Direct-to-Consumer Marketing of Predictive Medical Genetic Tests: Assessment of Current Practices and Policy Recommendations

Yuping Liu and Yvette E. Pearson

This research reviews the current state of affairs in the fast-growing area of direct-to-consumer marketing of genetic tests. The authors identify the unique nature of genetic tests and the ensuing consumer vulnerability. They also present a comprehensive examination of the current legal environment and an empirical analysis of genetic testing companies' online marketing practices. On the basis of the analysis and review, they make a set of policy recommendations that consists of consumer education, physician intervention and education, and direct regulation of marketing activities, especially as they relate to the online medium.

Keywords: genetic testing, direct-to-consumer marketing, public policy, health care, Internet marketing

With the completion of the Human Genome Project in April 2003, medical genetic tests have become more popular and have received a lot of media attention. Currently, genetic tests for more than 1200 diseases are available to consumers (Javitt 2007), and this number is likely to grow as additional disease-related genes are identified. Rapid developments in genetics have led to the quick growth of companies that market predictive genetic tests and have spawned a profitable marketplace expected to be worth $12.5 billion by 2009 (Alsever et al. 2006). According to its annual reports, Myriad Genetics (2007), a leading marketer of medical genetic tests, experienced a growth of 44% as its molecular diagnostic test revenues increased from $100.6 million in 2006 to $145.3 million in 2007.

Although genetic testing has traditionally been available to patients through their physicians, some companies have begun direct-to-consumer (DTC) marketing of genetic tests through the Internet or retail pharmacies. Some of these companies market at-home genetic tests that can be conducted by simply swabbing inside the consumer's cheek. This direct access to genetic tests offers consumers potential benefits, such as lower cost, more privacy with testing, and increased awareness of genetic diseases. According to a Harris Interactive poll (Taylor 2002), more than two-thirds of adults surveyed were willing to undergo reasonably priced genetic tests, and nearly half claimed that they would ask for a genetic test even if nothing could be done to prevent or treat the target disease.

The growing DTC marketing of genetic tests combined with heightened public interest suggests a need for more public policy attention to this area. Currently, genetic testing services are not regulated consistently across the United States, and existing federal regulations are minimal and often confusing or ineffective insofar as they fail to better inform or protect prospective consumers of genetic testing services. Although some states allow only physicians to order genetic tests, such restrictions are inconsistent across states and are unlikely to affect online sales of genetic testing services because the authority of individual states does not clearly extend into the online environment (Genetics and Public Policy Center [GPPC] 2007c). There are also questions about the clinical value of many genetic tests (Gollust, Wilfond, and Hull 2003). Repeated calls to the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) to improve regulation and oversight of genetic testing service providers have been largely ignored. A recently released report by the GPPC (see Javitt and Hudson 2006b) further confirms the failure in oversight of genetic testing laboratories and the need for vast improvements in the current regulatory climate.

As we discuss subsequently, the combination of consumer ignorance, scant government regulation, aggressive marketing practices, and the often overzealous media attention to genetic testing is a recipe for harm to individual consumers and public health. Although the probable negative outcomes of DTC sales of genetic testing services are not yet fully understood, problems with DTC marketing of pharmaceutical drugs suggest the need for careful scrutiny

Yuping Liu is Associate Professor of Marketing, College of Business and Public Administration (e-mail: YXXliu@odu.edu), and *Yvette E. Pearson* is Assistant Professor of Philosophy, Department of Philosophy and Religious Studies, and codirector of the Institute for Ethics and Public Affairs (e-mail: ypearson@odu.edu), Old Dominion University. The authors are listed in alphabetical order; both authors contributed equally to the article. The authors thank the four anonymous *JPP&M* reviewers for their valuable comments. Financial support from Old Dominion University Research Foundation's SEECR Grant is also gratefully acknowledged.

ISSN: 0743-9156 (print), 1547-7207 (electronic)

Vol. 27 (2) Fall 2008, 131–148

of DTC marketing of genetic tests. Some researchers have documented consumers' misconceptions about government oversight and the validity of information presented in advertisements (Wilkes, Bell, and Kravitz 2000). Others have noted consumers' inability to comprehend the content of drug advertisements (Weissman et al. 2004; Wilkes, Bell, and Kravitz 2000) or to determine accurately whether a particular drug is appropriate (Lexchin and Mintzes 2002).[1] Given the greater complexity of genetic information, consumers' failure to understand and properly use DTC information can result in undesirable outcomes, such as the use of an unnecessary or a low-quality test, needless anxiety about test results, a false sense of security or doom, harmful health and lifestyle choices, and inappropriate use of health care services (Hudson et al. 2007). Thus, it is important for marketing researchers, bioethicists, and those working in the field of business ethics to reflect carefully on DTC marketing practices and the context in which they occur so that harm to consumers and public health can be avoided.

To this end, this research assesses the current state of DTC marketing of genetic tests and services. As far as we know, this is the first comprehensive examination of the topic in the marketing field. In our analysis, we evaluate both business practices and government regulation of such practices. This includes an empirical examination of DTC marketing of genetic tests on the Internet, currently a major medium for marketing activities in this area. Through such analyses, we identify the potential benefits and problems with DTC sales of genetic testing services. Finally, we formulate a set of ethically sound public policy recommendations in this area. We begin with a brief description of genetic tests.

A Primer on Genetic Testing

A gene is a sequence of deoxyribonucleic acid (DNA) that codes for a specific function. Most genes provide instructions for the creation of proteins, which are sometimes called the "building blocks of life." A "permanent structural alteration in DNA" can occur, which is called a mutation (see http://www.genome.gov). Although some mutations have no effect, others contribute to impaired functioning of the organism. For example, a deletion of part of the DNA sequence in BRCA1, a tumor-suppressor gene, is a risk factor for increased susceptibility to a certain type of breast or ovarian cancer. Genetic tests aim to identify the presence of such mutations. In this research, we focus on one class of genetic tests—namely, predictive genetic tests, which include both tests that determine whether an individual is a carrier who can pass a gene to the offspring and tests that assess whether the individual him- or herself has an increased susceptibility to a disease.

Ideally, a genetic test should be analytically valid. Two components of analytical validity are sensitivity, which refers to how often a test is positive when the mutation is present, and specificity, which refers to the frequency of a negative result when the mutation is absent. Because analytical validity alone does not guarantee that the test will be valuable for patient management, it is also important to consider the value of a test in the clinical setting (i.e., clinical validity and utility). A gap between analytical and clinical validity occurs if the detection of a mutation does not correspond to symptoms observed in patients.

A common misunderstanding about predictive genetic testing is that it provides definite knowledge of the future. Although there are some rare diseases (e.g., Huntington's disease) for which having the gene means that the person will definitely get the disease, most diseases, including more common afflictions, such as cancers and diabetes, do not follow this straightforward pattern. Because many diseases are caused by gene–gene or gene–environment interaction, a genetic mutation alone may be neither necessary nor sufficient for the manifestation of a disease. As a result, knowledge that a person carries a particular mutation is often of limited value. Contrary to the prevalent false assumption of genetic determinism—the belief that future health status is determined entirely by genetic makeup—having a mutation does not guarantee that a person will get a disease associated with a particular mutation.

Both analytical and clinical validity can diverge from clinical utility if there are no preventive or curative measures for patients who carry what is believed to be a harmful mutation. Although the negative effects of some diseases (e.g., Phenylketonuria) are currently preventable with knowledge that a person carries a "bad" gene, the medical profession lacks not only preventive or curative measures but also treatments for many genetic diseases. However, the widespread publicity of the Human Genome Project has caused excessive optimism regarding the probability and proximity of procuring clinical benefits from emerging genetic technologies (Burke 2004; Conrad 2002). As Burke (2004, p. 9) points out, "the predictive power of genetic information is routinely overestimated, and testing possibilities that are no more than research ideas are presented as imminently available." Although the results of some genetic tests may be valuable to the patient, there is good reason to be cautious when making claims regarding the ability of genetic tests to contribute to more effective clinical care or improved patient health.

DTC Marketing of Genetic Tests: Promises and Perils

Emerging Trends in Genetic Testing

Genetic testing is not new, but the application of genetic tests has been changing in recent years. First, the way genetic testing is done is changing. In the past, physicians would order genetic tests as part of a broader panel of diagnostic tests and procedures or as part of a screening program. Although genetic testing is still done mainly through physicians, consumers can now undergo genetic testing at home. A typical at-home genetic test entails consumers collecting their own sample, sending it to a lab for analysis, and then receiving the results in the mail or through the Internet. An increasing number of genetic tests are offered through such means, and companies selling these tests have stepped up their DTC marketing efforts.

[1]Note that diverse opinions exist on the effects of DTC marketing of prescription drugs and that not everyone believes it is harmful. For a review of arguments on both sides, see Auton (2004) and Lexchin and Mintzes (2002).

Second, the rationale for undergoing genetic tests is also shifting. Until recently, genetic testing has been diagnostic and restricted mainly to prenatal and newborn testing (Taylor, Edwards, and Ku 2006). Increasingly, however, genetic testing is motivated by a desire to determine what might be rather than attempting to confirm a tentative diagnosis of a genetic disease. An asymptomatic adult may request a genetic test because his or her family history indicates affliction with a disease, or the person may simply be curious about whether he or she carries any genes that have been linked with an increased risk of a disease.

Finally, genetic testing is also rapidly broadening beyond rare, single-gene disorders that have a simple inheritance pattern (e.g., Huntington's disease). An increasing number of predictive genetic tests now target common diseases (e.g., cancers, cardiovascular diseases) that are more genetically complex. These tests ostensibly allow patients to learn whether they carry genes associated with increased susceptibility to common diseases. This scenario poses new problems in terms of interpretation and clinical application of results.

Potential Benefits of DTC Marketing of and Access to Genetic Tests

Although there are legitimate concerns about the validity and value of many genetic tests, DTC marketing of and access to genetic tests may benefit some consumers. First, DTC marketing can raise awareness of genetic diseases and the availability of genetic tests, and this may encourage patients to visit a health care professional to learn more about a genetic test or hereditary disease. In her discussion of DTC marketing of prescription drugs, Kelly (2004, pp. 247–48, n. 7) cites a study that showed that nearly two-thirds of "physicians serving a predominantly [African American] population reported that patients have come in solely because of a DTC ad." Second, Racine, Van der Loos, and Illes (2007) note that people who have or suspect they have a stigmatized illness (e.g., herpes, depression, incontinence) are more reluctant to seek help through traditional means because, for example, even visiting a psychiatrist suggests that a person has a mental illness. In the realm of genetic testing, we can imagine that a person who suspects that he or she has a hereditary form of a stigmatized illness might prefer to avoid going to a physician or genetic counselor to conceal his or her quest for personal genetic information. Because DTC access to genetic tests bypasses the traditional health care hierarchy, it may offer consumers greater privacy and thus reduce such psychological barriers. Relatedly, with fewer people sharing the information, DTC genetic tests may also keep genetic information out of the hands of those who might use it to the detriment of the individual tested.

