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Deborah J. Bowen, Kathryn M. Battuello and Monique Raats
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Marketing Genetic Tests:
Empowerment or Snake Oil?

Deborah J. Bowen, PhD
Kathryn M. Battuello, JD, MPH
Monique Raats, PhD, RPH Nutr

Genetic tests are currently being offered to the general public with little oversight and regulation as to which tests are allowed to be sold clinically and little control over the marketing and promotion of sales and use. This article provides discussion and data to indicate that the general public holds high opinions of genetic testing and that current media outlets for public education on genetic testing are not adequate to increase accurate knowledge of genetics. The authors argue that more regulation is needed to control and correct this problem in the United States.

Keywords: direct-to-consumer advertising; direct-to-provider advertising; consumer knowledge; genetic test; marketing

THE STATE OF AFFAIRS IN GENETIC TESTING

Genetic tests are likely to become a part of modern clinical medicine and public health. More than 500 tests to detect genetic differences are now clinically available, with hundreds more under investigation. Genetic testing and tailoring are considered to be a key area for future scientific and medical discoveries, and many, if not most, advances in modern disease control are hinging on the identification of genetic variations that influence individual response to treatment and preventive agents. Unfortunately, genetic information is not easy for the lay public to understand and use. Genetic tests are complex and primarily probabilistic. They predict disease risk or treatment response, with varying degrees of certainty regarding individual outcomes. Because of the therapeutic gap in this context surrounding genetic diagnoses, predictive genetic information currently has little impact on clinical management. Emotional, psychological, and social implications of predictive genetic information have yet to be fully identified and investigated. Finally, the primary care provider, often the first line in obtaining genetic testing, has limited understanding of genetics and testing, including provision of appropriate informed consent for genetic testing. These conditions leave a vulnerable public and health care provider
system to cope with the rapid changes in available technology and its potential usefulness.

The purpose of this paper is threefold: First, we want to discuss the current public opinion regarding genetics and genetic testing. This will provide an understanding of how people might approach and agree to use genetic information and provide a base for identifying public needs for education and intervention. Second, we will highlight three examples of current industry-driven advertising and promotion of genetic testing, as forms of public information exchange. Finally, we will close with a discussion of policy implications regarding marketing of genetic tests.

WHAT DO PEOPLE THINK ABOUT GENETICS?

Genetics is currently commonly represented in the popular media, although the portrayal of genetics as the all-knowing and all-influential science is vastly overrated. For example, the movie *Gattaca* (Niccol, 1997) portrayed a world in which a drop of blood could provide accurate information about future employment and worldly abilities, reliable and predictive, to the extent that choices were made during infancy about a person’s future opportunities and lifestyle. *The London Times* included a genetic education module in its Sunday paper, in 2004, to help the general public become educated. National U.S. and international magazines, such as *Time* magazine in the United States, have carried key stories about the potential for the “genetic revolution” to improve modern medicine and, more important, health outcomes of the general public. Reviews of print media portrayals of genetics have identified areas where the media portrayal falls short, such as the potential risks involved with genetic testing (Bubela & Caulfield, 2004). Condit (2001), in a recent discussion and review of multiple public perspectives on genetics, presents a mixed picture: Data from the lay public are generally more positive about genetics, whereas data from other public sources, such as public interest groups, indicate more balanced, thoughtful analysis.

Survey data collected by the authors support this view. Telephone survey data from a population-based sample of women aged 18 to 74 recruited using population-based methods with a response rate of 72% (Ariail, Watts, & Bowen, 2005) provide an indication that people consider genetics to be one of the key causes of cancer. Table 1 presents data on ratings of the importance of several possible causes of cancer. As seen in this table, women report that genetics is rated strongly as a cause of cancer, as is consuming fruits and vegetables. This endorsement of the importance of genetics in causing disease in the absence of data suggests that people might pay attention to genetics and genetic differences, to the exclusion of other causes.

