‘Be ready against cancer, now’: direct-to-consumer advertising for genetic testing

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ABSTRACT A recent addition to the debate about the benefits and harms of direct-to-consumer (DTC) advertising of medicines and pharmaceuticals is a growing critique of DTC marketing and sale of genetic tests. Academic and policy literatures exploring this issue have, however, tended to focus on the sale of genetic tests, paying rather less attention to the particular implications of advertising. The globalization of broadcast media and ever increasing access to the Internet mean that public exposure to advertising for medical technologies is a reality that national regulatory bodies will be hard pressed to constrain. Working through a case study detailing Myriad Genetics’ 2002 pilot advertising campaign for their BRACAnalysis genetic susceptibility test for hereditary breast and ovarian cancer, this paper highlights some of the diverse and often overlooked and unregulated approaches to DTC advertising, and the associated social, ethical and policy implications.

Introduction
The appropriateness of direct-to-consumer (DTC) advertising of pharmaceuticals and other health-related products is a hotly contested issue in Canada and Europe (Consumer’s Association, 2001; Lexchin & Mintzes, 2002), and to a lesser extent in the United States (Moynihan et al., 2000; Pinkus, 2002). A newcomer to this debate is commercial genetic testing that is advertised and sold through the mainstream media and the Internet. Consumers can now purchase tests for paternity, identification, or immigration purposes (GeneWatch UK, 2003; Zitner, 2002), or obtain health-related tests for genetically linked conditions (Gollust et al., 2003; Williams-Jones, 2003).

The social, ethical and policy implications of the commercialization of genetic testing for health related conditions (the focus of this paper) are coming under increasing scrutiny. Concerns include, for example, harms to individuals from accessing complex genetic information without adequate counselling support, the potential for discrimination and stigmatization of individuals or communities and the social and economic costs of private purchase of genetic services for
publicly funded health care systems (Burgess, 1999; Caulfield et al., 2001; Martin & Frost, 2003). But with the exception of a few academic articles (Gollust et al., 2002; Gray & Olopade, 2003; Hull & Prasad, 2001; Mykitiuk, 2004), and government reports (Human Genetics Commission, 2003; Secretary’s Advisory Committee on Genetic Testing, 2000), rather less attention has been directed at those issues particular to the advertising as opposed to the sale of genetic tests.

Advertising appearing on television, in print, on the radio and over the Internet is criticized for providing deterministic and simplistic explanations of genetics that ties into pre-existing public concerns in order to exacerbate individual anxiety and risk perception (Hutson, 2003; Tambor et al., 2002). Critics have argued that by exploiting a climate of genetic determinism and public anxiety, DTC advertising misleads consumers into believing they need and should purchase or demand from their physicians expensive genetic tests that are unlikely to be clinically useful. Given these serious concerns, one might reasonably assume that strict government regulations would ensure the highest standards of information content. However, the marketing of commercial genetic tests is a relatively new phenomenon and few governments have yet developed specific regulatory responses (Caulfield et al., 2001). Further, as approaches to controlling DTC advertising vary substantially between countries, what may be restricted in one is often permissible in another. When combined with the permeability of national boundaries made possible by global broadcast media and the Internet, uncertainty about what constitutes the best policy response will mean that exposure to DTC advertising will be hard to constrain. The situation is further complicated by the use of other more subtle methods of product promotion that rely on building public ‘awareness’. Internet websites, discussion lists and patient support groups are being variously used by life science companies as part of comprehensive marketing campaigns. As these methods of product promotion are not considered ‘advertising’ in the strict sense, they often fall outside existing ethical critique and government oversight.

Given the dearth of literature examining DTC advertising for genetic tests, this paper will draw upon the more substantial analyses of pharmaceutical industry drug promotion (Mintzes, 1998, 2000) to investigate Myriad Genetics’ 2002 advertising campaign for the BRACAnalysis test for hereditary breast cancer, one of the first and most dramatic instances (and unlikely to be the last) of a coordinated media campaign for a commercial genetic test.

DTC advertising and product promotion

The objectives of advertising and product promotion include building brand recognition, raising awareness and understanding of diseases and products, and targeting audiences in order to influence buying behaviour (Snow, 2002). In 2000, the pharmaceutical industry spent US$15.7 billion on drug promotion, mostly aimed at health care professionals, with only 15% dedicated to DTC advertising. Nonetheless, and directly related to a relaxation of restrictions on TV advertising in the US, annual spending on DTC advertising tripled between
1996 and 2000, reaching nearly US$2.5 billion (Findlay, 2001; Rosenthal et al., 2002).

