

Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing

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PATIENTS HAVE INCREASING opportunities to obtain information about health care products and services from sources outside the traditional health care setting, such as the print media, television, and the Internet. This consumer orientation in health care is particularly evident in the proliferation of direct-to-consumer (DTC) advertising for health-related products.¹⁻⁵ It is now common to see print advertisements and television commercials for pharmaceuticals, with their depictions of exuberant individuals free of symptoms and subtle voice-overs or a paragraph of fine print delineating adverse effects. Less familiar to consumers, however, are advertisements promoting clinical genetic tests and services, which have begun to appear in the popular press. Despite statements discouraging this practice⁶ and recommendations that these advertisements be controlled as are those for prescription drugs,^{7,8} such advertisements are appearing without regulatory oversight.

Currently available clinical genetic tests cover a range of purposes, including carrier testing, prenatal testing, newborn screening, pharmacogenomic testing, diagnostic testing, and predictive testing. Although genetic tests and services are available and advertised for a wider range of uses, including paternity, identity, genealogy, and DNA banking, this article focuses only on medical uses.

Advertisements for genetic tests and services have appeared in a variety of

Although direct-to-consumer (DTC) advertisements for pharmaceuticals have been appearing in the mass media for 20 years, DTC advertisements for genetic testing have only recently appeared. Advertisements for genetic testing can provide both consumers and physicians with information about test availability in an expanding market. However, 3 factors limit the value and appropriateness of advertisements: complex information, a complicated social context surrounding genetics, and a lack of consensus about the clinical utility of some tests. Consideration of several advertisements suggests that they overstate the value of genetic testing for consumers' clinical care. Furthermore, advertisements may provide misinformation about genetics, exaggerate consumers' risks, endorse a deterministic relationship between genes and disease, and reinforce associations between diseases and ethnic groups. Advertising motivated by factors other than evidence of the clinical value of genetic tests can manipulate consumers' behavior by exploiting their fears and worries. At this time, DTC advertisements are inappropriate, given the public's limited sophistication regarding genetics and the lack of comprehensive premarket review of tests or oversight of advertisement content. Existing Federal Trade Commission and Food and Drug Administration regulations for other types of health-related advertising should be applied to advertisements for genetic tests.

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print media, from local newspapers to nationally distributed magazines. While some of the advertisements were produced by commercial entities, others came from advocacy groups promoting genetic testing. For example,

- An advertisement for carrier testing in a Jewish community newspaper asks its readers, "Are you a carrier?" and lists 8 "Jewish genetic conditions" for which the audience may be at risk.⁹

- An advertisement in a local newspaper for an in vitro fertilization clinic announces the availability of "innovative services such as blastocyst transfer, preimplantation genetics, and gender selection."¹⁰

- A full-page advertisement in a popular pregnancy magazine shows a

newborn's huge blue eyes with the title, "A simple new test could save your baby's life." The text describes a newborn screening kit that can detect more disorders than most state screening programs "for your baby and for your peace of mind."¹¹

- In a cancer support magazine, an advertisement for a pharmacogenomic test for the HER2 protein in-

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volved in breast cancer treatment urges the female consumer to “Ask, learn, and participate in your treatment options.”¹² The subheading declares, “You have a choice.”

- An advertisement for diagnostic testing, appearing in a Jewish magazine, uses this headline above a photograph of a weary, dark-haired woman: “If you often feel tired, it could be anemia. If you’re Jewish, it could be Gaucher disease.”¹³

- A playbill advertisement for the BRCA-predictive genetic test for breast and ovarian cancer shows a distressed woman covering her breast with one hand, with this printed statement: “There is no stronger antidote for fear than information” and the reassurance that the information “could provide hope. And dispel fear.”¹⁴

These advertisements describe complex, confusing, and anxiety-producing genetic concepts for the consumer. Drawing on themes of “choice,” “hope,” “fear,” and “peace of mind,” these advertisements validate patients’ worries about their genetic risks and appeal to their desire to assert control over potential outcomes. Direct-to-consumer advertisements will likely become more frequent as increasing numbers of genetic tests become available and testing services seek to compete in this expanding market.¹⁵ This is signaled by plans for airing the first DTC marketing campaign for genetic testing on network television in selected cities this fall.¹⁶ Therefore, it is timely to examine the potential and limitations of DTC advertisements that promote genetic tests and services.