Public opinion about breast cancer genetic testing also supports the idea that genetics is considered positive and important in causing disease, although with exposure to genetic counseling, this positive opinion decreases. One of the earliest genetic tests for chronic disease was for breast cancer risk in high-risk families. Multiple surveys conducted during the past 10 years have found that the majority of women consider themselves to be appropriate candidates for breast cancer genetic testing (Caulfield & Wertz, 2001; Durfy, Bowen, McTiernan, Sporleder, & Burke, 1999) despite the fact that current breast cancer genetic testing is only informative in families with a large family history of breast cancer. Ultimately, after women receive genetic counseling and have time and information to ponder, the actual uptake of breast cancer genetic testing is relatively low,
often less than 20% of eligible women. Preliminary data indicate that in situations where genetic counseling is not routinely offered, as in the case of clinical offers of microsatellite instability testing, that uptake is relatively high (75%) (Lindor et al., 2004). These data indicate that as people learn about the limitations of genetic testing, they refuse to obtain genetic information about themselves.

Providing this exposure and experience to the key facts about genetics in medicine comes in multiple forms. Genetic counseling, focused on high-risk individuals and families, as a standard part of helping people get through the genetic testing experience, has been positively evaluated (Wang, Gonzalez, Milliron, Strecher, & Merajver, 2005). Other forms of counseling, like average risk genetic counseling (Burke et al., 2000), group psychosocial counseling, and educational counseling (Bowen, Burke, McTiernan, Powers, & Andersen, 2004), have been tested as methods of improving people’s understanding of their risk and coping with that risk, with some success. Tailored computer programs can also provide useful adjuncts to the personal counseling process (Green, Biesecker, McInerney, Mauger, & Fost, 2001). Therefore, multiple methods can be used to provide a useful and positive experience overall for people who want to know about their genetic risk. Little is known or published about educational or persuasive methods to be used with the general population.

Often people turn to primary care providers if they need health information on new technology. However, the low state of providers’ preparedness for helping their patients make informed and considered choices about genetic testing means that this avenue might not be generally available. Only about one fourth of primary care physicians consistently take a family history and use the information to counsel patients (Bowen, Ludman, Press, Vu, & Burke, 2003). Therefore, genetic risk is likely to be underrecognized and discussed in the provider-patient interaction.

Taken together, the generally positive perspective of the general public on genetics, coupled with lack of real understanding in providers, could lead to inappropriate use of genetics services as they become available. This could be a problem, given any potential harm that could come from the use of genetic tests. How, then, do people now learn about genetics and genetic testing, and are these methods adequate?

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Table 1. Women’s Opinions About the Importance of Several Causes of Cancer, Survey Data, 2001 (in percentages) (N = 254)
THE MASS MEDIA AS A SOURCE OF INFORMATION ABOUT GENETICS

There are a few organizations that have attempted some sort of public or provider education campaign to improve general genetic literacy and to provide information and support in the case of specific decisions regarding genetic testing. One example is the National Coalition for Health Professional Education in Genetics, which has developed and attempted to distribute genetic literacy materials for primary care providers. Another example is the public campaign to know one’s family history during Thanksgiving, hosted and designed by the National Society of Genetic Counselors and the U.S. surgeon general (Services, 2005). However, these efforts are not likely enough to improve the public’s understanding of issues of genetics in medicine. People are exposed to the mass media, both electronic and print, daily for information and opportunities regarding health. Therefore, it would be prudent to assess the current impact of media as a key source of information for genetics and genetic testing for providers and for the general public.

ADVERTISING AS A SOURCE OF INFORMATION ABOUT GENETICS

Direct-to-provider advertising is a recognized source of information for clinicians regarding new drugs and medical products (Avorn, Chen, & Hartley, 1982; Kopp & Bang, 2000; Linn & Davis, 1972; Spiller & Wymer, 2001). Indeed, the pharmaceutical industry allocates the greatest percentage of its marketing budgets to physician-directed promotional activities, which include industry-sponsored symposia and continuing medical education (CME), direct detailing by product salespeople, and print ads in medical journals (Rosenthal et al., 2002). Content analyses of direct-to-provider advertising of pharmaceuticals suggest that many print ads in medical journals fail to meet Food and Drug Administration requirements for objectivity, are misleading, and have limited educational value (Gutknecht, 2001; Nelson & Bloom, 2001; Stryer & Ber, 1996; Wilkes, Doblin, & Shapiro, 1992). If similar practices are commonplace in advertising for genetic tests, such commercial advertising could contribute to physician misunderstanding regarding indications for (and limitations of) genetic testing, ultimately contributing to a misuse of this technology.