Consumer Vulnerability and Its Consequences

The realization of potential benefits provided by DTC marketing of and access to genetic tests is context dependent. A genetic test is a unique product in that it involves complex information and requires a high level of knowledge for the product to be purchased and "consumed" properly. Existing research has shown that even physicians are often ill-equipped to provide genetic services (e.g., National Institutes of Health Task Force on Genetic Testing 1997; Taylor, Edwards, and Ku 2006). Average consumers are in a worse epistemic position, and most of them are unable to protect themselves adequately or to make genuinely informed decisions regarding genetic tests. Because consumers are encouraged to bypass rather than consult with genetic counselors or other relevant professionals, DTC marketing of genetic tests remains ethically questionable.

For many consumers and physicians (Goddard et al. 2007), the primary sources of information about genetics are the popular media and genetic test vendors, both of which can be misleading. The popular press is often driven by the enthusiasm and hype about discoveries of "disease genes." As a result, the public often hears a lot about exciting discoveries and little, if anything, about disconfirming evidence or failures to replicate study results connecting genes to traits or maladies (Conrad 2002). Because the "news media are the major avenue by which information about genetics enters the culture," failure to properly report disconfirmations can lead to obsolete or false information becoming "fossilized in the culture" (Conrad 2002, p. 75).

Skepticism is also warranted about the objectivity and scientific verifiability of information provided by marketers of genetic tests, given their dominantly for-profit motive. The limitations of marketer-supplied information have been well documented in the literature on DTC advertising of prescription drugs (Macias and Lewis 2005; Main, Argo, and Huhmann 2004; Wolfe 2002). Given the weaker regulatory oversight of genetic testing, information supplied by marketers of genetic tests is likely to be even more problematic. Consistent with this view, research has shown that physicians' use of pharmaceutical companies as a frequent source of information is a negative indicator of their knowledge of genetics (Hofman et al. 1993). Although the current situation may have changed from the much earlier study, our own analysis of commercial genetic testing Web sites, which we report on in greater detail subsequently, confirms the bias in the information provided by online genetic test marketers. Such findings raise serious doubt that consumers will be properly educated through existing marketing materials.

Although there are good information sources on genetics, consumers may be unable to distinguish between accurate and inaccurate sources or identify bias. To make matters worse, although physicians often realize their own knowledge deficits (Hofman et al. 1993), consumers may be unaware of their own ignorance of genetics and, therefore, unlikely to seek information. Prior research has found that such overconfidence is prevalent among consumers and that it leads to suboptimal search and purchase decisions (Alba and Hutchinson 2000).

Consumers' vulnerability in the decision-making process regarding genetic tests can endanger their long-term health and welfare (Cella et al. 2002; Lee and Brennan 2002). Those who are neither aware of nor warned about the risk of false positives and false negatives are likely to overestimate the significance of test results. This can induce unfounded anxiety and fear or a false sense of security in test takers. People genetically related to someone who undergoes genetic testing may also be affected nonvoluntarily by test results. Although there is some debate about whether and to what extent genetic test results affect patient

behavior, a recently released statement from the American Society of Human Genetics warns of the possibility of consumers making irrevocable decisions based on these results (Hudson et al. 2007). In the news, there have been multiple accounts of people making life-altering decisions based on genetic test results (usually combined with knowledge of their family history relative to the disease in question). For example, some women have reportedly had their breasts and ovaries removed when a genetic test revealed that they carried a mutation of the BRCA1 (or BRCA2) gene (Herel 2002). Burke and colleagues (2002) also note that a fatalistic attitude may result from knowledge of personal genetic risk. Along similar lines, De Melo-Martín (2006b) argues that relying on genetic tests as a means to ameliorate human suffering might prevent people from making necessary changes to the social contexts and institutions that contribute to the perpetuation of disease and disability. From a social welfare perspective, undergoing unnecessary testing and subsequently seeking remedial measures can overburden the health care system and divert precious resources from practices and procedures that have a much higher clinical value.

Current Regulation of Genetic Tests

The recently passed FDA Amendments Act of 2007, which requires the Secretary's Advisory Committee on Genetics, Health, and Society to complete an assessment of the quality and safety of genetic tests, is just one manifestation of justified concern about the current lack of regulation of genetic testing services. However, the GPPC notes that the lack of regulation and oversight is not due to a shortage of recommendations from task forces or advisory committees (GPPC 2007a; Javitt and Hudson 2006b). In particular, over a decade ago, the Institute of Medicine conducted an inquiry that addressed precisely these issues and made recommendations. Other large-scale studies were conducted by the 1995 National Institutes of Health Task Force on Genetic Testing and the 2000 Secretary's Advisory Council on Genetic Testing. Researchers have explained repeatedly that policy makers and public agencies should implement the recommendations that have been put forth (e.g., Javitt and Hudson 2006a, b). Thus far, however, policy makers, including legislators, are either unsure of how to proceed or unwilling to create and enforce much needed regulations.

Currently, certain parts of the genetic testing process are governed by a few federal regulations that were not formulated specifically for genetic tests. One such regulation is the Clinical Laboratories Improvement Amendments (CLIA) of 1988, which is administered by the CMS. The goal of the CLIA is to "ensure quality laboratory testing." However, the CLIA does not "address the inherent safety and effectiveness" of genetic tests (Andrews et al. 1994, p. 136), and it does not regulate laboratories' claims about such tests (Hudson et al. 2007). Until August 2006, the CMS appeared to be moving toward developing a specialty area for genetic testing, but it suddenly decided that it was not vital to do so (Javitt and Hudson 2006b). The absence of a specialty area in genetics threatens both the analytic and the clinical validity of genetic tests. Although the CLIA addresses only analytic validity, that analytic validity is a necessary but not sufficient condition for clinical validity or utility means that knowledge of a test's analytic validity would clarify which tests are definitely not going to be clinically valuable.

In addition to the CLIA, the FDA provides oversight over some genetic testing services, mainly in the area of premarket approval, but significant ambiguity remains about the FDA's regulatory authority over genetic testing services. Only genetic tests marketed as kits are under direct FDA regulation as in vitro diagnostic devices, but because most genetic tests are not marketed as kits, they can sidestep FDA approval. Javitt (2007) notes that the FDA has approved only eight genetic test kits, which indicates a preference on the part of test manufacturers to evade regulation. In addition to regulating in vitro diagnostic devices, the FDA also regulates "analyte-specific reagents," which it classified as medical devices in 1997. Analyte-specific reagents are the active ingredients in laboratory-developed tests, which, unlike test kits, do not include instructions and information regarding the purpose and proper use of a test; instead, the labs themselves determine the composition and application of tests (Javitt and Hudson 2006a). The FDA's regulation of analyte-specific reagents restricts their sale to labs, but it does not dictate their use in laboratory-developed tests.

Regulatory deficits become even more obvious with DTC marketing of genetic tests. Neither the CMS nor the FDA regulates the content of communications from genetic testing companies to the public. Advertisements for genetic tests are subject to the general principle of truthful advertising under Federal Trade Commission (FTC) regulations, which requires claims in advertisements to be true and substantiated (FTC 1984a, b). However, given the complex nature of genetic science and consumers' lack of knowledge in this area, FTC regulations are likely to be inadequate to oversee marketing activities in the genetic testing industry. This contrasts with the FDA's regulation of prescription drug advertising (21 CFR § 202.1), which treats prescription drugs as unique products and requires their advertisements to provide true and balanced information, including mandatory disclosure of the drugs' harmful effects alongside information about benefits.

At the state level, regulation is mixed. A GPPC (2007c) report indicated that there are no restrictions on DTC laboratory testing in 26 states and the District of Columbia. Only 11 states explicitly prohibit DTC access to genetic tests. In most states in which consumers are allowed direct access to genetic tests, the law says nothing. The current legislative silence leads to the assumption that DTC access to genetic tests is permissible and even desirable, though there is currently insufficient evidence to support such an assumption.

Online DTC Marketing of Genetic Tests: An Empirical Assessment

Overview

To further assess current DTC marketing practices, we content-analyzed genetic testing companies' Web sites. Our focus on the Internet was based on consumers' increasing use of this medium to look for health information (Sewak et

al. 2005; Waack, Ernst, and Graber 2004). Recent statistics show that 84% of U.S. Internet users have searched for health information online (Harris Interactive Inc. 2007), and more than half of the searchers reported that their most recent online search influenced how they cared for themselves or others (Fox 2006). Although large-scale advertising campaigns of genetic tests through the traditional media (e.g., the fall 2007 campaign by Myriad Genetics; see GPPC 2007b) are still rare, most genetic test marketers have developed a Web presence. Corporate Web sites are currently the main source of DTC marketing information and thus form the target of our empirical analysis. Similar to prior examinations of DTC advertising of prescription drugs (Macias and Lewis 2005; Waack, Ernst, and Graber 2004), our purpose is to determine the extent to which information provided by DTC marketing Web sites is biased or incomplete and whether such information is merely a persuasive ploy or a useful resource that helps consumers make more informed decisions. By identifying the problems in current practices, we hope to provide helpful input for public policy that can eventually address these problems.

Methodology

Sample Identification

To identify the Web sites that market genetic tests, a trained research assistant conducted searches using all major Internet search engines first in July 2006 and again in December 2007. Variations of keywords, such as "genetic tests" and "genetic testing services," were used. Online directories published by Yahoo and Google were also perused to identify relevant Web sites that might not have turned up during the search process. Of all the Web sites found, we then selected those that market predictive genetic testing services. We excluded information-only Web sites and Web sites of companies based outside the United States, consistent with our focus on regulatory issues in the United States. Because these classifications were fairly straightforward, we did not encounter any disagreement as to which ones should be included. The final list consisted of 63 Web sites, 46 of which had significant consumer-targeted content (see Table 1). Over five years, the number of DTC genetic testing sites has increased significantly, almost tripling the number of sites found in previous studies (Gollust, Wilfond, and Hull 2003; Williams-Jones 2003). This shows the rapid growth of online DTC marketing by the genetic testing industry. Some Web sites found in previous searches no longer existed or had changed their corporate identity by the time of our search, suggesting the volatile nature of the marketplace.

