Caveat Emptor: Direct-to-Consumer Supply and Advertising of Genetic Testing

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Caveat emptor: direct-to-consumer supply and advertising of genetic testing

Roxanne Mykitiuk, BA, LLB, LLM

Most Canadians who wish to access genetic diagnostic and susceptibility tests do so through the publicly funded health care system. However, some genetic tests are not covered under that system, and individuals may seek to purchase them from private sources. The Internet has become both a vehicle for advertising and a means to convey Canadians to private genetic testing sources. Usually, people are directed to international providers, but in the case of tests for a number of conditions such as breast and ovarian cancer they are also directed to local private laboratories such as the multi-city branches of MDS Laboratory Services, whose home office is in Toronto.

Normally, people interested in accessing genetic testing services must do so through a physician who may order the test. However, a few companies market their genetic testing products and services through direct-to-consumer (DTC) advertising, enabling patients to bypass physician involvement. In Canada, the perceived desire for access to genetic tests outside the public system is not only exploited but promoted through Internet availability. In the United States, DTC marketing of genetic testing through print and broadcast campaigns has begun, which contributes to the perceived desire for such testing. For example, in the fall of 2002, Myriad Genetics, Inc. (Myriad) began a DTC advertising campaign for its product BRACAnalysis (which tests for risk of breast and ovarian cancer) in both print and broadcast media.

The surge in recent advances in human genetics has fostered a trend towards commercialization, just as commercial interests have contributed to the recent advances in genetics: universities and government research centres frequently seek collaboration with (and funding from) private genome research companies, which in turn increasingly are developing cooperative relationships with pharmaceutical companies. In the context of DTC advertising and supply of genetic testing services, this raises concerns about the type of information that is provided to “consumers” through the commercial market. Companies who manufacture products necessarily participate in the creation of consumer demand, precluding the provision of unbiased and sufficient information that is not necessarily in the best interest of the consumer. Irrespective of the fact that DTC marketing effectively sidesteps physician involvement, there is also some question as to whether physicians themselves possess a level of knowledge adequate to comprehend these genetic tests and explain their import to their patients.

In the absence of any meaningful regulation restricting DTC advertising of genetic testing services, Canada is likely to witness an increase in print and broadcast advertising of genetic testing similar to the marketing campaigns now being launched in the USA. This article therefore has 4 intents:

1. to highlight the major players and targeted consumers in the realm of private access to genetic testing and DTC advertising
2. to canvass arguments for and against private access to commercially available genetic testing
3. to analyze the recent DTC campaign by Myriad as an example of what may be on the horizon for Canada
4. to question the adequacy of Canada’s current regulatory system to deal with advertisements of this nature and, by examining the routes taken in other jurisdictions, to explore the potential for an improved regulatory framework specific to genetic testing services

Access to commercial testing services for genetic susceptibility

Currently, Canadians access genetic testing primarily through the public health care system. Patients typically visit their family physician; given a clinical presentation or family history suggestive of an inherited condition, they are then referred to a genetics department in a hospital or cancer agency for genetic counselling. In Ontario, 9 linked regional genetics centres in Hamilton, Kingston, London, Mississauga, North York, Sudbury, Oshawa, Ottawa and Toronto operate as a genetics network for the province. In November 2001, base funding for the Provincial Regional Genetics Program in Ontario was $39 million. In light of the rapid growth in genetic testing capabilities, significant deliberation has been given to instituting a framework for the evaluation of public coverage of predictive genetic tests and services. To this end, the Ontario Provincial Advisory Committee on New Predictive Genetic Technologies recommended the assessment of 6 key factors in determining whether a particular genetic test will be granted provincial coverage: technical accuracy; clinical effectiveness; usefulness to tested individuals; adverse and additional effects; expansion potential; and cost.

Even if this comprehensive evaluation scheme is implemented, not all useful genetic tests will be covered by provincial health insurance plans. Moreover, access to government-funded tests will be limited to those individuals considered by their physicians and the referral centre to benefit clinically from testing. Not all individuals who seek genetic testing will be able to access it. And whereas some people may feel relieved to be told that they do not need genetic testing, others may feel neglected, fearful or anxious, and will turn to private options. Similarly, the “motivated consumer” with access to the Internet will soon discover the quick and accessible testing services that can be purchased privately.

