

**Direct-to-Consumer Genetic Testing:**  
**Why the Fear Factor Is a Dangerous Variable in Unregulated**  
**Ad Campaigns**

*Courtney Eichengreen*

You're depressed, they tell you. If *"things just don't feel like they used to...Talk to your doctor about Zoloft®."*

Or: *"Annoying sensations in your legs?"* they ask. *"Fortunately, there's Mirapex®."*

Or how about this one: *"There's no stronger antidote to fear than information,"* they purr. You need BRAC*Analysis*.

(Pfizer, Inc., 2008; Boehringer Ingelheim Pharmaceuticals, Inc, 2008; Myriad  
Genetic Laboratories, 2008)

Most Americans have seen many slick and compelling consumer-directed advertisements for pharmaceutical drugs on TV, urging them to ask their doctors for a prescription to treat a condition they didn't know they had. To protect uninformed and vulnerable viewers from manipulative, unbalanced, and fiercely emotional advertising claims, the US Food and Drug Administration has developed a set of strict legal standards for direct-to-consumer (DTC) advertisements for pharmaceuticals. FDA regulations mandate that these ads include indications, counterindications, and side effects, and that they direct the viewer to consult a medical professional for guidance and prescription

(Food and Drug Administration, 2001). Recently, a new marketing trend has extended the consumer-directed tactic to include advertisements for genetic testing services. Genetic testing is a new and exciting medical technology that can ideally provide information about a patient's current health or future risks based on mutations in his or her genome.

However, advertising for genetic testing services is not subject to any regulatory guidelines. Ads for testing services are not required to comply with any standards of accuracy or predictive value, nor are they required to provide other details that are essential to the consumer's understanding of the product offered and its implications. Unregulated ads that play on consumer fear can result in tangible adverse consequences.

While patients certainly have the right to be informed about their own genetic risks and the options available for managing them, they would be mistaken to consider private advertisements a substitute for the careful research, assessment, and planning required to make responsible decisions about disease risk and testing options. According to the National Cancer Institute (2008), it is imperative that patients take only tests that are specific and relevant to their medical histories and that can provide them with accurate, useful results. By capitalizing on consumer ignorance and fear, however, many DTC advertisements inappropriately pressure patients into bypassing a deliberate and rational decision-making process. Instead, anxiety-ridden viewers rush to request or order tests that may not be indicated for their genetic history. DTC marketing techniques show no regard for the relevance or usefulness of the information they provide to the individual or the community—but they do result in increased profits for the testing companies. An uninformed consumer, blinded by the convincing emotional appeals of these ads, may

choose unnecessary, inaccurate, or clinically irrelevant tests and will be left to interpret confusing medical information without any objective or expert guidance.

### **Genetic Testing, Defined**

Understanding the genetic foundations of disease offers unprecedented opportunities for treatment and cure of disorders previously thought to be incurable, even though scientists have not yet mapped the entire genetic code. Medical researchers are currently compiling an ever-growing list of suspected genes that can help doctors diagnose, treat, and even prevent many genetic disorders and diseases. While this valuable and exciting medical technology was originally available only to highly specialized medical professionals, gradual refinement of genetic testing techniques has made testing accessible to a wider market; today, there are over 1,200 genetic tests available from commercial laboratories (Allingham-Hawkins, 2008). Genetic testing offers important and very real benefits, but its relevance and usefulness are not without limits. It is important to define the value of a test by a common set of standards: an effective genetic test will provide valid information that is useful to the patient and appropriate to the individual context.

To be useful as a diagnostic tool, all genetic tests must provide patients and doctors with new and accurate information, although different tests serve many different clinical functions. Some tests are designed to confirm clinical diagnoses, such as adult polycystic kidney disease or hemochromatosis (blood iron imbalance), and help doctors tailor treatment plans to a very specific pathology. Other tests only hint at one of many causes that could potentially lead to a certain disease, like cancer. Geneticists and doctors use the term “clinical validity” to describe the *predictive value* of a test: some tests

definitively indicate the presence of the genetic mutation that is causing kidney cysts, for example, while others indicate an only slightly elevated statistical risk for developing conditions like pancreatic cancer. However, even a test that offers only statistical risk prediction can be very useful to doctors and patients, as long as both acknowledge the limitations of the test.