The other 17 Web sites in our final list targeted mainly health care professionals (see Table 2).[2] We retained these Web sites and analyzed them along with the DTC site group. The rationale for such comparative analysis was that, given the assumption, albeit problematic, that health care professionals are likely to have a higher level of "genetic literacy" than laypersons, it would be expected that they are better able to process and evaluate information (Alba and Hutchinson 1987), which may in turn motivate marketers to provide higher-quality information. However, our results cast doubt on some of these assumptions. In addition to professional versus DTC Web sites, we compared the professional versus consumer sections within the 24 DTC Web sites that had significant materials for both consumers and professionals.[3] Because these sections reside within the same Web sites, such an analysis can offer an even more telling picture of the different ways marketers may treat the two segments.

Content Coding and Data Analysis

Following recommended content analysis procedures (Neuendorf 2002), our analysis was guided by a codebook, which contained variables related to the availability and quality of information and to the use of emotional appeals. To develop information quality criteria, we examined prior research on genetic testing (Gollust, Wilfond, and Hull 2003; McCabe and McCabe 2004; Shepperd et al. 2006) and, more generally, on what is considered quality health care information (Charnock et al. 1999; Entwhistle et al. 1996). We also drew from the field of DTC marketing of prescription drugs (e.g., Main, Argo, and Huhmann 2004; Waack, Ernst, and Graber 2004; Woloshin et al. 2001). On the basis of these sources, we examined the presence/absence of the following in each Web site: (1) basic information on genetics, (2) probabilistic nature of genetics, (3) balanced information (i.e., both pros and cons of genetic testing), (4) alternatives to genetic testing, (5) privacy policy, and (6) scientific information for professionals. For the use of emotional appeals, we studied six positive emotional appeals (happiness/joy, warmth, pride, empowerment, assurance/peace of mind, and relief) and four negative emotional appeals (fear, guilt/shame, regret, and sadness). These emotional appeals were drawn from existing typologies of emotions (Bagozzi, Gopinath, and Nyer 1999; Roseman 1991) and from studies of emotional appeals in DTC advertising (e.g., Main, Argo, and Huhmann 2004; Wolfe 2002; Woloshin et al. 2001).

Two judges independently coded each Web site using the codebook. The overall intercoder agreement was 93.3%, the intercoder agreement for each codebook item appears in Table 3. Disagreements between the two coders were resolved through discussion. The coded data were then analyzed with SPSS. For the prevalence of a feature, we used frequency analysis. To compare between Web sites and between sections within the same DTC Web sites, we used chi-square analysis. For the use of emotional appeals, we also used t-tests to compare the total numbers of emotional

[2]We made this distinction by considering the following: (1) clear statement of Web site targeting only physicians; (2) consistent referencing of the reader as a health care professional (e.g., "your patients"); and (3) no separate page, document, or section specifically for nonprofessionals. The intercoder agreement was 95.0%. Disagreements between the two coders were resolved through discussion.

[3]This comparison applies only to the 24 DTC Web sites that had both a consumer section and a professional section. One of the DTC Web sites, CyGene Direct, requires that people log in to access professional information and is excluded from this analysis. We also note that certain features (e.g., privacy policy) are sometimes available as general sections of a Web site. In such cases, they are considered to belong to both the consumer section and the professional section.

Table 1. DTC Genetic Testing Web Sites

Company Name and Web Site Address	Tests Offered	Patient Direct Order	Doctor Intervention Required
23andMe (http://www.23andme.com)	Comprehensive genetic profile	Yes	No
Alzheimer's Mirror (http://alzmirror.com)	Alzheimer's disease	Yes	No
Andrology Laboratory Services (http://www.androlab.com)	Pregnancy loss	No	Yes
Baylor Health Care System (http://www.baylorhealth.com/medical specialties/metabolic/newbornscreening.htm)	Newborn screening for metabolic diseases	Yes	Yes
Center for Medical Genetics (http://www.geneticstesting.com)	Cystic fibrosis, pregnancy loss, prenatal, Tay-Sachs, Bloom syndrome, and others	Yes	No
Cincinnati Children's Hospital (http://www.cincinnatichildrens.org/svc/topics/genetics.htm)	Hearing loss, metabolism, mental retardation, lysosomal storage disease, and others	No	Yes
Consumer Genetics (http://www.consumergenetics.com/)	Risk of heart attack and infertility due to caffeine and wine intake	Yes	No
Cygene Direct (http://www.cygenedirect.com/default.html)	Osteoporosis, thrombosis, and others	Yes	No
DNA Direct (http://genesanddrugs.dnadirect.com)	Breast and ovarian cancer, cystic fibrosis, diabetes, and others	Yes	No
DNATraits (http://www.dnatraits.com)	Fragile X, clotting disorders, sickle-cell anemia, and others	Yes	No
Emory University Genetics Clinic (http://www.genetics.emory.edu/clinics.php)	Down syndrome, metabolic diseases, neurofibromatosis, and others	No	Yes
GenAssist (http://www.genassist.com/)	Preconception and prenatal	No	Yes
GeneCare Medical Genetics Center (http://www.genecare.com/)	Cystic fibrosis, Tay-Sachs, hereditary hemochromatosis, and others	No	Yes
Genelex (http://www.healthanddna.com/)	Nutrigenomics and pharmacogenetics	Yes	No
GeneLink (http://www.genelink.info)	Oxidative stress, cardiovascular health, bone health, metabolism problems, aging, skin health, and nutrigenomics	Yes	No
Genetics & IVF Institute (http://www.givf.com)	Cystic fibrosis, Tay-Sachs, familial dysautonomia, and others	No	Yes
Genova Diagnostics (http://www.genovadiagnostics.com)	Cardiovascular health, osteoporosis, immune system health, and others	No	Yes
Genzyme Genetics (http://www.genzymegenetics.com/default.asp)	Cystic fibrosis, fragile X, Down syndrome, and others	No	Yes
Graceful Earth (http://www.gracefulearth.com/)	Alzheimer's disease	Yes	No
Great Lakes Genetics (http://www.genetest.com/)	Cystic fibrosis, fragile X, sickle-cell anemia, and others	No	Yes

Table 1. Continued

Company Name and Web Site Address	Tests Offered	Patient Direct Order	Doctor Intervention Required
HealthCheckUSA (http://www.healthcheckusa.com/)	Celiac disease, thrombosis, and hereditary hemochromatosis	Yes	No
Health Tests Direct (http://www.health-tests-direct.com)	Cystic fibrosis	Yes	No
HIVMirror (http://www.hivmirror.com/)	HIV/AIDS progression	Yes	No
Holistic Heal (http://www.holisticheal.com)	Nutrigenomics	Yes	No
InterGenetics Incorporated (http://www.intergenetics.com/)	Breast cancer, cystic fibrosis, and others	No	Yes
Interleukin Genetics (http://www.ilgenetics.com/)	Nutrigenomics and gum disease	Yes for Gensona/ no for PST	No for Gensona/ yes for PST
John Stoddard Cancer Center (http://johnstoddardcancer.org/body.cfm?id=11)	Breast cancer, ovarian cancer, colorectal cancer, and related cancers	No	Yes
Kimball Genetics (http://www.kimballgenetics.com/)	Broad beta disease, celiac disease, cystic fibrosis, and others	Yes	Yes
LabCorp (http://www.labcorp.com/genetics/index.html)	Prenatal	No	Yes
MarketAmerica (https://www.marketamerica.com/corporate/index.cfm?action=services.wpGeneSNPInfo)	Nutrigenomics	Yes	No
MyGenome (http://www.mygenome.com/)	Alzheimer's disease, thrombosis, osteoporosis, and others	Yes	No
Myriad Genetic Laboratories (http://www.myriadtests.com/)	Breast cancer, ovarian cancer, colorectal cancer, endometrial cancer, and melanoma	No	Yes
NYU Human Genetics Program (http://www.med.nyu.edu/pediatrics/genetics/)	Cystic fibrosis, Tay-Sachs, Canavan disease, and others	No	Yes
Pediatrix (http://www.pediatrix.com/)	Newborn screening	Yes	Yes
PGx Health (http://www.pgxhealth.com/genetictests/familion/)	Heart disease	No	Yes
Quest Diagnostics (http://www.questdiagnostics.com/)	Breast cancer	No	Yes
Quixtar (http://www.quixtar.com/products/product.aspx?itemno=104009)	Heart disease	Yes	No
Salugen (http://www.salugen.com)	Nutrigenomics	Yes	No
Sciona (http://www.mycellf.com)	Nutrigenomics	Yes	No
Signature Genomic Laboratories (http://www.signaturegenomics.com)	Prenatal	No	Yes
Suracell (http://www.suracell.com)	Cellular health	No	Yes

Table 1. Continued

Company Name and Web Site Address	Tests Offered	Patient Direct Order	Doctor Intervention Required
University of California, San Diego Medical Center (http://health.ucsd.edu/specialties/medgenet/)	Angelman syndrome, Bloom syndrome, Canavan disease, and others	No	Yes
University of Rochester Medical Center (http://www.urmc.rochester.edu/genetics/)	Breast cancer, colon cancer, cystic fibrosis, sickle-cell anemia, thalassemia, and other hemoglobinopathies	No	Yes
Vanderbilt's Monroe Carell Jr. Children's Hospital (http://vanderbiltchildrens.com/interior.php?mid=178)	Newborn screening, prenatal	No	Yes
Vysis Aneuvysion (http://www.aneuvysion.com/)	Prenatal	No	Yes
Yale Cancer Center (http://www.yalecancercenter.org/genetics/index.html)	Cancer	No	Yes

appeals used and the numbers of positive and negative appeals used.

Results on Information Practices

A summary of results from the content analysis and a brief description of each variable appear in Table 3. Of 46 DTC Web sites, 43.5% allowed consumers to order directly from the company. Another 10.9% allowed consumers to order test kits directly but required doctor intervention to submit samples for analysis or to obtain results. The remaining Web sites allowed order placement and/or referral by a health care professional only. Test cost information was provided on half (52.2%) of the DTC Web sites. Some Web sites allowed consumers to order test kits for free but did not provide information on the cost of the sample analysis and results reporting. We surmised that test kits received by consumers would disclose cost information.