At present, only a handful of private Canadian laboratories offer genetic susceptibility testing for adult-onset conditions. Most Canadian companies focus their genetic interest instead on paternity testing (e.g., Helix Biotech) and pre- and post-natal diagnostics (e.g., Procrea). Although there are still few commercial genetic testing laboratories in the United Kingdom, the growing availability of genetic testing has prompted Britain’s Human Genetics Commission to devise a thorough study of oversight (i.e., the regulation) of direct genetic testing. Public demand for direct genetic testing services was found to be fairly low: over 60% of those surveyed stated that they were “unlikely” or “very unlikely” to use home genetic testing. On the other hand, 81% responded that they would consider genetic testing if offered by their physician.

In contrast, many more American companies have been involved in genetic testing; in 1996, there were “approximately 200 laboratories providing 175,000 genetic tests for over 300 diseases or conditions in the USA.” Although the majority of these tests are marketed to medical professionals, DTC advertising and supply is on the increase. Hundreds of commercial Web sites now direct consumers to companies that provide paternity testing, DNA “fingerprinting” or pre-natal testing, most based in the USA. There are also companies in Canada and Europe that provide access to testing over the Internet. Of these Web sites, a dozen or so also direct consumers to adult genetic susceptibility testing companies, and 4 offer DTC genetic testing services themselves. Increasingly, because of the “global marketplace” created by the Internet, provincial and national borders are becoming irrelevant.

DTC genetic testing is possible because of the relative ease with which genetic material can be retrieved for laboratory analyses. In most cases, tests are done on samples collected through non-invasive means such as mouth swabs or saliva samples. Most laboratories make the process even easier for customers by providing containers and detailed instructions for obtaining, packaging and shipping the samples, as well as referrals to local affiliated clinics if a blood sample is required. Payment for testing, either DTC or privately purchased but mediated by a physician, may be billed to a credit card through a
secure Web site or paid by a third party such as a private insurer.¹

Arguments in favour of direct-to-consumer supply of genetic testing

A prime attraction for consumers of private genetic testing services, and one that marketing campaigns target specifically, is the potential for enhanced privacy and individual control of genetic information.¹⁰ Patients can order tests online without having to meet the criteria required to obtain them through a physician’s office.¹ Also, as test results can be received at home, they are not automatically entered into medical records and therefore can be kept hidden from insurers or employers.¹ This may be a significant incentive for consumers, especially in the United States where the link between employment status and health insurance makes genetic discrimination a concern.¹¹ However, it should be noted that some jurisdictions have implemented and many others have recommended the implementation of regulations or legislation to avoid discrimination in the context of insurance.¹²

The privacy argument may have less weight in Canada and other countries where health coverage is provided universally regardless of one’s health or employment status, although concerns about life insurance may remain.¹ Where a test is not covered under a public health care system, genetic information may be desired nonetheless and considered worth paying for, out of pocket.¹³ Although a specific genetic test may not be covered because of a lack of evidence for clinical effectiveness,¹ consumers may have other motives to seek testing, including to reduce anxiety; to facilitate life planning; to initiate family discussions of issues such as social and psychological support and responsibility to and for other family members; and to help people plan career changes.¹³-¹⁵

A prominent argument in favour of DTC supply of genetic tests is consumer autonomy. Proponents of this view argue that the ability to obtain information about oneself, including information about one’s potential risk of disease, is an individual right that should be restricted only in cases where the interests of others might be harmed.⁹ This view is consistent with the shift from paternalism to individual self-determination that characterizes current approaches to health care and underpins many of the arguments in favour of DTC advertising and supply of genetic testing services.¹⁶

Other potential benefits include better-informed consumers, which may lead to superior quality of care stemming from improved diagnosis; to better matching of therapy needs to the preferences of patients; and possibly to enhanced compliance with treatments.¹⁷ Similarly, ads for genetic tests targeted directly to the public may have educational value if the information they provide is scientifically accurate. Such advertisements may provide relevant information about testing that could lead to therapeutic interventions or increased disease surveillance. They may also raise awareness of community resources such as associations and support groups for those dealing with various genetic diseases and predispositions, and of options for parents and potential parents about reproductive alternatives and screening tests for newborns.¹⁸ Nevertheless, profit-driven education is inherently suspect, and the public can be informed and educated by more trustworthy means.