The clinical validity of a genetic test is one important factor in determining its overall value to the patient, but it is not the only factor. The most accurate prediction is rendered useless if the patient is helpless to do anything about his genetic fate. As an example, breast cancers (like many other cancers) are caused by a large number of compounded factors, including genetic predisposition in about 5-10% of cases (Bennett, Gattas, & Teh, 1999). Genetic testing for the BRCA1 or BRCA2 mutations that are associated with a statistically higher rate of developing breast cancer can help doctors and patients to take more aggressive preventive measures, such as earlier and more frequent screening, prophylactic drug therapies, or even preventive surgeries. The technical term “clinical utility” describes this *preventive value* of a test. A test that has a high clinical utility is very likely to result in an improved health outcome for the patient by prompting an appropriate preventive intervention.

In addition to the clinical validity and utility of a given genetic test, the *personal value* or relevance of a particular test to a patient’s specific genetic circumstances greatly affects its usefulness in the clinical setting. Medical experts suggest genetic testing only when “a risk assessment suggests the presence of an inherited cancer syndrome for which specific genes have been identified” (National Cancer Institute, 2008), because otherwise test results are very likely to be misleading or inconclusive. The best indicator of whether a

test is appropriate in a specific case—that is to say, whether it could provide a conclusive and useful result—is a patient’s genetic history. There are many patient-specific medical patterns and familial disease patterns that could indicate a genetic disorder. For instance, multiple or early-onset cancers in close relatives, or cancer occurrence that follows a specific inheritance pattern, could point to an underlying genetic cause. However, even when it seems likely that recurring cancer in a family has a genetic basis, choosing a test that will provide useful information can be very complicated.

Because hundreds of inherited conditions are associated with an increased risk of cancer, testing for just any mutation doesn’t give patients or their doctors an accurate picture of patient health or risk. For instance, hereditary colon cancer may be caused by juvenile polyposis syndrome, the genetic factor FAP, Peutz-Jeghers syndrome, Lynch syndrome, or any number of other syndromes; each has a unique genetic basis and a different cancerous phenotype, which indicates specific treatment options (National Cancer Institute, 2008). If a patient has a high incidence of colon cancer in his family but tests negative for, say, the FAP gene, that result is inconclusive without supplementary information. The patient may not have the FAP mutation, but a different genetic disorder could be the cause of colon cancer in his family. In this case, the “negative” result is misleading: the patient may still be at high risk. One way that doctors and genetic counselors avoid inconclusive results is by testing a relative with the condition to determine which of many possible disorders is to blame. Other family members can then better understand their risk by being tested for the specific mutation that is most likely responsible for the incidence of cancer in their family.

Only a trained genetic specialist can effectively perform this type of screening, since many complex factors must be taken into account in developing the family's genetic profile. For instance, in a family where many individuals are affected by a suspected genetic disease, it is important to research and consider the context of each individual case. The genetic basis of most diseases is very complex. In most cases, the same disease can be caused by a known inherited mutation or unknown or acquired mutations, frequently the result of environmental factors. In order to compile the most complete and accurate familial profile, the geneticist must choose to test family members whose condition is least likely to be caused by environmental or other factors and most likely to reflect an actual incidence of the suspected inherited mutation. In the absence of a "close, living, affected relative," other genetic profiling, like pedigree analysis, can help indicate the proper test (National Cancer Institute, 2008). However, in this case it is important for patients and doctors to fully weigh the consequences of an uninformative test result, since testing an unaffected individual without confirming the relevant genetic factor may not give any information about the patient's actual risk.

Genetic testing has true benefit for many, and there are a huge number of factors relevant to a patient's decision to get tested. It is important that patients considering testing get adequate professional guidance in both selecting a test and interpreting the result. Only through a careful analysis of their family and personal genetic history can patients fully understand their risk for inheriting a genetic disorder. Confirming the genetic basis of the suspected disorder in the individual's own family will help the patient objectively consider the clinical validity and utility of the test's potential results. Because of the risks associated

with uninformative or misleading results, only tests that will have a high predictive and preventive value for the specific patient should be performed.

