchase decisions).

Given current concern about rising health care costs, the concrete impact of DTC genetic testing on demands for health care services and the health care system needs to be evaluated. Moreover, the effect of DTC genetic testing on the health professional-patient relationship needs to be better understood.

Finally, as some companies increasingly promote use of their consumers' genetic tests results for research purposes, the combined role of consumer-research participant and its implications for research ethics requirements need to be understood more fully. (Errikson et al, 2010)

References

Policies

American Society of Human Genetics (2007). ASHG Statement on Direct-to-Consumer Genetic Testing in the United States. *American Journal of Human Genetics*, 81, 635-37.

Council of Europe (2008), Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes. http://conventions.coe.int/Treaty/EN/Treaties/html/203.htm.

Federal Register (2010). *Oversight of Laboratory Developed Tests; Public Meeting; Request for Comments*, 75 Federal Register 116 (17 June 2010), p. 3444631, online: http://edocket.access.gpo.gov/2010/2010-14654.htm.

GAO (2010). Direct-to-consumer Genetic Tests: Misleading Test Results are further complicated by deceptive marketing and other questionable practices. Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives. July 22.

House of Lords, Science and Technology Committee, 2nd Report of Session 2008-09. *Genomic Medicine – Volume 1: Report*. (London: The Stationery Office Limited, 2009). Online: http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf.

Human Genetics Commission (2010). A Common Framework of Principles for direct-to-consumer genetic testing services: Online: http://www.hgc.gov.uk/client/Content.asp?ContentId=816.

National Institute of Health (US), 2010. Genetic Testing Registry website. Online: http://www.ncbi.nlm.nih.gov/gtr/.

Organization for Economic Cooperation and Development (2007). OECD Guidelines for Quality Assurance in Molecular Genetic Testing, online: http://www.oecd.org/dataoecd/43/6/38839788.pdf.

Secretary's Advisory Committee on Genetics, Health & Society, 2008. U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services. Online: http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf.

Statistics Canada (2010). Canadian Internet Use Survey. The Daily, May 10, 2010. http://www.statcan.gc.ca/daily-quotidien/100510/dq100510a-eng.htm.

Literature

Avey, L. (2008). Presentation to July 8, 2008 meeting of the Secretary's Advisory Committee on Genetics, Health and Society. Copy on file with author, N.M. Ries.

Begley, S. (2010). "DNA As Crystal Ball: Buyer Beware." Newsweek (18 May 2010) online: http://www.newsweek.com/2010/05/18/dna-as-crystal-ball-buyer-beware.html.

Berg, C. and K. Fryer-Edwards (2008). "The Ethical Challenges of Direct-to-Consumer Genetic Testing." *Journal of Business Ethics* 77:17-31.

Brand, A. (2009). "Integrative Genomics, Personal-Genome Tests and Personalized Healthcare: The Future Is Being Built Today." *European Journal of Human Genetics* 17:977-978.

Burke, W. and R.L. Zimmern (2005). "Ensuring the Appropriate Use of Genetic Tests." *Nature reviews-Genetics* 5:955-59.

Burke, W., L.E Pinsky, and N.A. Press (2001). "Categorizing Genetic Tests to Identify their Ethical, Legal and Social Implications." *American Journal of Medical Genetics* (Semin Med Genet) 106:233–40.

Carr, G. (2010). "A Special Report on the Human Genome: Biology 2.0." *The Economist*, June 17, 54-58.

Caulfield, T. et al (2010). "Direct-to-Consumer Genetic Testing: Good, Bad or Benign?" *Clinical Genetics* 77(2):101-105.

Caulfield, T. (2009). "Direct-to-Consumer Genetics and Health Policy: A Worst-Case Scenario?" *American Journal of Bioethics* 9(6/7):48-50.

Collins, F.S. et al (2003). "A Vision for the Future of Genomics Research: A Blueprint for the Genome Era." *Nature*, 422:835-47.

Einsiedel, E.F. and R.M. Geransar (2009). "Framing Genetic Risk: Trust and Credibility Markers in Online Direct-to-Consumer Advertising for Genetic Testing." *New Genetics and Society* 28(4): 339-362.

Eriksson, N. et al (2010). "Web-based, Participant-driven Studies Yield Novel Genetic Associations for Common Traits." *PLoS Genetics* 6:6:e1000993. doi:10.1371/journal.pgen.1000993.

Farrell, J. (2009). "Health Care Provider Capacity in Nutrition and Genetics: A Canadian Case Study." in D. Castle & N.M. Ries, eds. *Nutrition and Genomics: Issues of Ethics, Law, Regulation and Communication* (Elsevier, 2009), pp. 139-160.

Geransar, R.M. and E.F. Einsiedel (2008). "Evaluating Online Direct-to-Consumer Marketing of Genetic Tests: Informed Choices or Buyer Beware?" *Genetic Testing* 12(1):13-23.

Goddard K.A. et al (2009). "Health-related Direct-to-Consumer Genetic Tests: A Public Health Assessment and Analysis of Practices Related to Internet-based Tests for Risk of Thrombosis." *Public Health Genomics* 12(2):92-104.