Basic Genetic Information

The complexity of genetic information makes it critical for consumers to receive proper education and assistance in understanding such information (Gollust, Hull, and Wilfond 2002; kSERO Corporation 2003). We examined each Web site for explanations of genetic terminology and of how genes and genetic tests work. Of the DTC Web sites, 47.8% offered such information, often in the form of a glossary or a health library. Another 17.4% did not offer basic genetic information but provided links to other Web sites where consumers could find such information. Surprisingly, the professional Web site group did much worse ($\chi^2 = 5.35$, $p = .02$), with only 17.6% of the Web sites providing basic genetic information and another 17.6% offering links to such information. We observed similar differences between professional and consumer sections within a Web site, with 58.3% providing basic genetic information in the consumer section versus only 33.3% in the professional section. Another 16.7% of the consumer sections provided links to basic genetic information, whereas only 12.5% of the professional sections did so.

Probabilistic Nature of Genetics

As we noted previously, carrying a particular mutation does not always entail affliction with the related disease. Consumers who undergo genetic testing should be aware of this to avoid unnecessary stress caused by test results that indicate the presence of a mutation. For some consumers, knowing the probabilistic nature of genetics may also make them decide against taking genetic tests and avoid anxiety. Of the DTC Web sites, 45.7% provided information on inheritance patterns and the probability of getting a disease if a person carries the mutation. For professional-oriented Web sites, 47.1% provided such information. There was no significant difference between the consumer (58.3%) and the professional (50.0%) sections within a Web site. Three (6.5%) DTC Web sites contained statements and language reflecting genetic determinism. Notably, all three of these Web sites allowed consumers to order directly from them without any doctor's intervention, thus leaving consumers more susceptible to erroneous decisions that could negatively affect their health.

Pros and Cons of and Alternatives to Genetic Testing

Balanced information refers to information on both the benefits and the risks of genetic testing. Of the 46 DTC Web sites, only 15.2% discussed potential harmful effects of genetic testing. The professional Web sites performed equally poorly, with only 5.9% offering both pros and cons.[4] When we compared the consumer and professional sections, 16.7% of the consumer sections discussed pros

[4]Closely related to the pros and cons of genetic testing is the possibility of false positives and/or false negatives (i.e., clinical validity) of the tests provided. Our analysis showed that only 26.1% of the DTC Web sites provided specific false positive/negative rates, and 10.9% of the Web sites mentioned the possibility of a false positive/negative, but they did not give any rate. Professional Web sites performed similarly, with 35.3% offering false positive/negative rates and another 17.6% mentioning the possibility of a false positive/negative without specific rates.

Table 2. Professional Genetic Testing Sites

Company Name and Web Site Address	Tests Offered
Ambry Genetics (http://www.ambrygen.com)	Cystic fibrosis, pancreatitis, diabetes, pulmonary diseases, and others
Athena Diagnostics (http://www.athenadiagnostics.com)	Hearing loss, diabetes, obesity, and others
Baylor Medical Genetics Lab (http://www.bcm.edu/geneticlabs/)	Cystic fibrosis, fragile X, osteoporosis, Huntington's disease, prenatal, and others
BRT Laboratories (http://www.rhlab.com/P53.html)	Cancer tumor suppression
Case Western University Hospitals (http://www.uhhospitals.org/case/OurServices/Centersand Programs/GM/AddictionRecoveryServices/tabid/1196/Default.aspx)	Cystic fibrosis, fragile X, hearing loss, and others
Duke Medical Genetics (http://medgenetics.pediatrics.duke.edu/modules/services/index.php?id=1)	Neurofibromatosis, Down syndrome, fragile X, lysosomal disorders, and others
Genedx (http://www.genedx.com)	Prenatal, skin disorders, and others
Kennedy Krieger Institute Genetics Laboratories (http://genetics.kennedykrieger.org)	Peroxisomal disease, prenatal, Canavan disease, and others
LSU Health Sciences Center (http://www.lsuhsc.org)	Cancer, prenatal, and others
Molecular Diagnostics Laboratories (http://www.mdl-labs.com/)	Thrombosis
OHSU Cancer Genetics (http://www.ohsu.edu/outreach/cdrc/clinical/portland/genetics_cancer.html)	Cancer
Prometheus (http://www.prometheuslabs.com/212.asp?nav=products)	Celiac disease, metabolism, lactose digestion
Robert Guthrie Genetics Lab (http://www.rgbgl.org)	Metabolism, lysosomal storage disease, muscle disease
Stanford Medical Genetics (http://pediatricsgenetics.stanford.edu/patient_care)	Down syndrome, neurology, metabolism, cancer, and prenatal
UMDNJ Institute of Genomic Medicine (http://www.umdnj.edu/genesatwork/)	Prenatal, sickle-cell anemia, neurofibromatosis, and neuromuscular diseases
University of South Alabama Birth Medical Genetics (http://www.southalabama.edu/genetics/bdgc_index.htm)	Mental retardation, neurofibromatosis, Turner syndrome, Down syndrome, fragile X, and others
University of Washington Genetics Lab (http://depts.washington.edu/labweb/Divisions/MolDiag/MolDiagGen/index.htm)	Cystic fibrosis, hearing loss, fragile X, Factor V Leiden, Huntington's disease, and others

and cons, whereas 25.0% of the professional sections offered such information. This lack of evenhanded information contrasts sharply with the fair balance requirement governing DTC advertising of prescription drugs, possibly because of the aforementioned confusion over regulatory oversight of genetic tests. Although genetic testing may not cause the same side effects as prescription drugs, as we discussed previously, the potential negative financial and psychological effects of genetic testing can be equally severe and far-reaching (Cella et al. 2002; Lee and Brennan 2002).

To exacerbate the lack of balanced information, only 15.2% of the DTC sites suggested viable alternative means of predicting or diminishing the likelihood of being affected by a hereditary condition, such as maintaining a healthful lifestyle, relying on family history, or taking other non-gene-based tests. This absence is especially pronounced in Web sites that allowed direct orders, with 95.0% missing information about alternatives. Professional Web sites fared no better, with only 11.8% mentioning alternatives to genetic testing. We found a similarly low percentage (8.3%) in the professional sections of DTC Web sites. Without information about alternative approaches and potential negative effects of genetic testing, these Web sites effectively exaggerate the benefits of genetic testing and encourage unnecessary testing.

Privacy Policy

The extensive implications of genetics for health care make it critical to protect consumers' private information in this area (Lerman and Shields 2004). Currently, consumer pri-

Table 3. Content Analysis Results Summary

Coding Variable	Variable Description	Present in DTC Web Sites	Present in Professional Web Sites	Intercoder Agreement
Information				
Basic genetic information	Information on basic genetic terms and patterns of heritability (e.g., a glossary of terms).	47.8%	17.6%	86.7%
Probabilistic nature of genetics	Information about the probabilistic nature of genetics and genetic tests (e.g., probability of getting a disease if a person carries the mutation).	45.7%	47.1%	81.7%
Pros and cons	States both pros and cons of the products/services offered.	15.2%	5.9%	96.7%
Alternatives	Alternative means of predicting or diminishing the likelihood of being affected by a hereditary condition (e.g., a healthful lifestyle and non-gene-based tests).	15.2%	11.8%	93.3%
Privacy policy	Provision of a privacy policy stating the protection of patient health information.	71.7%	52.9%	91.7%
Scientific information for health professionals	Professional information to health care providers (e.g., scientific proof of test validity and reliability, disease information).	54.3%	100%	95.0%
Emotional Appeals				
Happiness/joy	Portrays situations that represent a good feeling, immense pleasure, and even ecstasy; a promise of happiness.	21.7%	0%	91.7%
Warmth	Portrays a positive warm and fuzzy feeling that is less intense than happiness/joy.	60.9%	29.4%	90.0%
Pride	Portrays a strong sense of self-respect, dignity, and superiority.	4.3%	0%	96.7%
Empowerment	Reflects an enhanced sense of power; appeals to a consumer's desire to be in control; it can apply to dealing with both desirable and undesirable situations.	60.9%	11.8%	93.3%
Assurance/peace of mind	Appeals to a sense of peace, knowing for certain of a positive outcome.	34.8%	23.5%	90.0%
Relief	Portrays a sense of relaxation after removal of something stressful; less outcome-related but rather the mere fact that "I finally know."	26.1%	12.5%	90.0%
Fear	Portrays a negative, undesirable scenario that may happen in order to arouse fear in the audience.	26.1%	5.9%	96.7%
Guilt/shame	Presents actual violation or a potential violation of the consumer's internalized standard of proper behavior.	2.2%	5.9%	98.3%
Regret	Portrays a dissatisfactory choice when a better choice is/was possible.	10.9%	0%	93.3%
Sadness	Portrays situations representing a downcast mood, unhappiness, and, in the extreme form, grief.	4.3%	0%	98.3%

vacy in the health care industry is protected by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, though HIPAA compliance is likely to be limited and varied among online vendors (Choy et al. 2001). Under HIPAA, health care professionals cannot share a consumer's health information without the consumer's explicit consent. Of the DTC Web sites, 71.7% claimed to follow HIPAA guidelines and posted privacy statements pledging confidential treatment and protection of consumer information. In comparison, 52.9% of the professional Web sites had a privacy policy. This lower presence of privacy policy may be due to the physician–patient confidentiality rule that requires physicians to protect patient information. It is worth noting that in May 2008, the Genetic Information

Nondiscrimination Act was signed into law, with the aim to prevent employers and insurance companies from using genetic information to the detriment of individuals. Although the act is likely to alleviate prospective consumers' fears, how it will affect genetic testing practices remains to be seen.

Scientific Information for Health Care Professionals

To help consumers make the right decision about genetic testing, it is necessary for health care professionals to have evidence of the validity and utility of a particular test. Of the 46 DTC genetic testing Web sites, only slightly more than half (54.3%) offered such information to health care professionals. With a low prevalence of professional-targeted information, these Web sites discourage professional participation in the decision-making process. Although the negative impact can be alleviated by professional genetic counseling, only 39.1% of the DTC Web sites offered genetic counseling services, and among these, only 2 made pretest counseling mandatory. The lack of a professional intermediary is dangerous for consumer welfare and may also put a strain on the patient–doctor relationship.

Results on the Use of Emotional Appeals

Our analysis of genetic testing Web sites suggests that far from providing only objective information, these Web sites appeal often to consumers' emotions. A typical positive emotional appeal is the promise or actual experience (through user testimonials) of positive outcomes from taking a test. For example, consumers may experience relief, assurance, and happiness when they receive positive test results. However, even with the possibility of negative test results, many Web sites still promoted the positive feeling of empowerment. The reasoning was that knowing about heightened risk allows a person to better control or manage his or her life and health. Negative emotional appeals were also used. Fear was most often portrayed in the pretest stage and was often elicited through a family history of a particular disease or through the severity of threat from a disease. In contrast, regret, guilt, and sadness were associated most often with potential negative outcomes if a person were not to take a test. In some cases, negative emotions were copresented with the promise of positive emotions if a person were to take a test, creating a powerful contrast.

