



## Direct-to-Consumer Genetic Testing: Empowering or Endangering the Public?

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Recent years have seen a proliferation of commercially available genetic tests, both for identifying health-related genes and for non-health-related applications, such as paternity, forensics and genealogy. Traditionally health-related genetic tests have been available only through health care providers, who decide whether a test is needed and interpret test results. However, these tests are increasingly marketed not only to health care providers but also to consumers themselves. Beyond the significant gaps that exist in the general regulation of genetic tests, direct-to-consumer (DTC) genetic testing raises additional concerns.

DTC testing encompasses two separate but related issues: claims made about the tests to induce purchase (e.g., through advertising); and the sale of genetic testing services and provision of test results directly to consumers. In regards to the former, critics argue that consumers are vulnerable to being misled by advertisements and lack the knowledge to make appropriate decisions about whether to get tested or how to interpret the results. Consumers with little knowledge of genetics might have difficulty distinguishing between tests widely used and accepted by medical professionals (such as those for mutations causing cystic fibrosis), and those whose validity is unproven in the scientific literature (such as those purporting to predict risk of depression or an appropriate skin care regimen). Advertisements may also underemphasize the uncertainty of genetic testing results, or exaggerate the risk and severity of a condition for which testing is available, thus increasing consumer anxiety and promoting unnecessary testing.

Some companies that advertise tests directly to consumers require that they see their doctors in order to have the tests performed, while others allow individuals to send samples directly to the laboratory and receive the results at home. In the first case health care providers have the opportunity to guide patients away from unneeded tests and to clarify the results when they arrive, although surveys have shown that many health care providers lack adequate knowledge and training to provide quality genetic counseling. Taking tests without a provider's supervision increases the likelihood of harmful outcomes to consumers, ranging from wasted money to loss of genetic privacy to basing major decisions — such as whether to have a child or take a certain medication — on faulty information.

Whether health care provider authorization is required to obtain a genetic test, or any laboratory test, is the province of state law. Some states explicitly authorize laboratories to accept samples from and deliver test results for specific tests (such as cholesterol or pregnancy tests) directly to patients without authorization from a health care provider. Other states categorically prohibit all DTC testing. And still other states are silent on the issue, which leaves it up to individual laboratories to decide whether to offer DTC

testing. Currently, 25 states and the District of Columbia permit DTC laboratory testing without restriction, whereas 13 categorically prohibit it. DTC testing for certain specified categories of tests is permitted in 12 states; these laws would likely not extend to genetic tests. It should be noted that even when a health care provider's order is required, the provider may have a conflict of interest if he or she is employed by the laboratory offering the testing.

The Federal Trade Commission (FTC) is charged with protecting consumers against unfair or deceptive trade practices, including false or misleading advertising claims. While the FTC has asserted that it has jurisdiction over genetic testing advertising, it appears to have taken no action against any genetic test advertisements, even those that would appear clearly false and misleading on their face. In 2006 FTC issued a consumer alert warning consumers to be skeptical of claims made by DTC test providers and to discuss test results with a health care provider.

The Food and Drug Administration (FDA) has authority to regulate claims made by products under its jurisdiction. However, currently, FDA regulates only those genetic tests that are sold as “test kits” and used by laboratories to perform testing. FDA considers test kits to be medical devices and requires that they undergo premarket review before they can be made commercially available. Since the vast majority of genetic tests are instead developed by the laboratory, neither tests nor claims made about them is subject to FDA oversight.

It would be a mistake, and ultimately an unsuccessful endeavor, to focus efforts on remedying the potential harms from DTC tests without considering the entire regulatory context. Without a system in which an upfront expert evaluation can be made with respect to the validity of genetic tests, it will be difficult if not impossible to make rational decisions about who can and should order the test and receive the results, and what claims are appropriate in advertising. The GPPC issue brief “Who Regulates Genetic Tests?” details the current state of oversight of genetic testing.

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