RISKS AND POTENTIAL BENEFITS OF DTC HEALTH PROMOTIONS

In contrast to the recent phenomenon of DTC advertisements for genetic testing, DTC advertisements for pharmaceuticals have appeared for 2 decades.¹⁷ The DTC pharmaceutical advertisements have proven to be important to the industry and compelling for consumers. In 2000, the US pharmaceutical industry spent more than \$2.4 billion marketing its prod-

ucts directly to the public,¹⁸ and the 4 top-selling drugs were among the top 10 most heavily marketed drugs.^{2,19} Consumers are responding to these advertisements by asking their physicians for drug information, requesting particular prescriptions, and inquiring about new medical conditions.²⁰⁻²²

Physicians and policy makers have speculated about the risks and benefits of DTC advertisements for pharmaceuticals.^{4,5,23-28} The potential harms include giving patients an inaccurate understanding of a particular drug’s appropriateness and effectiveness, putting tension in the patient-physician relationship, and increasing the possibility of medication overuse. At the same time, however, these DTC pharmaceutical advertisements may have educational value: informing patients of disease treatments, reminding patients to take their medicines, or encouraging patients to see their physicians about untreated conditions. There are few data to clarify which perspective has greater merit.

Although the relative merits and harms of pharmaceutical advertising in general are debatable, advertising for clinical products and services is more problematic when these products are characterized by complex information, a complicated social context, and lack of consensus regarding their clinical utility. The confusing nature of complex probabilistic medical information provides advertisers with the potential to manipulate consumers’ lack of full understanding. A social context characterized by intense fears and exaggerated expectations leaves potential consumers particularly vulnerable to manipulation by advertising. Advertising of new products for which there is no clear clinical value creates additional concerns. In such cases, market forces become the impetus behind the promotion of a new product or service. Many of the recent advertisements for genetic tests and services raise these 3 concerns. Advertising for other health products, such as full-body computed tomographic scans,^{1,29} cord blood banking,³⁰ laser eye surgery,³¹ and even

some pharmaceutical agents, may meet these criteria as well. However, the following analysis is focused on clinical genetic testing.

LIMITED EDUCATIONAL VALUE OF GENETIC TESTING ADVERTISEMENTS

Like their pharmaceutical advertisement predecessors, DTC advertisements for genetic tests and services may offer benefits to consumers. The information communicated in advertisements might have an educational effect; advertisements might promote awareness of diseases in community groups, educate couples about reproductive options, give parents options to pursue supplementary newborn screening tests unavailable in their state, or provide an individual with relevant information about testing that might lead to therapeutic interventions or increased disease surveillance. However, despite these potential informational benefits, the extent of advertisements’ educational value is limited by the complexity of genetic information, the complicated social context, and the lack of consensus regarding the desirability of testing.

Complex Information

Probabilistic figures are generally difficult for physicians and consumers to understand,³²⁻³⁴ and the risks and uncertainties associated with genetic information are particularly challenging.³⁵⁻³⁹ Moreover, test results can be ambiguous, making the validity and utility of tests a challenge to describe accurately in an advertisement. A positive test result does not always indicate a definitive clinical manifestation because of incomplete penetrance, variable expressivity, and environmental phenotypic influences. Furthermore, a negative test result does not indicate an absolute absence of disease risk, because testable mutations account for only a percentage of potential disease-causing mutations. These subtleties are known to be a challenge to communicate within the patient-physician dyad and would be similarly difficult to describe in the text of an advertisement.

Social Context

The public may have an inadequate, simplistic understanding of genetics.^{40,41} Furthermore, consumers have less practical experience dealing with genetics compared with pharmaceutical agents, suggesting that they may be ill-equipped to understand the purposes and limitations of genetic testing in their clinical care. Associating genetics with popular concerns about enhancement, the promise of cures for common diseases, and narratives in science fiction literature and film, the public has ambivalent beliefs about genetics, characterized by powerful hopes and fears.^{42,43} Print and television journalism conveys genetics to the public using metaphors, likening genetics to a “code,” a “language,” an “instruction book,” or a “Book of Life.”^{42,44} Additionally, the medical and scientific community frequently uses hyperbole to emphasize the clinical promise of genetics.⁴⁵ These influences may leave consumers with heightened expectations regarding the impact of genetics on their personal health care. This complex social context makes it easier to manipulate the public’s vulnerability regarding genetics to sell a product.

Clinical Consensus

Some genetic tests have become commercially available without professional consensus that such tests ought to be offered routinely. For example, the American Academy of Pediatrics has proposed a more uniform national policy for newborn screening,⁴⁶ yet the commercial availability of supplementary newborn screening tests contradicts efforts to create greater consistency. The *BRCA* test for breast and ovarian cancer became commercially available despite a lack of consensus regarding its appropriateness at that time.⁴⁷⁻⁴⁹ The availability of commercial genetic tests should be based on professional recommendations founded on empirical evidence, not merely on the technical feasibility of a test or its commercial potential.⁵⁰ Advertisements promoting a product for which the clinical value has not been substan-

tiated by supporting evidence have a heightened potential to mislead, because claims describing these products’ appropriate use are likely to be exaggerated.