This advertising, unsurprisingly, tends to paint a rather rosy picture of the safety and utility of new and existing drugs. Studies of pharmaceutical advertising in Canadian and American newspapers, for example, found significant positive bias with few reports of harmful side effects (Cassels et al., 2003; Moynihan et al., 2000). In an environment characterized by tough regulations and effective oversight mechanisms, it would not be in a company’s interest to make blatantly false claims—national oversight bodies would penalize the company, while consumer watchdogs would publicize any gross falsehoods, undermining the company’s credibility and profitability. But without strong enforcement and publicity, there will be powerful incentives for companies to use advertising to create consumer ‘need’ (Caulfield & Gold, 2000; Moynihan et al., 2002), to make optimistic claims to attract investors (Melzer & Zimmerman, 2002) and to provide incomplete risk information to underplay potential harms and boost consumer confidence (Davis, 2000).

One of the primary arguments in favour of DTC advertising for pharmaceuticals and other medical technologies is that information is empowering. Patients, framed as autonomous consumers of health care, have a right to be informed about breakthrough technologies and products so they can be active participants in managing their health care (Rubin, 2001). Advertising, it is argued, allows patients to better share their personal experiences and knowledge of health or illness with their physicians, request particular tests or drugs, evaluate the risks and benefits of treatment options, and become equal partners in the patient-physician relationship (Calfee, 2002; Deshpande et al., 2004). DTC advertising for pharmaceuticals also invariably encourages patients to seek professional advice and talk with their doctors, and thus ‘if used appropriately, direct-to-consumer advertising has the potential to increase patient awareness about treatment options and enhance patient-physician communication’ (Council on Ethical and Judicial Affairs of the American Medical Association, 2000, abstract). As with the case of pharmaceuticals, DTC advertising for genetic tests might improve relations between patients and their physicians and even promote information seeking in the form of family discussions about hereditary illnesses that could facilitate treatment and prevention of disease.

This positive framing of the patient as empowered consumer and active participant in health care decision making is not uncontroversial. When patients are encouraged to view medicines as consumer products, as something to be demanded from physicians by name, the ability of physicians to make informed decisions based on objective product information may be undermined (Findlay, 2001; Fisher, 2003). The concern is that advertising reduces the patient-physician relationship to a mere service delivery arrangement, threatening the professional responsibility of physicians and the safety of their patients (Lexchin & Mintzes, 2002; Pinkus, 2002). Moreover, advertising-induced patient demand for brand name drugs and medicines may put significant pressure on managers of public
or private health care insurance plans to cover more expensive drugs when equally effective lower cost generic drugs are available.

As health care systems begin to incorporate genetic technologies as an integral part of their services (Department of Health (UK), 2003), it will be essential that publics, academics, health professionals and policy makers be cognizant of the implications of DTC advertising for commercial genetic tests.

Genetic testing for hereditary breast cancer

Current epidemiological evidence suggests that 5–10% of all women who will develop breast and ovarian cancer are likely to have inherited a particular genetic mutation associated with increased risk of developing the disease (Carter, 2001; Narod, 2002). The discovery and sequencing in the early 1990s of two genes associated with hereditary breast and ovarian cancer (BRCA1 and BRCA2) helped to make possible genetic susceptibility testing (referred to here as ‘BRCA testing’, and involving the partial or full sequencing of the two genes) for patients to determine their risk status. BRCA testing, which is covered by public health care insurance plans in Canada and most European countries and by most private health insurance plans in the United States, is usually made available through medical genetics laboratories working in collaboration with clinical oncology programmes. These programmes have guidelines restricting test access to patients presenting with risk factors such as a strong family history (multiple cases of breast or ovarian cancer), early age of onset (pre-menopausal), or membership in a specific ethnic group (e.g., Ashkenazi Jewish, French Canadian) (Carter, 2001).