On the use of emotional appeals, our analysis revealed significant differences between DTC and professional genetic testing Web sites and between consumer and professional sections within the same DTC Web sites (for the distribution of total emotional appeals used, see Figure 1). On average, a DTC Web site used 2.52 emotional appeals, whereas professional Web sites used an average of .88 emotional appeals ($t = 3.77$, $p < .001$). Compared with professional Web sites, DTC Web sites used both more positive emotional appeals ($M_{DTC} = 2.09$ versus $M_{professional} = .76$; $t = 3.95$, $p < .001$) and more negative emotional appeals ($M_{DTC} = .43$ versus $M_{professional} = .12$; $t = 2.07$, $p = .04$). Emotional appeals were also used more in the consumer section ($M = 2.83$) than in the professional section ($M = 1.25$; $t = 2.79$, $p = .008$). This significant difference is attributable mainly to the higher use of positive emotional appeals (for consumer sections, $M = 2.29$, and for professional sections, $M = 1.00$; $t = 3.33$, $p = .002$). The number of negative appeals did not differ significantly between the sections (for consumer sections, $M = .54$, and for professional sections, $M = .25$).

Use of Emotional Appeals in DTC Web Sites

The most popular emotional appeals were warmth and empowerment, both of which were present in 60.9% of DTC Web sites. This frequent use of an empowerment appeal is not surprising, because it is the least dependent on actual test results and therefore is a versatile, persuasive tool. Even more revealing, the prevalence of an empowerment appeal varied significantly by whether a Web site allowed consumers to order directly ($\chi^2 = 13.81$, $p = .001$). The appeal was present in 90.0% of the direct-order Web sites but in only one-third of the non-direct-order Web sites. By using this popular ploy of appealing to a person's desire to be in control, the direct-order Web sites may unduly encourage consumers to take a genetic test without fully understanding the consequences.

The second most popular positive emotional appeal was assurance, which was present in 34.8% of DTC Web sites. Relief appeal, which portrays a sense of relaxation after the removal of stressful stimuli (e.g., worrying about getting a disease), was used by 26.1% of the DTC Web sites, followed by happiness/joy (21.7%). Together, these positive emotional appeals attempt to engender a positive feeling toward the advertiser, which may have nothing to do with what the product actually offers. For example, many Web sites portray healthy-looking, smiling people in a warm family setting, implying that genetic testing could bring about such desirable outcomes. Although the effects of these emotion-arousing images may seem subtle to a consumer, prior research suggests that feelings engendered by such messages can powerfully influence consumer attitudes and purchase intentions (Edell and Burke 1987).

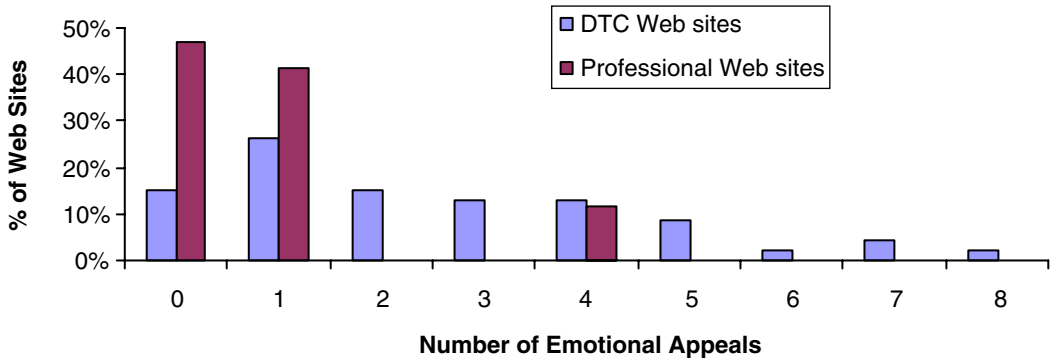
Although the use of negative emotional appeals was less prevalent in all Web sites, a significant portion (26.1%) of DTC Web sites used fear appeals. As a popular advertising tactic, a fear appeal is designed to alert consumers to a threatening scenario that leads to a negative consequence. By arousing the undesirable emotion of fear, these DTC genetic testing Web sites activate consumers' coping mechanisms, encourage them to comply with the solutions offered, and enhance consumers' attitudes toward the products and services offered (LaTour, Snipes, and Bliss 1996). The second most popular negative emotional appeal was regret, which was present in 10.9% of DTC Web sites. The least common emotional appeals were pride (4.3%), sadness (4.3%), and guilt (2.2%).

Use of Emotional Appeals Toward Health Care Professionals

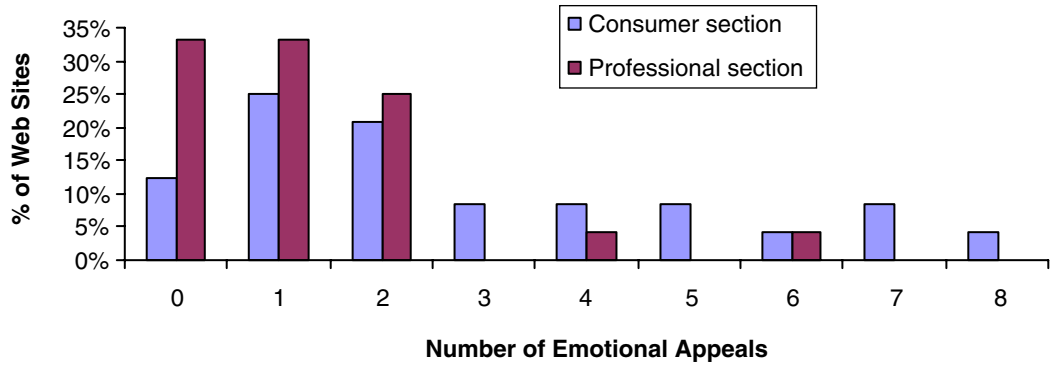
Although some of the emotional appeals used often by DTC Web sites (e.g., warmth, assurance) were also more dominant in professional sites, three important DTC emotional appeals—empowerment ($\chi^2 = 12.00$, $p = .001$), warmth ($\chi^2 = 4.93$, $p = .03$), and happiness/joy ($\chi^2 = 4.39$, $p = .04$)—were used significantly less by professional Web sites. Although empowerment was a major ploy in marketing genetic tests to consumers, companies may consider it ineffective with professionals, who already wield signifi-

Figure 1. Distribution of the Number of Emotional Appeals

A: DTC Versus Professional Web Sites



B: Consumer Versus Professional Sections of DTC Web Sites



cant power. For professional Web sites, warmth and assurance were the most frequently used emotional appeals, which were present in 29.4% and 23.5% of the Web sites, respectively. These were followed by empowerment and relief (both 11.8%). Of the professional Web sites, 5.9% used fear and guilt, and none employed the other emotional appeals (happiness, pride, regret, and sadness). When we compared the professional and consumer sections within the same Web sites, a few significant differences emerged. The professional sections used significantly less happiness/joy (0% versus 29.2%; $\chi^2 = 8.20$, $p = .004$), empowerment (29.2% versus 54.2%; $\chi^2 = 3.09$, $p = .08$), assurance (8.3% versus 37.5%; $\chi^2 = 5.78$, $p = .02$), and relief (12.5% versus 33.3%; $\chi^2 = 3.04$, $p = .08$) appeals than the consumer sections. Given that these sections reside within the same Web sites, such differences in the use of emotional appeals are astounding. It is apparent that companies deliberately employ more emotional appeals and present themselves as compassionate agents when communicating with consumers, potentially augmenting the persuasive power of their marketing messages.

Policy Recommendations

Our review of the current state of affairs suggests significant problems with existing practices of DTC marketing of genetic tests. The current lack of oversight of the genetic testing industry leaves consumers vulnerable as they strive to protect their welfare without the knowledge or tools necessary to do so. Oftentimes, such a failure to enact specific regulations can have a significant impact on social policy because its absence allows other forces to shape practices and policies; for example, as Clayton (2004) points out, litigation against physicians, rather than legislation, led to the inclusion of genetic testing in routine prenatal care. Although many view routine prenatal testing as a good thing, some drawbacks have been observed. For example, test results can put some women in the difficult position of having to decide whether to continue a pregnancy. Some critics of the practice have also noted that the availability of prenatal testing has altered society's view of children born with genetic diseases—that is, that they should not have been born. Furthermore, instead of viewing the birth of an impaired child as an unfortunate roll of the genetic dice, women are viewed as blameworthy for failing to prevent it.

The situation with prenatal care reveals the potential negative outcomes of policy creation through inaction. Although the exact effects of DTC marketing of genetic tests remain to be seen, we advocate proactive public policy aimed at preventing negative outcomes rather than reactive regulations aimed at addressing negative outcomes after

they have happened. Specifically, on the basis of our review, we recommend a three-pronged approach to public policy in this area: consumer education, physician intervention and education, and regulation of marketing activities.

Consumer Education

In discussing consumer vulnerability in the marketplace, Ringold (2005) recognizes the importance of education in reducing vulnerability. We concur and recommend a well-publicized campaign to educate consumers about the risks and benefits of genetic testing and to increase awareness of existing resources that provide information about genetic tests, such as the FTC Web site's concise and helpful brochure titled "At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription" (see http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.shtm). The American Academy of Family Physicians also has an informative Web site on this topic (see http://familydoctor.org/online/famdocen/home/healthy/prevention/462.html). We propose that a public health campaign use traditional mass media to ensure sufficient reach to the public. The goals of the campaign would be (1) to increase awareness of the complexities of genetic tests and consumers' lack of knowledge in this area, (2) to encourage consumers to seek more information in their decision making, and (3) to publicize quality information currently available in this area. The campaign should also involve industry and professional organizations to draw on their expertise and existing resources. We believe that the industry should be motivated to participate in such a campaign because it may also raise awareness of genetic tests.

This consumer education campaign should work in conjunction with DTC marketing from genetic testing companies. Research on DTC advertising of prescription drugs shows that consumers are likely to seek information after seeing a DTC advertisement (Calfee 2002; Liu et al. 2005). It is reasonable to expect that exposure to DTC marketing of genetic tests may lead to similar behavior. This post-exposure information seeking is a crucial juncture because it can potentially remedy the deficiency in DTC marketing and help consumers make the right decision. In an effort to direct information seeking to the right sources, public education campaigns could be timed to coincide with DTC marketing campaigns. Public education materials from unbiased sources could be distributed to patients through their physicians during patient consultation sessions that may result from DTC marketing campaigns. Because the Internet is a crucial source for health care information, genetic testing companies should also be encouraged to link to these public education materials from their Web sites. The ultimate goal of public education is to increase consumers' knowledge, to empower them, and, effectively, to "produce informed decision makers" (Andrews et al. 1994, p. 196).