Federal oversight is another approach used to convey consensus of a product’s safety and efficacy. Although advertised pharmaceuticals have undergone US Food and Drug Administration (FDA) premarket review, genetic testing services generally do not yet undergo comparable review. Only tests that are considered diagnostic devices or those that are packaged and sold as kits require premarket approval of the FDA. Those tests developed by laboratories and provided as a service do not receive premarket review beyond FDA regulation of the reagents used.⁸ The Secretary’s Advisory Committee on Genetic Testing (SACGT), which advised the US Department of Health and Human Services, called for a comprehensive premarket oversight system, including review of data regarding tests’ analytic validity, clinical validity, and clinical utility.⁸ The SACGT recommended that the FDA assume the bulk of the premarket review process, in collaboration with professional organizations, the private sector, and public representatives. Implementation of such a policy would help ensure that only safe and effective tests are made available to the public⁶; however, the FDA faces resource constraints in expanding its role.⁵¹

EXAMPLES OF PROBLEMS WITHIN ADVERTISEMENTS

The advertisements we identified do not adequately address the complexities inherent in genetic information; rather, they provide misinformation in key areas, compromising any secondary educational value. These advertisements downplay the uncertainties of genetic testing, obscure the phenotypic variability expected with positive results, and distort disease risk information for the consumer. Advertisements draw on hyperbole to describe the utility of their genetic tests, claiming that the test for *BRCA* will “dispel fear” and that the newborn screening

tests will “save your baby’s life.” Such statements overestimate the value of genetic tests for the target audience. In reality, there remains a risk for breast cancer and ovarian cancer even with a negative *BRCA* test result, and most infants will not have the extremely rare conditions for which parents are being urged to pursue expanded newborn screening.

The presence of advertisements in the mass media might convey an exaggerated message about disease risk, thus increasing consumers’ anxiety. Direct-to-consumer advertisements seek to cultivate widespread demand for genetic testing among consumers, although testing will not be appropriate for everyone. *BRCA* testing is recommended for individuals with specific risk factors,⁵²⁻⁵⁴ fewer than the wider consumer audience likely to see an advertisement for predictive *BRCA* testing. Disproportionate demand may lead to overuse of testing, a prospect that could be costly for consumers without offering meaningful results.

Advertisements might also endorse additional misconceptions, using words and images to conjure the most severe clinical presentation of a disease and reduce a complex phenotype to the genetic mutation(s) they are targeting—a deterministic description of genetics. Advertising operates within a media context that may be deterministic in its representation of genetics.^{44,55} A deterministic interpretation of a genetic test might increase an individual’s anxiety on receiving results, inhibit the ability to prepare for a disease or make appropriate behavior changes,⁵⁶ and elevate the relative significance of a genetic diagnosis compared with other kinds of medical test results.⁵⁷

Advertisements also might reinforce associations between genetic diseases and particular ethnic and cultural groups.⁵⁸ The 2 carrier testing advertisements described herein refer to diseases as “Jewish genetic conditions.” Labeling asymptomatic individuals as potential disease carriers could make these groups more vulnerable to discrimination and stigmatization.⁵⁹

IMPLICATIONS FOR CLINICIANS

The misinformation conveyed through advertising, superimposed on the public's inadequate foundation in genetics, will likely have implications for the clinical setting. Patients may be inappropriately motivated to seek testing because of fears evoked by advertisements rather than an accurate understanding of personal risk. Furthermore, advertisements may influence individuals' abilities to evaluate genetic testing options or understand the meaning of a genetic diagnosis. Clinicians will have to correct consumers' false impressions of testing; however, it may be difficult to modify consumers' inaccurate expectations.

The primary care physician will likely take on most of the testing and counseling duties as tests become more prevalent. However, several studies⁶⁰⁻⁶³ have revealed that physicians may not have the skills necessary to analyze modes of inheritance, calculate genetic risks, or communicate genetic information in a nondirective way, suggesting they will not be prepared for a flood of new consumers interested in genetic testing.

Physicians' suboptimal knowledge of genetics is of special concern because advertisements for genetic services in medical journals, mailers, and kits may be a physician's primary source of information about genetic tests. It appears that marketing campaigns for genetic tests directed toward physicians will continue to increase.⁶⁴ However, informational brochures produced by commercial genetic testing services may not educate effectively; in 1 study, they were unlikely to contain information on risks, limitations, or benefits of testing, and some statements about test accuracy were misleading, confounding test accuracy with specificity and probability of mutation with probability of having the disease.⁶⁵ Inaccuracies in materials seem to affect physicians' knowledge of genetics: physicians who relied on pharmaceutical companies as a frequent source of information about genetics had a significantly lower score on a test of knowledge than those phy-

sicians who did not cite a pharmaceutical company as a major source.³⁶ This suggests that physician-directed promotions are, like their consumer-directed counterparts, inadequate as primary sources of information about new genetic tests.