The purpose of restricting access is to ensure that testing is made available only to those people for whom it will be accurate, cost-effective and provide useful information. Of the 5–10% of women with hereditary breast cancer, testing for known BRCA mutations will account for only 17–25% of those at risk for the disease (Shih et al., 2002; Szabo & King, 1997; Frank et al., 2002); there are likely other unknown genes and environmental factors involved. Nevertheless, for those women with cancer ‘running in the family’, BRCA testing may still be a useful test. If a mutation is identified in affected family members (i.e., a positive result), then other members can be tested for the ‘family mutation’. This test can thus be used to confirm (or disprove) a patient’s putative high risk status, encourage physicians to more actively monitor their patients, and facilitate access to other health care services that might reduce cancer risk (d’Agincourt-Canning, 2003). Those patients found not to have the identified family mutation are considered to be no longer at high risk (they will have the same risk as the general population) and can thus avoid frequent, expensive and unpleasant monitoring. However, where no family mutation is identified in affected individuals and/or those with a strong family history of cancer, the test will be uninformative; the genetic component of the hereditary cancer is unknown and thus individuals remain at high risk based on their strong family histories.
BRCA testing can provide tangible clinical results for some women, but it can also have negative physical, social and psychological sequelae. Prophylactic surgery involving the removal of breasts and/or ovaries (Hartmann et al., 2001; Lynch et al., 2001) and drugs such as tamoxifen (King et al., 2001) can significantly reduce the risk of developing cancer, but these treatments are not cures and may be difficult to apply (Narod, 2002). Moreover, BRCA testing is not diagnostic or predictive in the sense that it will identify the onset of cancer; the test provides only risk information. ‘Simply put, positive tests do not always mean that an individual will develop cancer, and negative tests are not a guarantee that they will remain cancer-free’ (Gray & Olopade, 2003, p. 3192). This risk information, however, may be interpreted in a deterministic fashion such that it leads patients to develop fatalistic attitudes about developing cancer, increases fear and anxiety, or poses difficult choices about sharing results with family members (Hallowell et al., 2003).

Given the complexity of genetic information and the challenge of understanding the utility and limitations of a genetic test, not to mention the potentially profound psychosocial implications, genetic counselling (provided by physicians, oncologists, nurse educators, or genetic counsellors) is considered the medical ‘standard of care’. Under public or private health insurance plans in the US, Canada or Europe, testing is not provided to ‘patients off the street’ with little or no family history of disease; instead, testing is offered only to those patients presenting with a strong family history of the disease, as part of a comprehensive clinical programme that includes pre- and post-test genetic counselling, a range of treatment options and regular follow-up and monitoring (Peshkin et al., 2001). However, this situation may be changing with the DTC advertising and sale of BRCA testing.

**Myriad genetics and BRACAnalysis**

Myriad Genetics (a Utah-based biopharmaceutical and genomics company) is probably best known for its involvement with the international effort to discover, sequence and patent the two genes (BRCA1 and BRCA2) associated with hereditary breast and ovarian cancer and the deployment of a commercial genetic test, BRACAnalysis. Myriad has vigorously and successfully enforced its patent rights on the BRCA genes in the US—all hospitals and health insurance plans have been required to purchase Myriad’s test—as a means of establishing complete control of the US BRCA testing market (Borger, 1999; Murray, 1999). Myriad has also been trying to build markets in Canada and Europe, albeit with much less success; instead of acquiescence, Myriad has faced mounting public, professional and government opposition, culminating in a widespread rejection of Myriad’s patent rights to the BRCA genes (Williams-Jones, 2002).²

*The advertising campaign*

As part of Myriad’s attempt to control the market for BRCA testing, in September 2002 the company began piloting in two US cities (Denver and Atlanta) a public...
advertising campaign for its BRACAnalysis test (Myriad Genetics, 2002). Presented as a public service to educate women about the risks of and options for dealing with hereditary breast cancer, the campaign was timed to coincide with the US National Breast Cancer Awareness month. According to Myriad’s media campaign website:

Hereditary breast and ovarian cancer is underdiagnosed. That’s why Myriad Genetic Laboratories has launched an important pilot campaign to help women and their physicians learn about this syndrome, and ways to reduce cancer risk. … [An] effort to get the word out about the importance of learning who’s at risk for hereditary breast and ovarian cancer—so physicians and consumers can take action now to reduce that risk. (Myriad Genetics, 2002b)

The BRACAnalysis Integrated Awareness Campaign ran for five months and included TV, print and radio advertisements, coordinated with a toll-free telephone number and two websites (www.bracnow.com and www.myriadtests.com, accessed 14 December 2004). A one-minute commercial was shown during prime time on the major TV networks (NBC, CBS, ABC, Fox, WB), supported by print ads in Atlanta and Denver newspapers and magazines and ads on local radio stations. Advertisements also appeared in popular magazines such as People, Better Homes and Gardens, Ladies’ Home Journal, and Women’s Health Monitor.