### **A Climate of Fear**

Many direct-to-consumer advertising campaigns ignore the medical necessity of the deliberate, rational, personal approach to genetic testing outlined above. In these increasingly widespread ad campaigns, companies that offer genetic testing are appealing directly to the patient without regard for his or her medical history. The impact of this practice is more complicated than it may first appear. On one hand, patients have a right to be informed of available medical tests, whether that information comes from a medical professional or any third party. On the other hand, patients are often inadequately educated and underprepared to understand the risks and benefits associated with the testing; they could be easily misled—both by inaccurate or irrelevant tests and by the fear-based advertising campaigns that promote them.

In the modern marketplace, many genetic testing laboratories not only advertise but also actively sell their services and products directly to the consumer. These genetic tests, since they do not require a doctor's prescription, often bypass the involvement of any health care professional or rely on the minimal input of a counselor employed by the tester. Patrons of these independent labs are therefore left in ignorance to decide whether a specific test is relevant for them, and to interpret the sensitive and possibly misleading results that come back.

Genetic testing from independent companies is appealing because many people fear discrimination from insurance companies, employers, and even banks based on their

genetic profiles. Although President Bush signed the Genetic Information Nondiscrimination Act (GINA) into law in May 2008, many people still fear discrimination and stigma. The act states that employers and health insurance companies cannot discriminate against applicants on the basis of genetic information (Library of Congress, 2008). But GINA does not address life and disability insurance practices. Many critics are also concerned that the act will not apply to underwriting based on genetic test results or family history, or to self-insured health care plans (Hudson, Holohan, & Collins, 2008). The issue of discrimination based on genetic information is vitally important—and an ethical powder keg in the U.S. and many other nations today. However, it is *not* an issue to be taken on by private genetics labs. Independent labs that take advantage of the consumer's fear of prejudice to sell their product are capitalizing on unjust discriminatory practices, not fighting them.

While privacy of information might be a noble-sounding advertising point, these companies are not upholding patients' privacy rights as they claim but are instead deceiving patients by selling them unnecessary, misleading, or even inaccurate information. Independent companies are not held to any industry standards of laboratory protocol, and so accuracy and applicability of their testing products as medical diagnostics are questionable at best. The procedures used to properly extract and catalogue genetic information are delicate and very precise. In the absence of FDA oversight, the process of establishing clinical standards is affected by the competition among independent laboratories for access to patients (Kane, 2008). As a result, many standard analyses on the market are random and inaccurate, patented for novelty but not assessed for predictive

value, despite advertising claims that they provide vital and life-changing medical information.

Even when the laboratory procedure does provide technically accurate information, that information may be completely irrelevant. Various tests on the market are simply clinically invalid—that is, they have no predictive value because they do not identify mutations associated with a significantly greater risk for disease. For example, deCODEme, a testing company that promises to do a broad analysis and provide the consumer with a genetic profile describing relative risk for 31 genetic conditions, bases its risk assessment on just one or two single-nucleotide polymorphisms (SNPs) (deCODE, 2008). However, even according to studies that deCODE itself cites as justification for its testing practices, many conditions in the deCODEme analysis—such as increased risk for Alzheimer’s disease, heart attack, or colon cancer—are thought to be caused by much greater numbers of nucleotide mutations (Li et al., 2008; Samani et al., 2007; Tomlinson et al., 2007). Consumers drawn to inaccurate or useless tests by emotionally compelling or otherwise misleading ads are at risk of receiving substandard medical information that has little to no predictive value.

Advertising campaigns for independent genetic laboratories very rarely discuss the technical or practical limitations of the genetic technologies to which they offer access. Without trained medical guidance, patients never have the opportunity to obtain complete or accurate information, and have no way of objectively assessing the value of a given test. As a result, the undereducated and unguided consumer may very likely be deluded about his personal health. Inconclusive, insignificant, and clinically invalid test results may cause confusion, worry, fatalism, or even a false sense of security, all of which can affect the

choices the patient makes about disease management and preventive health care. “Medical ‘tests’ are sometimes viewed as inherently benign procedures, where there is little or no risk of harm to the patient,” affirms a Working Group from Stanford University’s Program in Genomics, Ethics, and Society (1998). “In light of the risks and consequences of false positives and negatives, this ... is definitely not true with genetic testing.” Consider, for example, the colon cancer example described above. In the absence of an identified mutation in the family, a negative test result for an FAP gene predicting hereditary colon cancer is not informative. The tested person’s risk status remains the same as it was prior to testing. However, the unguided consumer may get a false sense of security—and neglect regular screenings or other precautionary measures, as a result—because he is ignorant of the multitude of other genetic conditions that may cause the cancer patterns he sees in his family history, and he doesn’t understand that he is still at risk.

