

DNA tests of rare disorders approved by FDA

By ACSH Staff — February 20, 2015



Carrier screening is a type of genetic testing performed on

couples that are expecting or planning to have children to see if they may be at risk for passing a genetic disorder on to their children. In many cases, for a child to actually develop a genetic disease, both parents must be carriers of the abnormal gene. Although cystic fibrosis is the best-known disorder for which individuals are tested, there are others as well.

Now, individuals may have access to those tests without consulting a doctor. Genetic testing company 23andMe [won approval from the Food and Drug Administration](#) [1] for a test for carriers of a mutation that causes Bloom syndrome, characterized by short stature, skin rashes, and increased susceptibility to cancer. The approval went a step further, declaring that these carrier tests would no longer need advance approval before being marketed and voicing support for patients to have access to these tests without a doctor's involvement. This is a complete reversal from the previous ruling by the FDA.

Carrier tests will most likely be offered by 23andMe later this year. Anne Wojcicki, the company's chief executive, says they hope to be back on the market with meaningful information as soon as possible.

ACSH's Ariel Savransky had this to say: Although information from carrier tests can be very useful, the question of what to do with the results of these tests is a very sensitive one. Eliminating a health professional's involvement may leave couples struggling to make decisions. As [we ve discussed previously](#) [2], it's important that patients are counseled prior to testing on what the results of these tests may mean so that they are prepared to make decisions based on sound information, and not do something they may regret later due to the emotional response to receiving sudden bad news.

COPYRIGHT © 1978-2016 BY THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Source URL: <https://www.acsh.org/news/2015/02/20/dna-tests-rare-disorders-approved-fda>

Links

[1] <http://www.nytimes.com/2015/02/20/business/fda-eases-access-to-dna-tests-of-rare-disorders.html>

[2] <http://acsh.org/2015/01/screening-companies-pitch-genetic-testing-couples-planning-children/>