In Myriad’s TV advertisement and the corresponding print ads, a series of smiling women from diverse ethnic backgrounds, apparently between 30 and 45 years of age (Mykitiuk, 2004), talk about having family members with breast cancer and the need to learn about personal risk status in order to gain control over the disease. BRACAnalysis, ‘a blood test that’s helped thousands of women find their risk for hereditary breast and ovarian cancer,’ is portrayed as a tool for enhancing autonomy and empowering women. The genetic test provides only risk information and not a treatment for breast cancer, viewers are told, but is still effective at reducing uncertainty and counteracting the inevitability that people may feel about developing breast cancer. ‘After BRACAnalysis, I realized I could choose to do something now,’ says one woman in the ad; this advertisement suggests that with the BRACAnalysis test, an individual can learn about their risk status and then explore appropriate prevention and treatment options with their physician. The women in the ads are cheerful and optimistic because, it is implied, they are gaining control: ‘if breast and ovarian cancer runs in your family, BRACAnalysis can help you see the big picture so you can take steps to reduce your risk.’ The advert aims to convince the viewer with a family history of breast cancer (i.e., one family member with the disease) that the test is an important means of reducing risk. By emphasising the tests status as critical medical intervention, the advertising successfully ‘creates a chain between manufacturer, advertisement and doctor, with the ultimate profit going to … genetics testing companies’ (Mykitiuk, 2004, p. 28).
Myriad’s advertising acknowledges that only 5–10% of breast cancers will be hereditary, but what is not mentioned is that the BRCA test will, as discussed above, detect positive mutations in only 17–25% of patients with a strong family history (i.e., early age of onset, multiple affected family members, multiple cancers, etc.)³ Despite being an accurate test, it will still not provide any useful information for 75–83% of women with strong family histories—the heritable component of their cancer risk remains unknown and they continue to be at high risk (Carter, 2001). Further, given Myriad’s less stringent access criteria—one affected relative, which does not constitute a strong family history (Carter, 2001; Smith, 1997)—most people purchasing testing will be found not to carry a mutation, which would have been predicted by the person’s lack of a significant family history.⁴

Myriad’s pilot ad campaign is one of only a few instances of concerted DTC advertising for commercial genetic tests; other examples include University Diagnostics Ltd’s cystic fibrosis test in the UK (Harper, 1995), and more recently advertising by Sciona and Great Smokies Diagnostic Laboratory for a variety of nutritional and health related genetic tests (Zitner, 2002).⁵ These DTC advertisements have met with strong opposition. Myriad’s ad campaign, for example, led to numerous critical editorials and news stories (Agovino, 2002; Krasner, 2003), and the US Centers for Disease Control (CDC) even conducted a study of consumers and health care providers to evaluate the impact of Myriad’s DTC advertising.

The CDC study found that as compared with participants in two cities not involved in Myriad’s advertising campaign, consumers in Atlanta and Denver where much more aware of BRCA testing; health care providers in these two cities reported more questions about testing, more BRCA tests requested, and more tests ordered, but also reported lacking the necessary knowledge to advise their patients about hereditary breast cancer or the appropriateness of testing (Centers for Disease Control and Prevention (CDC), 2004). The advertising campaign was clearly effective at raising public awareness of BRACAnalysis. But in contrast to the image portrayed—that of an empowered, autonomous consumer engaging with her physician in a collaborative decision making process about suitable testing and treatment options—the reality is one of increased awareness (and anxiety?) but without a corresponding understanding on the part of consumers (or their clinicians!) of the utility or applicability of the test. The paucity of relevant information in the advertisements challenges the extent to which people can effectively decide on the suitability or necessity of BRCA testing, and it seems implausible to expect consumers to ‘make an accurate assessment of their risk when the advertisements build a strong case for testing based on fear’ (Gray & Olopade, 2003, p. 3192). By advertising BRACAnalysis to the general public, Myriad is deploying a technology that is speculative at best, exploiting a climate of genetic determinism and the public’s misunderstandings of and anxieties about susceptibility, probability and risk.

While not in the same league as the pharmaceutical industry in terms of scale of funding or consumer impact, biotechnology companies such as Myriad are nonetheless learning lessons from the pharmaceutical industry and deploying
comprehensive and coordinated media campaigns. The growing diversification of media technologies, especially public access to international programming through cable and satellite TV and the Internet, means that advertising can now more easily reach an international audience. While companies will still use country-specific advertising through local media outlets, they are also deploying global branding strategies (Betts, 2002; Burton & Rowell, 2003).