Physician Intervention and Education

Public education alone is unlikely to produce sufficient knowledge for an average consumer to make sound decisions about genetic testing. Physicians will likely play an important role in this area. In a study of consumer information seeking after exposure to DTC advertising of prescription drugs, Liu and colleagues (2005) show that despite consumers' stated intentions, they ultimately sought physician consultation about drugs they had seen advertised. Although consumers intended to use the Internet as a substitute, it ended up being a supplement rather than a replacement. Because physicians are also likely to be key players in genetic testing, it is important to clarify their role in this process and to educate and prepare them for the genomic era.

Physician Intervention

In formulating public policy in this area, useful guidance can be drawn from the distinction between prescription and over-the-counter drugs. Currently, the FDA can approve a change in a drug's status from prescription-only to over-the-counter if its benefits have been proved to outweigh its risks, if consumers can self-diagnose their conditions and easily understand the drug's label, and if the potential for abuse is low (Cohen, Paquette, and Cairns 2005; Jacobs 1998). These rules imply that it may be too soon to allow "over-the-counter genetic tests." Although the effects of genetic tests vary from the side effects of prescription drugs, uncertainty about the consequences of undergoing genetic tests makes it inappropriate to assume that the benefits will outweigh the risks. Furthermore, although genetic test kit labels can be made relatively accessible, a key step in "consuming" genetic tests is the interpretation of test results, which is much trickier for the average consumer. The probabilistic nature of genetics and many other factors that affect a consumer's health condition make accurate self-diagnosis and determination of an appropriate course of treatment difficult. Thus, genetic self-tests at this time would fail to meet classification criteria similar to those used to designate drugs as over-the-counter.

For these reasons, we recommend that predictive genetic testing be offered only through a physician intermediary and that patients be discouraged from undergoing genetic tests in the absence of indications that it would be useful (e.g., family history, clinical symptoms). When clinical justification for a genetic test is lacking but the patient's desire for it is present, the physician should warn the patient of "the possibility of psychological stress induced by knowledge that the test will reveal" (Bayley 2004, p. 183). This warning should accompany the usual information regarding the possibility of false-positive, false-negative, or inconclusive results, as well as about the likely clinical and personal value of the test for the patient. Moreover, patients should be warned that even if a positive result is later disconfirmed, the initial positive result might cause short- or long-term psychological distress. In agreement with Munson (2007), however, we acknowledge that a test's lack of clinical value does not mean that its results are of no value to the patient; there may be defensible reasons for undergoing a genetic test even if it does not facilitate prevention or treatment of a disease. For this reason, we recommend a prohibition on DTC marketing of genetic tests that lack analytic or clinical validity, but we withhold such a recommendation for tests that merely lack clinical utility.

Although our recommendation is more restrictive than the recent American Society of Human Genetics statement

(Hudson et al. 2007), our decision is based on the current lack of other protections that are in place. In the future, as more data on the effects of genetic tests on consumer health and welfare become available, we may alter this conclusion. Eventually, over-the-counter-like status for some genetic tests may be reasonable, but a clear guideline for conversion must first be established. The guideline must consider the test's analytical and clinical validity, the prevalence and nature of the target disease, and whether test results will prompt consumers to alter their behavior and how. Along these lines, Javitt (2007, p. 646) proposes "a tiered approach that matches the level of risk to the degree of [FDA] oversight"; that is, the regulatory focus should not be on whether the test is a laboratory-developed test or is sold as a kit (Javitt 2007; Katsanis, Javitt, and Hudson 2008).

Initially, it might be expected that genetic testing companies would resist the physician intervention requirement, but self-interest may dictate their support for such a move. In Pines's (1999) discussion of DTC marketing of prescription drugs, he notes that pharmaceutical companies have often employed the "learned intermediary" defense, claiming that they are clear of liability because the use of the drug is controlled not by the pharmaceutical companies but by the health care professionals whose duty is to inform the patient regarding risks, benefits, and proper use of the drug. Using *Perez v. Wyeth* as an example,[5] Pines (1999, p. 515) notes that DTC advertising "alters the calculus of the learned intermediary [such that] the learned intermediary doctrine 'does not apply to direct marketing of drugs to consumers.'" Consequently, in the interest of protecting themselves from potential legal liability, genetic testing companies may welcome physicians as gatekeepers and refrain from DTC selling.

Physician Education

Although there are good reasons physicians may favor their role as gatekeepers (e.g., better management of relationship with patients, protection of consumer welfare, increased revenue), existing evidence shows that physicians—primary care physicians, in particular—are still somewhat reluctant to integrate genetic testing into their practices (Bayley 2004). This may be partially due to their current lack of knowledge of genetics and an accompanying lack of confidence in handling requests for genetic tests or interpreting test results. Although medical schools are improving genetics education, many physicians currently practicing medicine received inadequate training in clinical genetics; thus, many on the front line are unprepared to deal with patients' inquiries about genetic testing (Bayley 2004). To address this issue, significant improvements in genetics education in medical schools, residency programs, and continuing medical education programs are necessary. The National Coalition for Health Professional Education in Genetics is currently working to improve physician knowledge of genetics. This group has recently created a CD titled *Genetics and Common Disorders: Implications for Primary Care and Public Health Providers*, which can be obtained for free through the Internet and used for educational purposes. With the rapid advances in genetic medicine and a new interest in its possible role in preventive care, physicians will likely welcome educational programs that help them function more effectively.

Regulation of DTC Marketing of Genetic Tests

Regulation of DTC marketing of genetic tests must address quality control and content of marketing communication. In terms of quality control, in accordance with the recommendations of the National Institutes of Health Task Force on Genetic Testing (1997) and Munson (2007), we propose a prohibition on offering to the public any genetic test that is not analytically valid. Furthermore, we recommend that either the FDA or the CMS publish a clear and accessible list of analytically and clinically valid tests and widely publicize its existence so that both providers and laypersons can easily determine whether the test they intend to use has been shown to be accurate. We agree with Javitt's (2007, p. 647) recommendation that the FDA and CMS jointly develop a "guidance document outlining the type of data required to support [a claim of] clinical validity." Furthermore, a link to this resource should be included in the standard information section that we propose should be included in every DTC genetic testing Web site. Exposing consumers to this list would help correct the mistaken belief that all genetic tests on the market are FDA approved or scientifically valid (Donohue, Cevasco, and Rosenthal 2007; Javitt 2007). We also recommend that the CMS provide a clear and accessible resource for determining whether labs conducting genetic tests are qualified to do so.

Regarding the content of DTC marketing communication, we recommend that more specific guidelines be devised for genetic tests and that, in agreement with Javitt (2007) and Katsansis, Javitt, and Hudson (2008), FDA and FTC enforcement of existing prohibitions against misleading advertisements be intensified. Beyond the truthful advertising and fairness principles governing all advertisements, regulation of marketing communications in this area needs to consider the intricate nature of genetic tests and their far-reaching effects on consumer health and social welfare. Although the FDA regulation of DTC advertising of prescription drugs may be a useful guide in formulating policy in this area, its limitations, such as the lack of clarity and its inadequate consideration of laypersons (Pines 1999), must also be acknowledged and addressed. Minimally, we recommend that all DTC marketing materials specify the potential harms of a test, point out the probabilistic nature of genetics, and provide indicators of test accuracy and utility.

Internet-Specific Issues

According to a PEW Internet & American Life study, only 15% of online health information seekers examined the source and date of online resources (Fox 2006), leaving most consumers vulnerable to incorrect and low-quality information. These findings, together with our analysis, suggest a need to regulate online marketing materials. Although the FTC (2000) has specified that its laws are not media specific and thus apply to the Internet, regulations of online genetic test marketing need to address at least two

[5] *Saray Perez v. Wyeth Labs., Inc.*, 734 A. 2d 1245 (N.J. 1999).

unique issues: presentation of information and linking to external information.

Presentation of Information

A unique aspect of online resources is the often-complex navigational structure of Internet sites, which makes them trickier to regulate than traditional advertisements. This raises two issues. First, the amount of space available on the Internet enables a Web site to offer far more information than traditional marketing media. However, increased quantity provides no assurance of good quality. As a *Journal of the American Medical Association* editorial notes, "The problem is not too little information but too much, vast chunks of it incomplete, misleading, or inaccurate" (Silberg, Lundberg, and Musacchio 1997, p. 1244). Genetic science is complex even in small doses, and in any case of information overload, comprehension of the material can be lost. Second, Web site content is not always presented in a way that promotes sound decision making. As the FTC (2000) points out, companies sometimes present critical information, such as disclosures, in such a way that it is easily overlooked by consumers. During our analysis, we often needed to drill down deep into a Web site to find certain information. Given the more casual nature of most consumers' information searches, there is reason to doubt that consumers will find the information needed to make informed decisions.

To address these issues, we recommend that a standard section be included in every DTC genetic testing Web site. The information in this section should be written in layman's terms so that an average consumer can easily understand it. A link to this standard section should be prominently displayed on every page within the Web site for easy access. Standardized icons can also be created to identify information in the section so that consumers can easily compare multiple DTC Web sites. The goal of this standard section is to offer objective, accessible information to help consumers make prudent decisions about whether to undergo a certain test.

We expect that the presence/absence of this standard section could function as a starting point for creating an online list of FTC-compliant and noncompliant companies. Although enforcing regulations in an online environment is likely to be significantly more challenging than in the bricks-and-mortar context, the 24-7 public availability of online materials makes it considerably easier to monitor Web sites for compliance. The new mentality of consumer participation and collaboration in the newer generation Web may propel grassroots-level monitoring (Tapscott and Williams 2006). If the FTC lacks the resources to conduct all the monitoring itself, other interested groups or individuals may do so on a volunteer basis after the FTC clearly establishes the compliance criteria.