Perhaps the most confusing and dangerous aspect of DTC ad campaigns is their utter disregard for the personal value or relevance of the marketed test to the target audience. To better understand this effect, consider the example of a pharmaceutical ad currently on American airwaves. Current legal standards from the FDA assume, based on the ad announcer’s descriptions of symptoms like “twitches,” “fidgets,” and “creepy-crawlies”—and of stated side effects like severe drowsiness and hallucinations (Boehringer Ingelheim Pharmaceuticals, 2008)—that viewers have enough information to decide for themselves whether they have the symptoms of restless leg syndrome and might benefit from a prescription for Mirapex®. While DTC ads for pharmaceuticals like Mirapex® are certainly not neutral, their manipulative effect is limited because they are required to

provide concrete information, like symptoms and side effects, about their product and the condition it treats.

Now consider an advertisement for a genetic test marketed by the Myriad Genetics Corporation in 2002: “Breast cancer runs in my family,” it opens. With skyrocketing rates of cancer in the United States, most Americans have had a close personal experience with the disease; this ad makes an indiscriminate emotional appeal rather than helping viewers better understand how and whether the test relates to them specifically. A quick succession of young and middle-aged women listing relatives with breast cancer follows: “My mother.” “My grandmother.” “My dad’s sisters.” “I wondered if it would be...inevitable,” the women admit fearfully, playing to a very human anxiety, and capitalizing on the viewer’s ignorance of the technical genetics of disease. Then, as a solution for the highly emotional problem posed, this ad implies that the testing provider offers instant and much-needed answers. “I found out my risk,” affirms one relieved actress. Subtle, compelling, precisely targeted, and skillfully crafted, the Myriad campaign ran under the slogan “Be ready against cancer” (ad content from Gray & Olopade, 2003). You can’t “be ready,” this ad campaign implies, if you don’t have the sacred information only Myriad Genetics can provide.

This brief, compelling ad is typical of the modern genetic testing industry, but it does not provide the viewer with enough information to understand a given test’s relevance or meaning. Instead, the testing company exploits the viewer’s anxiety and ignorance to sell its products and services. As the director of cancer genetic counseling at the Yale Cancer Center, Ellen T. Matloff, commented in a 2007 *New York Times* interview, “It really preys on the fears of our society, and one of those fears is getting breast cancer.” The

advertising tactics of the Myriad campaign, like most contemporary DTC advertisements for genetic testing, rely on fear-based emotional appeals and rarely provide accurate information on the limitations and consequences of the testing results. Even if the patient later seeks a doctor's advice and is referred to a specialist, genetic counseling cannot be expected to retroactively remedy the fears and worries stirred by abusive and unfair advertising images.

Advertisements that, like this Myriad campaign, capitalize on the consumer's emotional vulnerability are destructive and harmful because they provoke fear, doubt, and stress that may be completely irrelevant and unnecessary. That highly compelling campaign was targeted indiscriminately at the general population despite its very low statistical likelihood of personal value: it is not useful or relevant for a majority of individuals. Only 2% of women have genetic histories that indicate that the Myriad *BRCAAnalysis* test for breast and ovarian cancer could provide them with clinically useful results (Pollack, 2007).