The Internet

The Internet offers a way for advertisers to quickly and cheaply provide potential consumers with a wealth of information that would not, given cost and time constraints, be possible with mainstream media. Myriad’s BRACAnalysis media campaign was coordinated with a dedicated website entitled, ‘BRACAnalysis—Be Ready Against Cancer’ (Myriad Genetics, 2002c), which had been listed in the print and TV advertisements. This site presents the viewer with the question: ‘Does breast or ovarian cancer run in your family?’ If concerned, ‘[y]ou can reduce your risk. We can help’, because

Even if breast or ovarian cancer runs in your family, cancer doesn’t have to be inevitable. BRACAnalysis® is a blood test that can provide answers about your risk of hereditary breast and ovarian cancer by analyzing the BRCA1 and BRCA2 genes. After BRACAnalysis®, you and your doctor can discuss effective options and steps you can take to reduce your cancer risk. Your results are kept confidential, and most health insurance plans provide coverage for testing.

If you answer ‘yes’ to either of the following questions, you may benefit from BRACAnalysis®.

- Have you had breast cancer before age 50 and ovarian cancer at any age?
- Has anyone in your family (mother’s or father’s side) had breast cancer before age 50, ovarian cancer at any age or male breast cancer at any age? (ibid., original italics)

As with its TV and print advertising, Myriad’s bracnow.com website describes breast cancer as if it is a uniform entity, the risk of which can be eliminated by using their test. No mention is made of the complexity or diversity of types of breast cancer, or the fact that the vast majority of cancers will be sporadic, even for those people who answer ‘yes’ to having one family member with the disease! The BRACAnalysis test is presented as a powerful diagnostic tool, and not as is the case, a technology that will only provide risk information to a subset of those people with a hereditary form of the disease.

The relative ease with which sophisticated and detailed websites can be created and targeted to particular consumer groups, along with the growing numbers of people with Internet access, makes the Internet an increasingly important site for advertising (Lerer, 2002). There is, for example, some evidence that the level of consumer trust in online pharmaceutical advertising is similar to trust
in drug information from traditional media sources, and trust in online sources stimulates further information searching and exposure to drug advertising (Menon et al., 2002). Of concern, however, is that as with DTC advertising in the mainstream press (Cassels et al., 2003), prescription drug websites tend to underplay the risks while highlighting the benefits of their products, e.g., by having risk information in a smaller font or located on a different webpage (Huh & Cude, 2004). Yet consumers may be quite critical of the quality and veracity of information they find online. In one US study of 157 adults attending two genetics clinics, 47% of patients had searched online for genetics related information prior to their clinic visits but many (41%) found the information confusing; interestingly, 92% of all respondents stated that they would be likely to visit a genetics information website recommended by a geneticist (Taylor et al., 2001).

Nonetheless, the convergence and internationalization of advertising media raise serious concerns about how to protect the public from misleading or exploitative advertising. In the case of Myriad, the company provides accurate and accessible information about the risks of developing breast cancer along with recommendations for risk reduction strategies and links to patient support groups. But in the overwhelmingly positive descriptions of the utility and effectiveness of BRACAnalysis, Myriad’s websites only briefly mention the possibility that the test may provide ambiguous or uninformative results (e.g., mutation of unknown status), or that even when no mutation is found a person may still be at risk of developing cancer due to other gene mutations or social and environmental factors.

**Patient groups and public awareness**

Supported by Internet websites and email discussion lists, non-governmental organizations—known variously as patient-, advocacy-, disease awareness- or public action groups—are becoming influential in shaping what services and which medicines are made available to patients through public and private health insurance plans. These groups develop for a diverse set of reasons: they may translate disease-specific medical information and disseminate it to their members and health care professionals, offer counselling and support services, work to ensure that patients’ voices are heard, or engage in charitable fund raising and advocacy for medical research (Mills, 2000). But these groups are often run by volunteers and poorly funded, making them vulnerable to corporate capture. More worrying is the insidious role of product manufacturers in the creation of such groups where none previously existed.

The growing status and influence of patient groups, along with their ability to directly access specific populations, makes them attractive to companies interested in building ‘partnerships’ to support comprehensive product promotion (Hayes, 1999). Patient groups are often already involved in raising awareness of a particular condition or illness, along with the virtues of new drugs or diagnostics. These groups also have enviable levels of public credibility, so information they present will not be discounted as biased as might be the case for industry
sources. Companies thus have a strong interest in enrolling patient groups as advocates for products, particularly in environments where DTC advertising is restricted or prohibited (Herxheimer, 2003).