Concerns about the direct supply of genetic testing services

Genetic testing provides information that is often complex and difficult to understand; nevertheless, it may profoundly affect a person’s sense of self and have important implications for family members. Patients who, in the estimation of their physicians, do not need or are unlikely to benefit from genetic testing may nonetheless be influenced by marketing that plays on or increases anxiety, and may be harmed by the resulting genetic information.¹⁹-²⁰ Misunderstandings about risk estimations, how the information should be integrated into one’s life, and what to explain to family members are frequent.²¹,²²

Consumers may gain a false sense of security from negative test results, spend limited financial resources on testing that could better be used elsewhere, or become unnecessarily anxious about risk for disease.²³ Furthermore, individuals who have misunderstood information from genetic tests, received incorrect information or misinterpreted predictive health information could consequently make poor health-related
decisions, such as delaying seeking medical advice, seeking inappropriate medical treatment, or making expensive and unproven lifestyle or dietary changes. The risk of both physical and psychological harm thus justifies consumer protection relating to both the advertising and supply of health related products.

As much as consumers may desire straightforward choices and “solid” information, genetics is a complex and rapidly changing area. Cancer itself has a great many contributing factors beyond inherited genes, and the interactions are complicated and often unclear. The risks and uncertainties associated with genetic information are difficult for many physicians to grasp, let alone the general public. DTC advertising of tests enables genetics companies to take advantage of peoples' incomplete understanding of genetics and exploit their worries about their and their family’s health and future. Advertising in general plays on the emotions of the target audience and can not provide the type of information that consumers need to make informed decisions, particularly about pharmaceutical and genetic products.

False positives and false negatives constitute another concern. Currently there is little or no professional consensus in the scientific community about the clinical value of many genetic tests. For example, the BRACAnalysis test for breast and ovarian cancer was put on the market despite disagreement on the test’s “appropriateness” at the time. It is a consequence of commercialization that commercial pressures become the leading reason for the entrance of items into the marketplace, which may lead to the introduction of health care products prematurely.

In addition, inadequate opportunities for qualified genetic counselling may leave patients psychologically unprepared to deal with the genetic information they do receive. Genetic counselling for patients and families undergoing genetic susceptibility or diagnostic testing has become the standard of public health care in Canada, but only a few private companies provide or require counselling as part of their genetic testing services.

Given the current shortage of genetic counsellors, it will most likely be family physicians who will receive requests for access to private testing. They may have to interpret advertisements for interested patients, explain why tests may be inappropriate and provide additional counselling. This increase in workload will add to their stress, with serious consequences for their patients. Time constraints may limit the effectiveness of their counselling, and many family physicians will not have had the necessary background in genetics, let alone specific training in counselling, to provide and interpret test results and help patients understand the complex scientific, social and psychological issues. Nor is it likely that physicians will have had the training to evaluate the validity of claims made by industry about the accuracy and benefits of testing. Thus, many family physicians may be open to the influence of companies’ marketing strategies and unable to effectively criticize the information they receive, as has been argued with respect to prescription drugs.

DTC advertising and supply of genetic tests also raises concerns about strains on the financial resources of the health care system and has implications for equal access to health care services. Inappropriate demands by patients for genetic testing can burden public health funds; so can post-test costs such as counselling, follow-up of results and associated treatments—all of which are likely to be covered under the public health care system.

Access to and cost of genetic tests through public health care systems are controlled by the patent owners, who legally control access to and development of any type of test, treatment or cure that uses the patent. For example, Myriad Genetics, Inc., owner of the Canadian patents for the BRCA1 and BRCA2 genes linked to hereditary breast cancer, is attempting to enforce its gene patents and oblige public agencies to provide BRCA testing exclusively through use of its BRACAnalysis test.

Myriad’s monopoly over the BRCA1 and BRCA2 genes illustrates the growing phenomenon of biotechnology companies patenting the development, marketing and provision of genetic tests and therapeutics. Public health care systems like Canada’s could lose the ability to provide coverage for many types of genetic testing, since companies are driven to market their gene-based diagnostic products and therapeutics in a restrictive and costly fashion to recoup their research investments.

There are also serious concerns about the safety, accuracy and quality control of commercial genetic
tests. Regulatory agencies and oversight mechanisms are in place in the USA, Canada and other countries to inspect national laboratories and to review staff and technical qualifications. But even when present, these review mechanisms may be implemented by agencies that are understaffed and under-resourced, and able to respond only afterward to serious breaches in standards. Because the Internet allows companies to cross national borders, using the Internet as a marketing and delivery mechanism enables testing providers to avoid being subject to the national regulatory regimes of a consumer’s home country. Since there are as yet no international regulations for genetic testing facilities, consumers will be unlikely to know if a given provider is meeting their local standards for safety and accuracy. 1

Ontario’s health care system facilitates quality assurance in genetic testing by integrating pre-test preparation, laboratory analysis and interpretation into clinical practice, along with support consultation about test results. The standards used by professionals and institutions when delivering other services will apply to the provision of genetic testing and ancillary services integrated into Ontario’s public health care system. Since the procedures of private laboratories are not transparent, there is no guarantee that they are implementing standards of quality assurance or confidentiality.