Linking to External Information

New regulations should also specify firms' obligations and liability for external information linked from their Web sites. Many of the genetic testing sites we analyzed contained convenient links to information from third-party sources, some of which functioned as endorsements for the products or services marketed by the referring site. Such information can have a persuasive effect in favor of the referring site; yet in the current regulatory climate, it is unclear under what conditions firms are held responsible for hyperlinked information. As a result, it has been suggested that companies can reduce liability by linking to the external source's home page rather than to a specific page within that external site and by displaying explicit disclaimers before consumers navigate to the external Web site (Heather 2001). Although these measures may diminish liability, they do not necessarily reduce the persuasive effect of such information on consumers. We recommend creating specific guidelines that will close such loopholes and thus protect consumers.

In his work on online marketing of prescription drugs, Heather (2001) suggests that the treatment of hyperlinked external information from pharmaceutical companies' Web sites can be partially borrowed from guidelines used in the investment community. Specifically, the Securities and Exchange Commission (2000) considers three factors when determining liability for hyperlinked information: (1) context of the link, such as whether the referring site explicitly endorses the external information; (2) risk of confusion by users about information sources; and (3) presentation of the linked information, such as the actual external page that is linked to and the layout of the link in the referring site. Similar guidelines can be issued on how hyperlinked information from genetic testing companies' Web sites should be treated.

Resource Considerations

In recommending more stringent regulations, we acknowledge the necessary costs that come with implementing such regulations. Currently, FDA staff and other resources are limited. However, in the interest of protecting public health, conserving individual and collective health care resources, and preserving the present and future credibility of genomic science, Congress should give greater priority to providing adequate funding for oversight and regulation of genetic tests. This is especially critical given the likely expansion of the role of genetics in twenty-first-century health care.

In the meantime, creative solutions can be used to draw available resources from various entities and, thus, to lessen the burden on one particular agency. Here, we offer a few possibilities. First, as we mentioned previously, the CMS has moved toward establishing a specialty area for genetic testing. Given the rapid development of the field, reconsidering such a specialty area may constitute a quick and efficient solution because some preparation may have been done previously in anticipation of establishing the area. Second, in addition to government agencies, it may be desirable to appeal to the prudential interests of companies that market their tests directly to consumers. However, this strategy is unlikely to be effective in all cases. Therefore, it may be necessary to align the interests of these companies with public welfare in other ways. For example, it is in insurance companies' long-term interest to pay only for tests that are analytically and clinically valid because only such tests are likely to lead to long-term health benefits. This may discourage genetic testing service providers from marketing bogus genetic tests because such tests will incur out-of-pocket expenses and thus put the marketer at a competitive disadvantage. Finally, as we discussed in the preceding section, the open nature of the Internet facilitates

collaborative citizen efforts in implementing regulation through this medium. This involvement of civil and trade organizations can further lessen the burden on limited federal resources.

Further Research

In this study, we assessed the status of DTC marketing of genetic tests and regulations in this area. Our analysis revealed that current business practices are problematic and that existing public policy has largely neglected to address these problems. Combined with consumers' lack of knowledge, this is an undesirable situation. Consequently, we issue a call to marketing and ethics scholars to contribute to a sound genetic testing marketplace through continued inquiry into the impact of genetic tests and the DTC marketing of such tests on individual consumers and society as a whole. A few topics deserve special attention.

First, although this research assesses current business practices, our understanding is incomplete without knowledge of how consumers respond to these marketing messages. Can consumers process these messages and discern misleading information? How and to what extent does information from DTC marketing sources affect consumers' decision making? More generally, how do genetic test results alter consumers' health-related decision making? Consumer information-processing and decision-making theories, especially as they relate to consumer knowledge (e.g., Alba and Hutchinson 2000), will prove useful in answering these questions. Furthermore, recent research shows that both the content and the design of a DTC Web site can affect consumer information processing and attitudes (Sewak et al. 2005). In this research, with the exception of emotional appeals, we focused primarily on the informational aspect of DTC Web sites. This can be extended in the future to include executional elements of a Web site. Further research should also include a more in-depth examination of the quality of information provided on genetic testing Web sites.

Second, further research should focus on health care professionals. With the extensive impact of genetic sciences on the health care industry, the ready availability of genetic tests to consumers is bound to affect the nature of patient care. Related to our policy recommendations, it is necessary to better understand physicians' knowledge of and attitude toward genetic tests. Researchers should also examine the marketing of genetic tests targeted specifically toward health care professionals to determine its impact on their knowledge, judgment, and practices. Moreover, similar to studies of DTC advertising of prescription drugs, researchers should examine the impact of DTC marketing of genetic tests on patient–physician relationship. It would be particularly worthwhile to examine the potential interaction between DTC marketing and professional-targeted marketing on patient–physician relationship and on market outcomes. Research in these areas would enable a more accurate assessment of the impact of DTC marketing of genetic tests on public health and consumer welfare.

Third, further research could also address the impact of expanded genetic testing on the practice of informed consent. The many unknowns in clinical genetics call into question the very possibility of informed consent as traditionally construed. Will the expansion of genetic testing require the retooling of informed consent requirements? Does the emphasis on individual autonomy, so prominent in U.S. bioethics and medical practice, make sense when faced with complex genetic information? Although we recommend improved education of the public and increased awareness of the need for scrutiny of claims about genetic tests, it is doubtful that the extent of transformation of the public will render guidance from genetic professionals unnecessary. The current emphasis on individual autonomy and "value-neutral" genetic counseling, which some have already begun to question, will become more problematic to sustain in the face of complex genetic information and the decisions that will be based on it.

Finally, an inquiry into the impact of DTC access to genetic tests on particular groups would be an important area for further research. Along these lines, De Melo-Martín (2006a) cautions against ignoring the social contexts in which people must decide whether to undergo genetic testing, at the risk of reinforcing and perpetuating injustices against vulnerable or underprivileged groups. This includes consideration of, for example, access to resources that will be needed by those who undergo genetic testing. Policy makers should work to narrow gaps between DTC access to genetic tests and the means to treat or prevent the problems revealed or predicted by these tests. It is already the case that women's experience with genetic tests and any accompanying burdens is, for various reasons, greater than that of most men (De Melo-Martin 2006a). Thus, it would be important to examine the distribution of benefits and burdens of genetic testing across gender and socioeconomic lines and formulate means of amending any inequitable distribution.

References

Alba, Joseph W. and J. Wesley Hutchinson (1987), "Dimensions of Consumer Expertise," *Journal of Consumer Research*, 13 (4), 411–54.

——— and ——— (2000), "Knowledge Calibration: What Consumers Know and What They Think They Know," *Journal of Consumer Research*, 27 (2), 123–56.

Alsever, Jennifer, Sidra Durst, Jeanette Borzo, and Saheli S.R. Datta (2006), "The Patient Knows Best," *Business 2.0*, 7 (9), (accessed May 31, 2008), [available at http://money.cnn.com/magazines/business2/business2_archive/2006/10/01/8387104/index.htm].

Andrews, Lori B., Jane E. Fullarton, Neil A. Holtzman, and Arno G. Muotulsky (1994), *Assessing Genetic Risks: Implications for Health and Social Policy*. Washington, DC: National Academy Press.

Auton, Frank (2004), "The Advertising of Pharmaceuticals Direct to Consumers: A Critical Review of the Literature and Debate," *International Journal of Advertising*, 23 (1), 5–52.

Bagozzi, Richard P., Mahesh Gopinath, and Prashanth U. Nyer (1999), "The Role of Emotion in Marketing," *Journal of the Academy of Marketing Science*, 27 (2), 184–206.

Bayley, Carol (2004), "The Challenge of Physician Education in Genetics," in *Genetics and Ethics: An Interdisciplinary Study*, Gerard Magill, ed. St. Louis: St. Louis University Press, 176–85.

Burke, Wylie (2004), "Genetic Testing in Primary Care," *Annual Review of Genomics and Human Genetics*, 5, 1–14.

———, David Atkins, Marta Gwinn, Alan Guttmacher, James Haddow, Joseph Lau, et al. (2002), "Genetic Test Evaluation: Information Needs of Clinicians, Policy Makers, and the Public," *American Journal of Epistemology*, 156 (4), 311–18.

Calfee, John E. (2002), "Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs," *Journal of Public Policy & Marketing*, 21 (Fall), 174–93.

Cella, D., C. Hughes, A. Peterman, C. Chang, B.N. Peshkin, M.D. Schwartz, et al. (2002), "A Brief Assessment of Concerns Associated with Genetic Testing for Cancer: The Multidimensional Impact of Cancer Risk Assessment (Micra) Questionnaire," *Health Psychology*, 21 (6), 564–72.

Charnock, D., Sasha Shepperd, G. Needham, and R. Gann (1999), "Discern: An Instrument for Judging the Quality of Written Consumer Health Information on Treatment Choices," *Journal of Epidemiology and Community Health*, 53 (2), 105–11.

Choy, Angela, Zoe Hudson, Joy Pritts, and Janlori Goldman (2001), "Exposed Online: Why the New Federal Health Privacy Regulation Doesn't Offer Much Protection to Internet Users," report of the PEW Internet & American Life, (November), (accessed May 31, 2008), [available at http://www.pewinternet.org/pdfs/PIP_HPP_HealthPriv_report.pdf].

Clayton, Ellen Wright (2004), "Policy Challenges: Ethical, Legal, and Social Implications of Genetics," in *Genetics and Ethics: An Interdisciplinary Study*, Gerard Magill, ed. St. Louis: St. Louis University Press, 23–34.

Clinical Laboratories Improvement Amendments (1988), 42 CFR 493 § 176.

Cohen, Joshua P., Cherie Paquette, and Catherine P. Cairns (2005), "Switching Prescription Drugs to Over the Counter," *British Medical Journal*, 330 (7481), 39–40.

Conrad, Peter (2002), "Genetics and Behavior in the News: Dilemmas of a Rising Paradigm," in *The Double-Edged Helix: Social Implications of Genetics in a Diverse Society*, Joseph S. Alper, Catherine Ard, Adrienne Asch, and Jon Beckwith, eds. Baltimore: Johns Hopkins University Press, 151–74.

De Melo-Martin, Immaculada (2006a), "Furthering Injustice Against Women: Genetic Information, Moral Obligations, and Gender," *Bioethics*, 20 (6), 301–307.

——— (2006b), "Genetic Testing: The Appropriate Means to the Desired Goal," *Journal of Bioethical Inquiry*, 3 (3), 167–77.

Donohue, Julie M., Marisa Cevasco, and Meredith B. Rosenthal (2007), "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine*, 357 (7), 673–81.

Edell, Julie A. and Marian Chapman Burke (1987), "The Power of Feelings in Understanding Advertising Effects," *Journal of Consumer Research*, 14 (3), 421–33.