In the case of Myriad, while the company does have links on their websites to a range of breast and ovarian cancer support organizations, there is no evidence that the company directly funds or partners with these groups. Nevertheless, Myriad is clearly aware of the utility of coordinating with community initiatives. By timing the launch of their pilot DTC advertising campaign to coincide with the US Breast Cancer Awareness month, Myriad effectively tied BRACAnalysis to an already increased public awareness. As mentioned above, in Myriad’s ads risk of breast cancer is portrayed as a unitary phenomenon, something that can be resolved by genetic testing and appropriate medical treatments. There is a subtle determinism at play in this message. The inevitability of the disease—‘I wondered if it would be inevitable ... it didn’t have to be’—is challenged by the certainty of a test that accurately links genetics with risk. Concern is raised and then resolved by the technology. This type of marketing may be attractive to patient groups whose mandate includes lobbying for research and access to medicines and diagnostics. Thus while biotechnology companies such as Myriad may not (yet) be actively supporting patient groups, even limited enrolment will build powerful allies for extending a company’s market.

A failure of oversight

In the United States and New Zealand, the political consensus seems to be that the benefits of DTC advertising outweigh the costs; while there is still some opposition from public and professional groups (Coney, 2002; Kmietowicz, 2003), both countries allow DTC advertising for prescription pharmaceuticals and medical products (Hoek & Gendall, 2002). Until 1997, the US Food and Drug Administration (FDA) had taken a position that made it very difficult for companies to advertise medical products and services direct-to-consumer. Following intense lobbying from industry and a range of interest groups, the FDA changed its position to allow brand name and disease indications to appear in the same advertisement, greatly facilitating DTC advertising of prescription pharmaceuticals (US Department of Health and Human Services et al., 1999). Oversight of advertising practices that affect commerce fall under the aegis of the Federal Trade Commission (FTC), and the FDA is responsible for reviewing medical and pharmaceutical safety and advertising, i.e., ‘labelling’. The FDA restricts what claims can be made about a pharmaceutical and requires certain disclosures (e.g., of common side effects) through the device of labelling, including that there should be a ‘fair balance’ of information about product risks and benefits.

The actual practice of oversight, however, is less encouraging. Numerous pharmaceutical companies have been charged by the FDA (sometimes repeatedly) with violating advertising regulations by oversimplifying drug risks and overstating benefits. Studies of TV and Internet drug advertising have found repeated
failure in the ‘fair balance’ requirement, undermining the claim that DTC advertising is unproblematic and a positive means of conveying health information and empowering consumers (Huh & Cude, 2004; Kaphingst et al., 2004). As Wolfe notes, ‘the FDA is grossly understaffed for this important oversight function: the entire Division of Drug Marketing, Advertising, and Communications has had only 28 to 30 employees since 1997 . . . [and are further handicapped by lacking] the legal authority to impose civil monetary penalties on companies, even when they repeatedly violate the law’ (Wolfe, 2002, p. 526).

By contrast, Canada, the United Kingdom and most other European countries continue to restrict DTC advertising of prescription pharmaceuticals and other medical products. Some even have regulations to constrain industry use of patient groups for product promotion (Jackson, 2003). While it might thus be tempting to think that DTC advertising is only a concern for the US and New Zealand, this is not the case. In Canada and Europe, for example, there has been pressure to lift restrictions on DTC advertising (Jaderberg, 2002), and reduced government funding of medical technology assessment has meant that oversight bodies are finding it increasingly difficult to control even relatively well-known types of DTC advertising (Brill-Edwards, 2000). This situation may be even more problematic in the case of genetic testing.

Currently, most countries have little or no oversight of DTC advertising for genetic testing. There tends to be no pre-market review of commercial genetic tests or their advertisements, even though it would be within the purview of many regulators (Holtzman, 1999). In the US, neither the FTC nor the FDA appear to have the resources or the inclination to take up this task, while in Canada there are similar difficulties (Caulfield et al., 2001). Pharmaceuticals and medical devices are governed by the Canadian Medical Devices Bureau, but there is nothing in the supporting legislation (the Food and Drugs Act and the Broadcasting Act) or regulations ‘that would prohibit or regulate DTC advertisements of genetic testing similar to Myriad’s campaign in the USA’ (Mykitiuk, 2004, p. 29). In the UK, the Advertising Standards Authority (an industry body) regulates voluntary Codes of Advertising and Sales Promotion for non-broadcast advertising, and the Office of Fair Trading has the power to seek court orders to stop misleading advertisements. Both mechanisms could be applied to DTC advertising for genetic testing, but as in the US and Canada, more willingness and resources are required if the broad range of advertising media (e.g., TV, Internet, patient groups) are to be adequately regulated.