In response to some of these concerns a number of Internet health service providers (not specifically genetic testing companies) have attempted some form of self-regulation. For example, some providers have chosen to adopt codes of ethics, such as the e-Health Ethics Initiative, Draft Code or the HON Code of Conduct for Medical and Health Web Sites (www.ihealthcoalition.org/ethics/ehcode.html and www.hon.ch/HONcode/Conduct.html, respectively), that include guidelines about protection of privacy, quality, authority and accuracy of information, and transparency of interests. 1

Such efforts at self-regulation may convince legislators that overt regulation is unnecessary; however more formal regulation and oversight is advised, particularly in the area of genetic testing services, to protect consumer privacy of personal health information and to ensure the accuracy of marketing claims and efficacy of tests. Given the international scope of commercial health care provision, national governments must also work toward harmonizing regulation and oversight mechanisms. 1

An example of DTC marketing of genetic susceptibility testing: the Myriad campaign

Myriad’s DTC advertising campaign for breast cancer testing, which included both broadcast and print media, was piloted beginning September 13, 2002 in Denver and Atlanta. According to Myriad’s press release, the “campaign is designed to alert women with a family history of cancer to recent advances in cancer prevention and early disease detection. It is no longer appropriate for these women to simply consider breast cancer their destiny, even in the context of a strong family history of the disease.” Myriad goes on to say that “medical interventions have been shown to be effective in lowering the risks of cancer in individuals [with a family history of the disease].” Whereas their earlier marketing and educational efforts had been aimed toward cancer specialists, they state that there is now a need to “reach those with a family history of breast or ovarian cancer who do not themselves have cancer,” because this group of individuals “stands to benefit the most” from this tool of predictive medicine.

The broadcast ad features several women each stating their concern about breast cancer and the benefits of taking a BRACAnalysis test. They appear calm and in control, as if the knowledge they have gained from taking the test has made them more confident. Toward the end of the minute-long advertisement, a woman’s voice explains that BRACAnalysis “can help you see the big picture.”

The ad is notable in several ways. First, it features women of visibly diverse racial origins, almost all apparently between the ages of 30 and 45. The campaign is aimed at women between the ages of 25 and 54 and targets major cities with large minority populations: Hispanics in Denver and African-Americans in Atlanta (Sandra Blum, BRACAnalysis Project Manager, Myriad Genetics, Inc., Salt Lake City, Utah: personal communication, 2002 Oct. 21). To achieve the broadest potential market Myriad is clearly attempting to demonstrate that the risk of breast cancer cuts across the population. Moreover,
by targeting relatively young women in their thirties and early forties, the campaign is attempting to capture women with significant disposable income, at an age when they are making important choices about career and family life. The BRACAnalysis Integrated Awareness Campaign ran for 5 months and included ads broadcast during major television shows, including ER, The Practice, CSI: Miami, Providence, Oprah, Regis and Kelli, and The Today Show. In addition, print advertisements ran in regional versions of publications such as Better Homes and Gardens, The Ladies' Home Journal and Women's Health Monitor. The choice of many of the marketing venues indicates an attempt by Myriad to target a demographic of women who already have a general interest in issues relating to health and well-being.

Second, the fact that the ad never uses the words “gene” or “genetic” but instead talks about “family history” implies to viewers that BRACAnalysis can identify individuals at risk for heritable forms of breast cancer. This is a sweeping and exaggerated claim: BRACAnalysis can only identify 2 genetic mutations associated with about 7% of all breast cancers. 10

Third, the ad suggests that a woman who takes the test will be able to “reduce her risk through effective medical options,” but these options are never identified. Instead, the ad cultivates an overall impression that taking “a simple blood test” will enable the viewer to reduce her risk of breast cancer. The uncertainties of genetic testing are downplayed, and the lack of professional consensus on the clinical validity and efficacy of the test goes unmentioned. The symbolism of the “big picture” theme that pervades the ad covertly implies that the advertisement is providing thorough and unbiased information.