OVERSIGHT OF ADVERTISING

The potentially misleading content of advertisements for genetic testing suggests a need for scrutiny. Both the FDA and the Federal Trade Commission (FTC) have roles in the oversight of advertising of health products and services, including pharmaceuticals, medical devices, and dietary supplements. The FDA considers monitoring advertisements for genetic tests within its purview, in conjunction with the FTC; however, the FDA currently lacks the resources to focus on all advertisements in this area.⁶⁶ Similarly, although the FTC has the authority to oversee advertisements for genetic testing, the agency has not yet done so. The SACGT recommended the application of current FDA and FTC regulation to the area of genetic test promotion.⁸

The FTC is authorized to control deceptive or unfair practices that affect commerce. It has emphasized the prevention of deceptive health-related claims,⁶⁷ intervening if advertisements are unfair, are deceptive, or do not provide substantiation for claims being made. Advertisements determined by the FTC to be deceptive contain a representation or omission that is likely to mislead a reasonable consumer; this representation must be "material" to the consumer, affecting his or her conduct or decision to purchase a product.⁶⁸ The FDA has primary responsibility for enforcement in the case of false or misleading pharmaceutical advertisements.⁶⁷ The FDA regulations require that advertisements include a "true statement" of information about adverse effects, contraindications, and effectiveness in all print advertisements. An advertisement that fails to present a fair balance of information relating to adverse effects and effectiveness violates this true statement requirement.⁶⁹

The FTC and the FDA should use their continuing authority over advertising and genetic diagnostics to oversee DTC advertisements for genetic tests. Using these FDA and FTC regulations as a framework illuminates several problematic areas in DTC advertisements for genetic tests. When communicated through the potentially manipulative medium of advertising, genetic information may be misinterpreted by reasonable consumers. Furthermore, hyperbolic statements of test effectiveness lack appropriate substantiation, and statements that describe the usefulness of tests without professional consensus might be deceptive.

Most important, the advertisements described herein fail to include risk information in fair balance with claims of effectiveness. They neglect to mention the potential risk of genetic discrimination, whereas the advertisement for *BRCA* testing specifically provides incorrect information about the comprehensiveness of current statutory protections against genetic discrimination.¹⁴ In addition, each advertisement fails to mention the psychosocial risks to individuals or family members that may result from learning genetic information.⁷⁰ Some advertisements also encourage consumers to contact testing services directly, depreciating the role of the health care practitioner or genetic counselor to share in counseling and decision making regarding genetic testing. All of these concerns, using misleading, unsubstantiated, and deceptive information without appropriate balancing of risk information, are indeed "material" to the consumer, because they relate to a consumer's decision to pursue testing.

CONCLUSIONS

This analysis of DTC advertisements is based on a descriptive assessment of a small number of selected print advertisements. This analysis does not consider genetic test marketing on the Internet, which raises similar concerns about advertising content but also introduces the potential for direct pur-

chasing of genetic tests. A more systematic analysis of the scope of DTC advertisements and their impact on consumers and their testing decisions is needed. However, tentative conclusions can be made about the value of this mode of advertising.

Advertisements can increase awareness about the availability of new clinical genetic tests. Comprehensive pre-market review would help ensure that tests that become commercially available will benefit, not harm, consumers. However, even for tests with established clinical utility, DTC promotions will have only limited educational value when materials are inaccurate or misleading. To provide more useful information, advertisements should convey both the risks and potential benefits of testing, as is standard practice with pharmaceutical advertisements. Additionally, genetic testing services ought to be mindful to avoid misleading consumers by clarifying text that may be confusing and editing information that might exaggerate the relevance of a particular genetic test. Shared FTC and FDA oversight of DTC advertisements would help ensure that advertisements meet these minimal recommendations.

However, even with more suitable content, consumer-directed promotions may be premature. Public understanding of genetics is characterized by misconception and exaggerated expectation, a context advertisers can use to their advantage. They capitalize on the hope and fear that genetics evokes to sell their products and perpetuate a deterministic conception of genetics, thereby exacerbating consumers' distorted beliefs. Furthermore, many clinicians currently lack the knowledge and resources to help individuals appreciate the role of genetic tests in their clinical care. Although a broad educational strategy targeted at clinicians and consumers is indicated, education alone will not be sufficient. Research is needed to expose and address the underlying misconceptions and associations that form the public's foundation in genetics, the context that allows advertisers

to manipulate consumers. Only once the public has a more sophisticated appreciation of genetics can advertisements appropriately promote genetic testing options directly to consumers. Ultimately, sound empirical data and consensus, rather than commercial forces, should motivate the increased use of genetic testing.

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The fundamental purpose of the artist is the same as that of a scientist: to state a fact.
—Sir Herbert Read (1893-1968)