Entwhistle, Vikki A., T.A. Sheldon, A.J. Sowden, and I.S. Watt (1996), "Supporting Consumer Involvement in Decision-Making: What Constitutes Quality in Consumer Health Information," *International Journal of Quality in Health Care*, 8 (5), 425–37.

FDA Amendments Act (2007), Public Law No. 110-85 § 1103, 121 Stat. 824.

Fox, Susannah (2006), "Online Health Search 2006," PEW Internet & American Life, (October 29), (accessed July 23, 2007), [available at http://www.pewinternet.org/pdfs/PIP_Online_Health_2006.pdf.

FTC (2000), "Dot Com Disclosures: Information About Online Advertising," (accessed July 23, 2007), [available at http://www.ftc.gov/bcp/conline/pubs/buspubs/dotcom/].

——— (1984a), "FTC Policy Statement on Deception," 103 F.T.C. 110, 174.

——— (1984b), "FTC Policy Statement Regarding Advertising Substantiation," 104 F.T.C. 648, 839.

Genetic Information Nondiscrimination Act (2008), Public Law 110-233.

Goddard, Katrina, Cynthia Moore, Denae Ottman, Kathleen Szegda, Linda Bradley, and Muin Khoury (2007), "Awareness and Use of Direct-to-Consumer Nutrigenomic Tests," *Genetics IN Medicine*, 9 (8), 510–17.

Gollust, Sarah E., Sara Chandros Hull, and Benjamin S. Wilfond (2002), "Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing," *Journal of the American Medical Association*, 288 (14), 1762–67.

———, Benjamin S. Wilfond, and Sara Chandros Hull (2003), "Direct-to-Consumer Sales of Genetic Services on the Internet," *Genetics in Medicine*, 5 (4), 332–37.

GPPC (2007a), "Amendment to Pending Bill Would Require IOM Study of Genetic Tests," *GPPC eNews*, 19, (accessed June 13, 2007), [available at http://www.dnapolicy.org/news.enews.php?action=detail2&newsletter_id=22].

——— (2007b), "Myriad Genetics Launches Brca Testing Ad Campaign in Northeast," (accessed July 19, 2008), [available at http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=85].

——— (2007c), "Survey of Direct-to-Consumer Testing Statutes and Regulations," (accessed August 6, 2007), [available at http://www.dnapolicy.org/resources/DTCStateLawChart.pdf].

Harris Interactive Inc. (2007), "The Harris Poll #76," (July 31), (accessed August 4, 2007), [available at http://www.harrisinteractive.com/harris_poll/index.asp?PID=792].

Health Insurance Portability and Accountability Act (1996), 45 CFR § 164.102-164.534.

Heather, Justin Lee (2001), "Liability for Direct-to-Consumer Advertising and Drug Information on the Internet," *Defense Counsel Journal*, 68 (4), 412–20.

Herel, Suzanne (2002), "Research Questions Breast Cancer Risk: Report Suggests Mutant Gene May Not Warrant Mastectomy," *San Francisco Chronicle*, (August 21), A1.

Hofman, Karen, Ellen S. Tambor, Gary A. Chase, Gail Geller, Ruth R. Faden, and Neil A. Holtzman (1993), "Physicians' Knowledge of Genetics and Genetic Tests," *Academic Medicine*, 68 (8), 625–32.

Hudson, Kathy, Gail H. Javitt, Wylie Burke, and Peter Byers (2007), "ASHG Statement on Direct-to-Consumer Genetic Testing in the United States," *American Journal of Human Genetics*, 81 (3), 635–37.

Jacobs, Lori R. (1998), "Prescription to Over-the-Counter Drug Reclassification," *American Family Physician*, 57 (9), 2209–2214.

Javitt, Gail H. (2007), "In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests," *Food and Drug Law Journal*, 62 (4), 617–52.

——— and Kathy Hudson (2006a), "Federal Neglect: Regulation of Genetic Testing," *Issues in Science and Technology*, 22 (3), 59–66.

——— and ——— (2006b), "Public Health at Risk: Failures in Oversight of Genetic Testing Laboratories," Genetics and Public Policy Center, (accessed May 31, 2007), [available at http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf].

Katsanis, S.H., Gail H. Javitt, and Kathy Hudson (2008), "A Case Study of Personalized Medicine," *Science*, 320 (5872), 53–54.

Kelly, Pat (2004), "DTC Advertising's Benefits Outweigh Its Imperfections," *Health Affairs*, W4 (April 28), 246–48.

kSERO Corporation (2003), "New Poll Shows Dramatic Rise in Americans' 'DNA I.Q.': Threefold Increase Delights Educators, but Is It Enough?" (accessed June 3, 2007), [available at http://www.eurekalert.org/pub_releases/2003-02/kc-nps022603.php].

LaTour, Michael S., Robin L. Snipes, and Sara J. Bliss (1996), "Don't Be Afraid to Use Fear Appeals: An Experimental Study," *Journal of Advertising Research*, 36 (2), 59–67.

Lee, Thomas H. and Troyen A. Brennan (2002), "Direct-to-Consumer Marketing of High-Technology Screening Tests," *New England Journal of Medicine*, 346 (7), 529–31.

Lerman, Caryn and Alexandra E. Shields (2004), "Genetic Testing for Cancer Susceptibility: The Promise and the Pitfalls," *Nature Reviews Cancer*, 4 (3), 235–41.

Lexchin, Joel and Barbara Mintzes (2002), "Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No," *Journal of Public Policy & Marketing*, 21 (Fall), 194–201.

Liu, Yifei, William R. Doucette, Karen B. Farris, and Dhananjay Nayakankuppam (2005), "Drug Information-Seeking Intention and Behavior After Exposure to Direct-to-Consumer Advertisement of Prescription Drugs," *Research in Social and Administrative Pharmacy*, 1 (2), 251–69.

Macias, Wendy and Liza Stavchansky Lewis (2005), "How Well Do Direct-to-Consumer, DTC, Prescription Drug Web Sites Meet FDA Guidelines and Public Policy Concerns?" *Health Marketing Quarterly*, 22 (4), 45–71.

Main, Kelley J., Jennifer J. Argo, and Bruce A. Huhmann (2004), "Pharmaceutical Advertising in the USA: Information or Influence?" *International Journal of Advertising*, 23 (1), 119–42.

McCabe, Linda L. and Edward R.B. McCabe (2004), "Direct-to-Consumer Genetic Testing: Access and Marketing," *Genetics IN Medicine*, 6 (1), 58–59.

Munson, Ronald (2007), "Genetize Me! The Case for Direct-to-Consumer Genetic Testing," in *Ethics of Genetic Commerce*, Robert Kolb, ed. Boston: Blackwell Publishing, 55–69.

Myriad Genetics (2007), "Myriad 2007 Annual Report," (accessed May 28, 2008), [available at http://www.myriad.com/downloads/Myriad-Annual-Report-2007.pdf].

National Institutes of Health Task Force on Genetic Testing (1997), "Final Report of the Task Force on Genetic Testing," (accessed August 4, 2007), [available at http://www.genome.gov/10001733].

Neuendorf, Kimberly A. (2002), *The Content Analysis Guidebook*. Thousand Oaks, CA: Sage Publications.

Pines, Wayne L. (1999), "A History and Perspective on Direct-to-Consumer Promotion," *Food and Drug Law Journal*, 54 (4), 489–518.

Racine, Eric, HZ Adriaan van Der Loos, and Judy Illes (2007), "Internet Marketing of Neuroproducts: New Practices and Healthcare Policy Challenges," *Cambridge Quarterly of Healthcare Ethics*, 16 (2), 181–94.

Ringold, Debra Jones (2005), "Vulnerability in the Marketplace: Concepts, Caveats, and Possible Solutions," *Journal of Macromarketing*, 25 (2), 202–214.

Roseman, Ira J. (1991), "Appraisal Determinants of Discrete Emotions," *Cognition and Emotion*, 5 (3), 161–200.

Securities and Exchange Commission (2000), "SEC Interpretation: Use of Electronic Media," 17 CFR Parts 231, 241, and 271.

Sewak, Saurabh S., Noel E. Wilkin, John P. Bentley, and Mickey C. Smith (2005), "Direct-to-Consumer Advertising via the Internet: The Role of Web Site Design," *Research in Social and Administrative Pharmacy*, 1 (2), 289–309.

Shepperd, Sasha, Peter Farndon, Vivian Grainge, Sandy Oliver, Michael Parker, Rafael Perera, et al. (2006), "Discern-Genetics: Quality Criteria for Information on Genetic Testing," *European Journal of Human Genetics*, 14 (7), 1179–88.

Silberg, William, George D. Lundberg, and Robert A. Musacchio (1997), "Assessing, Controlling, and Assuring the Quality of Medical Information on the Internet," *Journal of the American Medical Association*, 277 (15), 1244–45.

Tapscott, Don and Anthony D. Williams (2006), *Wikinomics: How Mass Collaboration Changes Everything*. New York: Portfolio.

Taylor, Humphrey (2002), "The Harris Poll #26," Harris Interactive, (June 5), (accessed August 1, 2007), [available at http://www.harrisinteractive.com/harris_poll/index.asp?PID=304].

Taylor, Matthew R.G., Janice G. Edwards, and Lisa Ku (2006), "Lost in Transition: Challenges in the Expanding Field of Adult Genetics," *American Journal of Medical Genetics: Part C: Seminars in Medical Genetics*, 142C (4), 294–303.

Waack, Katherine E., Michael E. Ernst, and Mark A. Graber (2004), "Informational Content of Official Pharmaceutical Industry Web Sites About Treatments for Erectile Dysfunction," *Annals of Pharmacotherapy*, 38 (12), 2029–2034.

Weissman, Joel S., David Blumenthal, Alvin J. Silk, Michael Newman, Kinga Zapert, Robert Leitman, et al. (2004), "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs*, W4 (April 24), 219–33.

Wilkes, Michael S., Robert A. Bell, and Richard L. Kravitz (2000), "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications," *Health Affairs*, 19 (2), 110–28.

Williams-Jones, Bryn (2003), "Where There's a Web, There's a Way: Commercial Genetic Testing and the Internet," *Community Genetics*, 6 (1), 46–57.

Wolfe, Sidney M. (2002), "Direct-to-Consumer Advertising: Education or Emotion Promotion?" *New England Journal of Medicine*, 346 (7), 524–26.

Woloshin, Steven, Lisa M. Schwartz, Jennifer Tremmel, and H. Gilbert Welch (2001), "Direct-to-Consumer Advertisements for Prescription Drugs: What Are Americans Being Sold?" *The Lancet*, 358 (October), 1141–46.