Fourth, the ad cleverly plays on 2 common themes often used in pharmaceutical advertising. 31 On the one hand, the ad promotes the idea of interventionist medicine, which places a high value on action while rejecting the “wait and see” model of health care. 32 Traditionally, the “take-action” approach to health care refers to the notion of physician control. This emphasis on medical intervention creates a chain between manufacturer, advertisement and doctor, with the ultimate profit going to drug companies or, in this case, genetics testing companies. 31

On the other hand, by advertising BRACAnalysis directly to the consumer, Myriad introduces the secondary concept of “participatory and autonomous roles in the context of medical decision-making.” 11 In drawing on the theme of “choice,” Myriad’s ads “validate patients’ worries about their genetic risks and appeal to their desire to assert control over potential outcomes.” 18 This encourages the move away from the paternalistic doctor–patient relationship and stresses the consumer’s right to gain knowledge about their own risk for disease and hence their right to be in control.

Interestingly, the voice-over at the end of the broadcast ad states “Talk to your doctor,” which seems to dismiss the notion of consumer autonomy. Conversely, this statement gives viewers the impression that physicians will corroborate the “information” from the ad, and grants patients who have decided to undergo BRACAnalysis testing the reassurance that they are making the proper choice. Thus, the advertisement conveys the notion that the medical profession does not have a monopoly on knowledge about our bodies, and reinforces the notion that patients will reap a benefit from choosing to act autonomously and get a genetic test.

Fifth, contrary to Myriad’s claim that BRACAnalysis is the tool of choice for women to reduce their risk of breast cancer, the ad’s repeated use of the words “risk” “choose” and “ready” demonstrates that the campaign’s true purpose is to heighten the perception of risk of cancer among a broader segment of women than would be identified through physician advice or evidence-based medicine. Playing on women’s fears and suggesting that all women are at risk is a common feature of DTC pharmaceutical advertising. 32

Overall, there is little doubt that the main objective of the ad campaign is to target women and to bypass the role of physicians as the gate-keepers of medical knowledge, despite claims to the contrary that it is an “integrated” campaign addressed both to physicians and to women with a family history of the disease. Interestingly enough, the product manager for BRACAnalysis indicated that the campaign was aimed at women because they are known to be the managers of health care in the family and not just.
because the incidence of breast cancer is much higher in women. Just days into the campaign, Myriad cited with pride the 40 phone calls a day received on their toll-free number as a direct result of the campaign.11

Myriad asserts that since physicians are not adequately informed about genetics and testing, a DTC advertising campaign is warranted to educate consumers so they can make better health-care decisions. There is some credibility to this argument in private systems like that of the United States, where no governing public body bears the responsibility for promoting consumer awareness and undertaking health education programs. In Canada’s public health systems, this responsibility lies with provincial health departments; in Britain’s, with the National Health Service. The danger is that the information provided is motivated by market incentives and is thus not primarily designed to educate.

Current regulations of DTC supply and advertising of genetic testing in Canada

The advertising of pharmaceutical drugs and medical devices in Canada is governed by the Food and Drugs Act33 and the Broadcasting Act,34 but there is nothing in these Acts or their regulations that would prohibit or regulate DTC advertisements of genetic testing similar to Myriad’s campaign in the USA. The Food and Drugs Act prohibits advertising to the public of any food, drug, cosmetic or device as a treatment, prevention or cure for a number of diseases indicated in a schedule in the legislation.33 A “device” is any article, instrument, apparatus or contrivance that is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease.35

It is uncertain whether a device, as defined, includes commercial genetic test kits, since the uses listed may not fully describe the purpose of a genetic test such as the BRACAnalysis product. The Medical Devices Bureau, an agency enabled by the Medical Devices Regulations and the Food and Drugs Act, is responsible for issuing licences to manufacturers to sell medical devices in Canada. Sections 26 and 27 of the Medical Devices Regulations control the advertising of products that fall under Class III, meaning they present a moderate risk in terms of public health implications.35 These provisions indicate that a licence must be held in order to sell genetic tests, and that if they are advertised there must be a warning stating that they may not have been licensed in accordance with Canadian law. Before the product is available for sale in Canada, a pre-market review is done, at which time a genetics company will attempt to obtain a licence by satisfying safety effectiveness and clinical standards. Advertising is a post-market activity under the mandate of the Inspectorate. Identifying which oversight bodies are expected to regulate DTC advertising tells only half the story: tight government resources and pressure in Canada to lift restrictions on DTC advertising means that the agencies with the mandate to regulate in this area are having difficulty doing so.36

It is important to note that what is actually being regulated by the aforementioned legislation and regulations are commercially offered genetic test kits that might be marketed to individuals for their own private use, rather than genetic testing that is offered as a service. For the most part what is on offer today, and what consumers are purchasing, are not genetic test kits but testing services that fall outside the scope of current legislation.