Direct-to-consumer advertising can also be a source of accurate information and product choice support, as it might help consumers sort through the options for genetic testing and feedback. However, the current literature on direct-to-consumer advertising for pharmaceutical products indicates that often drug advertisements are not simply lists of accurate information but are meant to create positive images connected with specific pharmaceutical products that are unrelated to function, side effects, or use in treatment. As such, these advertisements do not inform but have the potential to confuse already confused consumers about the usefulness of genetic testing.

An evidence-based critique of the content of a prominently placed advertisement for BRACAnalysis® suggests that concern about the objectivity and educational value of commercial advertising for genetic tests could be justified. Figure 1 presents an advertisement that appeared in several issues of Obstetrics and Gynecology, published during the
2001-2002 calendar year. Several messages in the ad are misleading when compared with the state of scientific and medical evidence available at the time of publication. For example, the ad states, “Traditional means of assessing risk of sporadic breast cancer fail to identify women with hereditary risk.” In fact, the traditional approach to identifying hereditary risk is through family history, which continues to be the most important and reliable predictor (Institute, 2002a, 2002b, 2002c). Indeed, BRACAnalysis® should not be considered in the absence of a family history that involves multiple affected and
closely related family members with an early age of onset, over sequential generations. Another example is the statement, “She was told not to worry about her risk of breast cancer; unfortunately she’ll be diagnosed next year.” This line of text implies that “she”—the woman pictured in the ad—is at imminent risk when, in fact, the average woman in her 40s has a 1.6% (1 in 60) risk of developing breast cancer by the time she is 50, and her risk of breast cancer mortality during this same time frame is 0.3% (1 in 333) (Feuer et al., 1993). To be sure, if she carried the relevant mutations in the BRACA 1 or BRACA 2 genes, her risk would increase significantly, but these mutations are very rare (Malone et al., 1998; Newman et al., 1998).

As for educational value, this ad fails to mention several aspects of genetic testing that are generally recognized as critical for informed decision making by providers and their patients including a description of test performance (accuracy and predictive value of results); the risks, limitations, and benefits of testing; the importance of genetic counseling in conjunction with testing; a description of who is an appropriate candidate for testing; or any mention of the medical management options and outcomes for patients whose test results are positive (Cho, Arruda, & Holtzman, 1997).

Advertising directed to consumers could also influence interest in, and use of, genetic testing, perhaps encouraging inappropriate and potentially harmful applications. Direct-to-consumer marketing complements marketing directed toward providers and is another important focus of industry spending on promotional activities (Rosenthal et al., 2002). The wisdom of direct-to-consumer marketing of pharmaceuticals and other medical products is a subject of ongoing debate, with proponents suggesting this practice enhances patient autonomy and critics voicing concerns about the objectivity of commercially driven promotional information (Robinson et al., 2004). Underlying these concerns is some evidence suggesting that patient demand may influence physician prescribing behavior (Mintzes et al., 2002). Commentary around direct-to-consumer marketing of genetic tests suggests that commercial marketing campaigns for these products may provide simultaneously manipulative and misleading messages regarding the indications, outcomes, benefits, and risks of genetic tests (Gollust, Hull, & Wilfond, 2002; Gollust, Wilfond, & Hull, 2003; Gray & Olopade, 2003; Hull & Prasad, 2001).

Increasingly, the Internet is becoming an important advertising venue for a wide range of products, including genetic tests. Figure 2 presents a Web page from a Web site promoting the use of a genetic test to guide dietary choices. A person can provide a sample via the mail and in return receive a tailored guide to what to eat, based on the latest scientific information from “the genetic age.” One problem with this proposal is that there are no clinically supported and approved genetic tests currently available for such use, and the scientific evidence at this point for using genetic testing to guide dietary choices for the general public is lacking. Given the wide and frequent traffic of the Internet for health reasons, it is likely that many people see this offer, but no public data exist on how frequently these sites are approached or used. However, this type of offer is likely to become more popular in the future if it is found profitable.