In Europe, these regulatory challenges are to some extent offset by the presence of universal health care insurance plans. Though there are no exact figures documenting uptake of commercial testing, but where genetic tests such as BRCA testing are available free of charge, e.g., from the UK National Health Service (NHS), it will be difficult for commercial markets to develop. Indeed, while Myriad licensed the Scottish company Rosgen to market BRACAnalysis in the UK (Myriad Genetics, 2000), competition with the NHS meant that Rosgen was unable to bring in sufficient funds to stay solvent and folded in 2001. By contrast, in Canada, the ad hoc nature of decision making and inconsistency of service
Coverage across various provincial health care insurance plans means that many potentially beneficial genetic services are not covered, raising concerns about equity of access and leading to a potential market for commercial genetic services (Caulfield et al., 2001; Williams-Jones & Burgess, 2004). DTC advertising thus has the potential to be more effective in Canada and the US, although it still poses challenges for the UK and the rest of Europe particularly in an age of global advertising.

Conclusion and suggestions for improving oversight

The case of Myriad Genetics’ BRACAnalysis pilot advertising campaign, when situated in the larger context of an increasingly international media environment, highlights the difficulties that will be faced by countries attempting to restrict DTC advertising. Regardless of local legislation, the permeability of national boundaries that has resulted from the growth of the Internet will mean that people can access information that would otherwise be restricted. While Myriad’s TV commercial was only aired in two US cities for a period of 5 months in the Fall of 2002, an electronic version was easily accessible on Myriad’s website and thus available to anyone until the middle of 2003 (Myriad Genetics, 2002b, www.myriad.com/media/tv_brac.mpg, accessed 3 July 2003, on file with author). Even where countries have in place regulations to control DTC advertising, such legislation tends to ignore the more subtle or indirect forms of product promotion. Be it the co-opting of patient groups and public awareness campaigns, or highly publicized websites, indirect advertising will continue to be an effective and important means of product promotion (Burton & Rowell, 2003).

Notwithstanding these problems, I believe there is still room for some optimism about developing mechanisms to control DTC advertising. A growing body of academic literature is seriously questioning the appropriateness of DTC advertising and sale of genetic tests (Caulfield et al., 2001; Gollust et al., 2002; Martin & Frost, 2003), and influential advisory groups in the US, Canada, and the UK have highlighted the need for better oversight and control (Human Genetics Commission, 2003; Ontario Ministry of Health and Long Term Care, 2002; Secretary’s Advisory Committee on Genetic Testing, 2000).

Lessons can and should be learned from analyses of the negative consequences of unrestricted DTC advertising for pharmaceuticals. Recent evidence clearly demonstrates a dose-response effect such that in environments with less accessibility to drug ads, there are fewer patient requests to physicians for those drugs (Mintzes et al., 2002). In Canada and Europe, and to a lesser extent in the US, the growing cost of pharmaceuticals as a portion of overall health care expenditures is being taken sufficiently seriously that governments are increasing support to the generic drug sector and even considering restructuring their patent systems to weaken the monopoly powers of the pharmaceutical industry.
In light of such moves, it would be incoherent to not also strengthen oversight of DTC advertising for pharmaceuticals.

In a similar vein, governments should be more aggressive at enforcing DTC advertising regulations for genetics-related products and services. This might necessitate devoting substantial resources to better support already over-stretched regulatory agencies. But I would go further and argue that new regulatory and oversight bodies are needed to specifically address the challenges raised by new genetic technologies (Hoedemaekers, 2000; Human Genetics Commission, 2003). The Internet, global communications channels and the variability of international regulation will make it difficult if not impossible to control all forms of DTC advertising. Nonetheless, a government that is sufficiently concerned about promoting the health of its citizens and controlling the health care cost effects of DTC advertising is not without options. For example, following the UK Human Genetics Commission’s recommendations, governments can take a proactive stance by supporting credible groups to develop websites and public resources that provide complete and balanced information and evidence about commonly promoted genetic tests (Human Genetics Commission, 2003). This type of ‘official’ source, particularly if it actively targets physicians to whom patients are still turning to for advice, could be very influential in shaping patient demand and supporting physicians in prescribing appropriate services.

