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FDA Approves First Direct-to-Consumer Genetic Test After Year-Long Ban

By Philip Merksamer, J.D. Candidate 2017 | February 27, 2015

Last week the U.S. Food and Drug Administration (FDA) granted approval to the personal genetic testing company, 23andMe, to sell a genetic carrier test for Bloom Syndrome directly to consumers. Bloom Syndrome is a rare inherited disorder associated with short stature and an elevated risk of cancer. This marks the first FDA authorization of a direct-to-consumer genetic test and creates a path towards regulatory approval for future related genetic tests.

Genetic tests broadly aim to measure specific DNA sequence variations that are associated with disease. Clinically, genetic tests may predict the likelihood of developing a particular disease or the likelihood of success for certain therapies. Genetic carrier tests represent a subtype of genetic testing that are used to determine whether parents carry gene variations that may place their future children at risk for rare inherited disorders. Generally, both parents must be carriers for their offspring to be at risk.

In 2013, the FDA ordered 23andMe to stop marketing and selling its direct-to-consumer genetic testing service for all health-related information. The FDA was concerned over potential negative health consequences resulting from inaccurate or misinterpreted health reports. For example, the agency noted the potential harm from consumers interpreting information related to the BRCA1/2 genes and breast cancer. A false positive test may spur an unneeded prophylactic surgery while a false negative could induce consumers to ignore actual risks and abandon therapies.

Now, the FDA's approval of 23andMe's genetic carrier test for Bloom Syndrome marks an important first step in bringing genetic tests back to the consumer. To win approval, 23andMe conducted two studies to prove that the test is accurate and that consumers understand the test's results. In addition to approving this specific test, the FDA set forth a proposal to bring related genetic carrier tests to market without a premarket review. In granting approval, Alberto Gutierrez, director of the FDA's regulatory office for diagnostic tests commented, "The FDA believes that in many circumstances it is not necessary for consumers to go through a licensed practitioner to have direct access to their personal genetic information. Today's authorization and accompanying classification, along with the FDA's intent to exempt these devices from FDA premarket review, supports innovation and will ultimately benefit consumers."

Despite this announcement, 23andMe's genetic carrier test will not be immediately available to the public. The company must first take additional compliance measures including the development of product labels that explain the test's outcomes and risks, as well as instructions for consumers to contact professional genetic counselors. In response to the FDA's decision, 23andMe CEO Anne Wojcicki stated, "This is a major milestone for our company and for consumers who want direct access to genetic testing. We have more work to do, but we remain committed to pursuing a regulatory path for additional tests and bringing the health reports back to the U.S."