Does all this advertising and exposure have effects on the ways in which people think about genetics? The limited data on this topic suggest an affirmative answer (Caulfield & Wertz, 2001). As previously indicated, popular opinion is relatively favorable on topics of genetics and genetic testing in general. Uptake of genetic tests has been lower than expected in at least two cases (Decruyenaere, Evers-Kiebooms, Denayer, & Welkenhuysen, 1998; Quaid & Morris, 1993), perhaps due to the complexity of the test and its output once the decision and facts about the test are made apparent through counseling and education.
One example of the effects of a specific advertising campaign was an evaluation of a recent direct-to-consumer pilot effort in selected cities in the United States. Myriad Genetics conducted a pilot promotion of its breast cancer genetic tests to two cities in the United States, and the Centers for Disease Control and Prevention evaluated changes in women in these campaign cities, compared with two control cities. The campaign was conducted using multiple media outlets (television, radio, print media, Internet) for 6 months. Women aged 25-54 from the general population were the target of the campaign. The stated purposes of the campaign were to raise awareness of BRCA1/2 and to motivate women to ask providers about genetic testing. Providers received precampaign information packets and patient materials for distribution. This campaign marked the first time that an established clinically available genetic test was marketed direct to the public.

The evaluation was multilevel in each of the four cities (two campaign and two control cities) and included random digit dial surveys of women in the target age range and mailed surveys to randomly selected physicians in four specialties (family practice, internal medicine, obstetrics/gynecology, and oncology). Results of the consumer survey indicated that women in the campaign cities were significantly more likely to have heard of the test and to have seen advertisements of the test, compared with women in control cities. No differences between campaign and control city respondents were found for knowledge of testing, talking to anyone about the test, or in level of concern about risk (Centers for Disease Control and Prevention, 2004) on genetic testing. Providers in the campaign cities reported that they saw more advertisements, reported an increase in questions about testing, and reported an increase in patient requests for referrals to counseling and for testing, all compared to the comparison cities. Providers reported ordering more tests in the last 6 months in the campaign cities, compared with control providers.

These results indicate that advertising campaigns targeting people from the general public can have effects on both patient and provider. Although women from the general
public did not report requests for more testing, providers did. We do not know from this survey whether requests were received from women who might be considered appropriate candidates for testing (i.e., women with a strong family history). However, all women and providers reported increased awareness of testing. Given the low state of accurate knowledge in both the general population and among providers regarding genetic testing utility, this could promote increased usage in inappropriate ways. This type of advertising could be monitored closely. It also could be a target for regulatory activities.

CONCLUSIONS AND POLICY IMPLICATIONS

These data identify the need for closer consideration of the effects of public exposure to genetic testing information and for potential regulation of genetic testing marketing and promotion. This is not new; calls for increased regulation have come from senior scholars in the field (Holtzman, 1999). The debate about the amounts and types of regulation for genetic testing should continue and should receive more attention at the national and international level, as well as in academic journals. The National Institutes of Health’s Task Force on Genetic Testing and the Department of Health and Human Services’ Secretary’s Advisory Committee on Genetic Testing are two government bodies that provide recommendations for further regulation; these recommendations have not yet been implemented. A recent article discusses the regulatory issues in detail (Javitt, Stanley, & Hudson, 2004).

How should decisions about marketing genetic testing be made? The first step is to determine whether the release of a genetic test into the marketplace is warranted. One technique for making this determination would be to apply commonly held scientific standards used for other types of tests to genetic test procedures. These include judgments of analytic and clinical validity and clinical utility, all used to determine the fate of screening procedures and other medical tests. The recent debates about breast cancer and prostate cancer screening illuminate the difficulty of these judgments. However, these debates must occur for genetic testing in public forums to enable adequate regulatory processes to occur.

The second part of testing regulation would be to include enhanced oversight by the Food and Drug Administration for both pre- and postmarket periods. Again, these models have been used in the United States to help to ensure the safety of pharmaceutical products and could be applied in the case of genetic testing. Laws for regulating the accuracy and content of genetic testing advertisement and promotional activities are another piece of the regulatory system that could be enacted, using experience with other products’ advertising and promotional activities.

References