Green R.C. et al (2009). "Disclosure of APOE Genotype for Risk of Alzheimer's Disease." *New England Journal of Medicine* 361:245-54.

Helgason, A. and K. Stefánsson (2010). "The Past, Present, and Future of Direct-to-Consumer Genetic Tests." *Dialogues in Clinical Neuroscience* 12(1):61-8.

Heshka, J.T. et al (2008). "A Systematic Review of Perceived Risks, Psychological and Behavioural Impacts of Genetic Testing." *Genetic Medicine* 10(1):19–32.

Hogarth, S., G. Javitt, and D. Melzer (2008). "The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues." *Annual Review of Genomics and Human Genetics* 9:161-182.

Janssens, A.C. et al (2008). "A Critical Appraisal of the Scientific Basis of Commercial Genomic Profiles Used To Assess Health Risks and Personalize Health Interventions." *American Journal of Human Genetics*, 82(3):593-99.

Javitt, G. et al (2010). "Developing the Blueprint for a Genetic Testing Registry." *Public Health Genomics* 213(2):95-105.

Kalb, C. (2010). "Inside Information: New Research Has Found that a Majority of Americans Want To Know the Details of their Genetic Codes." *Newsweek* (9 June 2010) online: http://services.newsweek.com/id/238631/page/1 [reporting on findings from focus group studies conducted through the Genetics and Public Policy Centre, Johns Hopkins University].

Khoury, M. (2009). Quoted in Nancy MacDonald, "The DNA Discount: The Falling Cost of Genetic Testing Opens a Whole New Market." *MacLean's* (23 July 2009) online: http://www2.macleans.ca/2009/07/23/the-dna-discount/.

Lachance C.R. et al (2010). "Information Content, Literacy Demands, and Usability of Websites Offering Health-related Genetic Tests Directly to Consumers." *Genetic Medicine* Apr 9. [Epub ahead of print]

Lakhman, K. (2010). "OIVD Needs a Consumer Genetics Game Plan, and Fast." *Genome Web Daily* (18 May 2010) online: http://www.genomeweb.com/blog/oivd-needs-consumer-genetics-game-plan-and-fast.

Lee, S.S. and L. Crawley (2009). "Research 2.0: Social Networking and Direct-to-Consumer (DTC) Genomics." *American Journal of Bioethics* 9(6-7):35-44.

McBride, C. et al (2010). "The Behavioral Response to Personalized Genetic Information: Will Genetic Risk Profiles Motivate Individuals and Families to Choose More Healthful Behaviors?" *Annual Review of Public Health* 31:89-103.

McGuire, A.L. et al (2009). "Social Networkers' Attitudes toward Direct-to-Consumer Personal Genome Testing." *American Journal of Bioethics* 9(6-7):3-10

McGuire, A.L. and W. Burke (2008). "Raiding the Medical Commons: An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing." *JAMA* 300(22):2669-2671

Melzer, D. et al (2008). *Evidence and Evaluation: Building Public Trust in Genetic Tests for Common Diseases*. Public Health Genomics Foundation, Online: http://www.phgfoundation.org/reports/4981/.

Murray, A. (2007). *The Regulation of Cyberspace: Control in the Online Environment*. Abingdon: Routledge Cavendish.

Ng, P.C. et al (2009). "An Agenda for Personalized Medicine." *Nature* 461(8):724-726.

Petit, E., A.M. Tassé and B. Godard (2008). "An Empirical Analysis of the Legal Frameworks Governing Genetics Services Labs in Canadian Provinces." *Health Law Review* 16(3):65.

Prainsack, B., et al (2008). "Misdirected Precaution." *Nature*; 456:34–35.

Ries, N.M. (2010). *Analysis of Privacy Policies and Practices of Direct-to-Consumer Genetic Testing Companies: Private Sector Databanks and Privacy Protection Norms*. Online: http://www.law.ualberta.ca/centres/hli/userfiles/file/Full%20Version%20OPCC%20Report%20March%2028%202010.pdf.

Ries N.M. (2009). 'Risk-based Regulation of Direct-to-Consumer Nutrigenetic Tests" in D. Castle & N.M. Ries, eds. *Nutrition and Genomics: Issues of Ethics, Law, Regulation and Communication* (Elsevier, 2009), pp. 85-102.

Shuren, J. (2010). "Direct-to-Consumer Genetic Testing and the Consequences to the Public," Statement delivered to US FDA Subcommittee on Oversight and Investigations (22 July 2010) online: http://www.fda.gov/NewsEvents/Testimony/ucm219925.htm.

Singer, E. (2009). "Off-the-shelf Genetic Testing on Display." *Technology Review*, online: http://www.technologyreview.com/biomedicine/22765/page1/.

University of Michigan Comprehensive Cancer Center (2010). "Testing for Breast Cancer Gene: No Simple Answer." News release (14 January 2010), online: http://www.cancer.med.umich.edu/news/breast-cancer-genetics10.shtml.

Wright, C. (2009). *Ban on Direct-to-Consumer Genetic Tests in Germany.* Public Health Genomics Foundation (28 April 2009). Online: http://www.phgfoundation.org/news/4562/.

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