Furthermore, the content of ads of this nature are not subject to regulation under the Broadcasting Act, but to a voluntary system of regulation through voluntary adherence to guidelines established by the Pharmaceutical Advertising Advisory Board (PAAB). An organization of interested groups, including manufacturers, PAAB has developed a Code of Advertising Acceptance for what they term advertising and promotion systems. The advisory board operates independently of government regulatory structure. The PAAB Code37 applies to “all communications in which claims, quotations and references are made for single-entity and compound prescription and non-prescription (over-the-counter) pharmaceutical products.” Moreover, a pharmaceutical product is defined as “a substance or mixture of substances manufactured, sold or represented by a specific manufacturer for in vivo use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or in restoring, correcting or modifying function(s) in humans.” Again, it is necessary to ex-
amine the purpose of the product put forth by the manufacturer to determine whether or not it fits into the PAAB Code's definition and is thus subject to regulation. It is questionable whether genetic tests will ever fit this definition.

An examination of how DTC advertising and supply of genetic testing is regulated in other countries identifies paths Canada could follow in developing its own regulatory scheme.

Future regulatory framework: ideas from other jurisdictions

The British Human Genetics Commission found that in the United Kingdom there was a general interest in placing restrictions on advertising of DTC genetic testing. Many of the Commission's general recommendations on DTC advertising and supply of genetic testing are pertinent to the development of a regulatory scheme for Canada.

Current controls on genetic testing in the United Kingdom include the Advertising Standards Authority, which administers the British Codes of Advertising and Sales Promotion. Many of those participating in the Commission's study supported strengthening the Codes, especially in relation to direct genetic testing services, which could take the form of an additional section in the Codes with specific requirements. The report stated that most genetic tests that provide predictive health information should not be supplied directly to the public or through a non-medical health professional such as a pharmacist. For direct genetic tests to be provided over-the-counter, a manufacturer would have to "convince a regulator that the test is sufficiently well validated and that anyone involved in providing the test has the right training and expertise to give good quality advice to the consumer," an approach that resembles the way medicinal products classified as "pharmacy-only" are regulated.

In the United States, both the Food and Drug Administration and the Federal Trade Commission have roles to play in monitoring advertisements of genetic tests, yet neither has exercised their authority in this area. Some suggest that "shared oversight" of DTC advertising of genetic testing by these administrations would help ensure that advertisements provide information about the risks as well as the benefits of using genetics tests and avoid hyperbolic statements about their effectiveness. After the Myriad campaign, the Centers for Disease Control and Prevention also launched a study similar to that of the British Commission to investigate the effects of DTC advertising of genetic testing.

Regardless of the regulatory mechanisms put in place for the advertising and supply of genetic testing, Canadians will remain exposed to advertising through American and internationally based Web sites — thus the additional need for Internet regulation. The CRTC has already stated that it will have no role to play in the development of regulations for the Internet.

While ideas from other jurisdictions may prove to be instructive, to understand the full implications of DTC advertising of genetic testing the particulars of Canada's health care system must be considered. Canada's "ad hoc nature of decision-making and diversity of service coverage within provincial health-insurance plans" may mean that DTC advertising will be especially effective, since beneficial genetic services might not be covered consistently across Canada (Bryn Williams-Jones, "'Be ready against cancer, now': Myriad Genetics' direct-to-consumer advertising campaign," currently under peer review; on file with R.M.). Moreover, given the existence of the global marketplace, the choice of regulatory framework will be conditioned not only by federalism but also by Canada's obligations under and participation in various international trade agreements.

Conclusion

Private genetics companies seek new and expanded markets in which to sell their products. Increasingly, jurisdictions have become targets of DTC advertising campaigns marketing genetic tests. The concern is that this trend will soon penetrate the Canadian market as well. Without proper and thorough regulation, the only guiding principle with respect to decision-making on genetic testing will be caveat emptor; a principle strikingly out of place in a health care system structured around physician responsibility and protection of patient interests.
The problems explored in this article with respect
to DTC advertising and supply of genetic tests de-
mand further study. We need to investigate possible
regulatory frameworks appropriate to a publicly
funded health care system. If left only to the principle
of caveat emptor, the danger is that a “buyer beware”
mentality will come to characterize the relationship
between physician and patient, subtly transforming
the Canadian health care environment.

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