Moreover, as appears to be the case in the UK and some European countries, serious consideration must be given to the comprehensive evaluation and provision of suitable genetic testing services as part of national health insurance plans. Such public access would be an important countervailing force and means of constraining the costs of DTC advertising. Health insurers—be they European governments, provincial health authorities in Canada, or private US insurance plans—can control appropriate provision of genetic tests by making them only available to those people likely to show a clinical benefit. The heterogeneity of US insurance coverage, however, makes it much more difficult to control access to genetic services than would be the case in health care systems with universal insurance coverage.

Myriad Genetics is only one of many companies exploiting a climate of genetic determinism and public anxiety to sell speculative technologies (Williams-Jones, 2003). There are significant social, ethical and political implications of such behaviour, and I suggest that these can to some extent be mitigated by regulations that address the diverse means by which companies promote their products. As Mintzes (1998) argues, ‘all promotion by definition is information whose aim is to market a product and as such has an inherent bias towards showing the product in the best possible light’. However, given ‘the current level of scientific uncertainty, gaps in consumer protection and low levels of consumer education’, the situation is sufficiently worrying to support the strong proposal of the UK Consumer’s Association that ‘for the foreseeable future … adverts for direct genetic testing services should be banned’ (Consumer’s Association, 2002, p. 6).
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Notes

1. The intent is not, however, to directly analogise DTC advertising of pharmaceuticals with that of genetic testing. Clearly, the therapeutic benefit and potential harm of drugs, alongside their more prevalent use (and cost) as part of health care service provision will mean that the associated social, ethical, and policy concerns are likely to differ substantially from those associated with commercial genetic tests. Instead, the purpose of exploring DTC advertising of pharmaceuticals is to clarify the various means by which a company can create public awareness and consumer demand for its products.

2. In the US, with its largely decentralized employment-based health insurance system, Myriad had only to challenge local hospitals and insurers with the threat of patent infringement suits to convince those institutions to desist in their local provision and agree to purchase testing from Myriad (Merz, 1999). By contrast, in Canada and Europe, BRCA testing is commonly part of universal health insurance plans, thus it was governments that were ultimately responsible and these were willing to use their greater financial and political powers to reject Myriad’s patent claims. In Canada, this opposition took the form of provincial governments simply ignoring Myriad’s demands and waiting for Myriad to sue (which has yet to occur), while in France a consortium of laboratories and European countries successfully challenged and overturned Myriad’s EU BRCA1 and BRCA2 patents in 2004, further weakening Myriad’s control of the BRCA testing market (Mayor, 2004; Pollack, 2004).

3. A 2002 study by Myriad researchers detected BRCA mutations in 17.2% of 10,000 individuals tested (Frank et al., 2002), information only available (and somewhat buried) on the company’s breast cancer information webpage for Health Professionals (Myriad Genetics, 2002d, www.myriadtests.com/provider/mutprevo.htm, accessed 14 December 2004).

4. A UK study by Pharoah et al. (2000), based on 2809 cases, estimated that in the general population 6.8% of women under the age of 50 would have at least one first degree relative with breast cancer; only 2% of women under 50 would have a family history conferring significantly increased risk (at least 2.5 times). The authors conclude that a family history of breast cancer is common in the general population, but that preventive interventions for women at high risk (based on family history) will have limited impact on breast cancer morbidity as a whole (Pharoah et al., 2000).

5. There are many companies selling a variety of genetic tests direct to consumers, but their advertising tends to be limited, often restricted to company websites. An exception to this would be paternity tests, which are heavily advertised in the mainstream press and on the Internet (Gollust et al., 2003; Williams-Jones, 2003).

6. Concerns about accuracy of information have led some online health information companies to publicly subscribe to codes of ethics (such as the HON Code) that include principles related to protection of privacy, quality, authority and accuracy of information, and transparency of interests (Cho, 2000; Williams-Jones, 2003).

7. For example, in contrast to the position taken by provincial governments across Canada, the British Columbian government acquiesced to Myriad’s patent claims and for a period of two years (2001–2003), in effect prohibited the provision of BRCA testing through the provincial public health care system; agencies providing testing would have to purchase
the service directly from Myriad at triple the cost, exceeding their limited budgets. This situation led to two categories of patients, those who could and those who could not afford the test—patients were treated differently depending on the province where they lived.

References


Williams-Jones, B. (2003) Where there’s a web, there’s a way: commercial genetic testing and the Internet, Community Genetics, 6(1), pp. 46–57.