Not all tests advertised directly to the consumer ignore the valuable input of medical professionals; some tests, like Myriad's *BRCAAnalysis*, are available only on a doctor's prescription. Although prescription-based genetic tests certainly save the patient from many of the problems of misinformation and consumer ignorance associated with unregulated independent tests, ad campaigns for prescription tests can still be manipulative and dangerous. Many would argue that requiring a prescription for genetic tests solves all of the aforementioned problems because it is exclusively the physician's responsibility to help patients understand the complexities of their own genetic histories, as well as how or whether a genetic test may be appropriate for them personally. However, DTC advertising

campaigns undercut the effectiveness of the patient-physician conversation by presenting emotionally convincing but incomplete information before the patient has the benefit of informed, objective medical advice. When patients request a pharmaceutical drug by name that they have seen advertised elsewhere they are more likely—one study suggests up to 17 times more likely—to receive a prescription for that drug than patients who don't make a request (Mintzes et al., 2003; Kravitz et al., 2005). A similar effect can be expected to take place in the doctor's office when patients, scared and compelled by DTC ads, demand genetic tests. Unnecessary genetic testing in the doctor's office puts patients at risk for the same emotional and physical harm as unnecessary testing through an independent company.

### **Minimizing Harm and Reaping the Benefits**

While genetic testing companies claim that their advertising campaigns perform some public service by educating the public about available and useful medical technologies, the truth is that many individuals and corporations outside the medical profession, with a bigger stake in their own business plans than in public or individual health, are currently involved in the genetic testing industry. As a result, tests that may be unnecessary and confusing are aggressively marketed to the consumer for profit. Advertising campaigns, such as that for Myriad's *BRCAAnalysis* test, aim to take advantage of the consumer's emotional vulnerability to get her to pay thousands of dollars for a test that may not be accurate, relevant, or indicated by her genetic history: the Myriad BRCA test costs upwards of \$3000 for most women—and the company estimated that it received 38 times more inquiries by phone in Denver and Atlanta, where the ads were first

run in 2002, than in control cities. Myriad's advertising campaigns have been so successful in boosting sales that the campaign will be extended again this fall to include Texas and Florida, at an additional estimated cost of \$8 million to the Myriad Corporation—on top of the tens of millions invested in the previous campaigns (Myriad Genetic Laboratories, 2008).

Some genetic tests can benefit patients and society, and some advertisements may help raise awareness and lead to increased identification of people with potentially treatable or manageable genetic predispositions. The problem lies with specific tests that are pushed without any regard for relevance or clinical utility because they make the manufacturer money. Sensitive information, including the risks, benefits, and consequences of the testing results, needs to be handled and dispensed responsibly. Right now, testing companies are within their legal rights to advertise and market genetic tests directly to consumers. However, as has been illustrated, this can cause direct and preventable harm to the consumer, harm from which the consumer can and should be protected by a governmental or other impartial organization.

To prevent corporation-driven advertising campaigns that misinform and potentially exploit the consumer, ad campaigns for genetic testing technologies must be held to standards of accuracy, fairness, applicability, and utility. In parallel to the FDA guidelines for DTC pharmaceutical advertising, consumer-directed ad campaigns for genetic testing must be legally required to describe risks, benefits, and consequences of the information that they provide. Because prescription systems offer a more accessible way to regulate laboratory practices and assure accuracy and clinical validity—the bare minimum required to assure patients and doctor access to useful information—ad campaigns must

openly advocate for physician involvement in educating patients about tests that may be right for them.

Advancements in decoding the genetic basis of disease have presented contemporary doctors and patients with unprecedented resources for understanding, preventing, and treating many aggressive disorders. Genetic testing can be an invaluable diagnostic and predictive tool, when used properly. However, many testing companies readily abuse patients' fears and vulnerabilities to sell their services. An objective legal organization could prevent this abuse by regulating DTC advertisements for genetic testing to protect consumers from unfair, misleading, or otherwise inappropriate—but dangerously appealing—marketing tactics. Patients and doctors would retain all of the medical benefits of appropriate genetic testing. Patients would be less vulnerable to misleading scare tactics and better prepared to carefully and rationally discuss their testing options with their doctors. Doctors would be better able to serve their patients because they wouldn't have to wade through the fear of so many patients demanding increasingly expensive but medically irrelevant testing. As a result, patients would have a better opportunity to fully understand the testing process and properly interpret their results, and so could make more educated, autonomous decisions about their personal health. Even the testing companies would benefit, since they would gain credibility and could better fulfill their stated purpose of serving patients and the public. It is time to put an end to abusive testing advertisements that capitalize on consumer fear and ignorance to the exclusion of providing relevant medical information, so that we can all fully reap the benefits of genetic testing as a new and powerful medical resource.

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