

Consumer-Directed Promotion of Regulated Medical Products; Public Hearing
Docket No. 2005N-0354
Comments of Gail Javitt, JD, MPH, on behalf of the
Genetics and Public Policy Center
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The Genetics and Public Policy Center was founded in 2002 with the mission to create the environment and tools needed by key decision makers in both the private and public sectors to carefully consider and respond to the challenges and opportunities that arise from scientific advances in genetics. These comments address a serious problem raised by direct to consumer advertising of genetic tests.

Genetic testing is becoming an increasingly important part of health care. Genetic tests can help diagnose genetic conditions and guide treatment decisions, help predict risk of future disease, inform reproductive decision-making, and assist medication choices for a variety of diseases including some types of cancer. But while the number of tests available is exploding, genetic tests are subject to far less scrutiny than other medical products, and FDA oversight in particular has been very limited.

In recent months, several news reports have discussed a genetic test called the “Baby Gender Mentor.” The test, which is advertised and sold over the Internet, claims to diagnose the sex of a fetus as early as five weeks of pregnancy with *more than* 99.9 percent accuracy. According to news reports, the test has been sold to thousands of women, many of whom have received false reports. In other words, the test predicted a baby of one sex and a baby of the other sex was born.

The Baby Gender Mentor is sold to consumers as a kit over the Internet. It claims to diagnose the sex of a fetus, which, while merely a matter of curiosity for some expectant parents, also can correlate with sex-linked genetic disease. The Baby Gender mentor is therefore a diagnostic device. But to date FDA has taken no action regarding the claims being made by the product or regarding the test itself.

This one genetic test is the tip of the iceberg. The past few years have seen a proliferation of genetic tests advertised and sold directly to consumers. These tests run the gamut from the mainstream to the truly alarming. One website advertises and sells a test that it claims can diagnose genetic predisposition to addiction and other behavior disorders such as ADHD. The website also advertises and sells a variety of so-called “nutraceuticals” to treat conditions such as alcoholism, cocaine addiction, tobacco addiction, ADHD and PMS. Again, FDA has taken no action to date against these claims or the products advertised.

Another website advertises genetic testing for the purpose of predicting and avoiding adverse reactions to prescription drugs. The company claims such testing can “improve the safety and effectiveness of more than one-third of the most commonly prescribed drugs such as anti depressants, heart medicines [and] pain killers. . . .”. The test claims to predict, based on an individual’s genetic makeup, how he or she will metabolize a particular drug, and thus whether and in what dose a drug will be helpful or harmful to

them. In other words, the website claims that results of these tests can improve the response to an FDA-approved drug or, conversely, indicate that the drug is contraindicated. Yet, to date, FDA has not reviewed the claims being made for these tests or the tests themselves. While FDA has approved one test kit that can be used for drug reaction testing, laboratories are not required to use it, leading to a lack of regulatory parity for this type of genetic testing.

These are only a few examples of tests currently available directly to consumers over the Internet. The unregulated advertising of genetic tests for myriad conditions, some of which are highly dubious, leaves consumers vulnerable. According to a 2004 survey conducted by the Genetics and Public Policy Center, the public widely believes that the government already regulates genetic tests, and, moreover, a majority believes that it should. However, contrary to this widespread belief, FDA has done little to ensure that the claims made about genetic tests are truthful or that the tests are safe and accurate. Of the more than 800 genetic tests currently clinically available, FDA has approved only about a dozen. While there may be independent jurisdictional limits to the agency's activities with respect to some genetic tests, FDA can and should do far more. Moreover, FDA can and should collaborate with its sister agencies with independent jurisdiction in this area, including the Center for Medicare and Medicaid Services and the Federal Trade Commission, to create a seamless web of safety to protect consumers from the harmful consequences of bad information and bad tests. Public health and the public's expectations demand such protection from the federal government.

In July 2005, the Genetics and Public Policy Center launched the Genetic Testing Quality Initiative. The goals of this initiative are to foster a framework of oversight in which (1) the validity of tests is supported by the science before they are offered to patients and uses of outcomes of tests are evaluated over time, (2) all laboratories must demonstrate their ability to get the right answer reliably, (3) health care providers are educated about these tests and able to provide them to patients with adequate context and counseling; (4) patients have confidence in the claims made about tests and in the tests themselves.

As with DTC advertising of prescription drugs, FDA has a critical role to play in ensuring that accurate and sufficient information is available regarding genetic tests, particularly when these tests inform drug selection. Over the coming months, we hope to work with the agency to discuss ways that FDA can help ensure that the information directed to consumers regarding genetic tests is truthful and adequate, and that the tests being advertised are accurate and reliable.