

# FDA approves DNA report on Drug absorption

The U.S. Food and Drug Administration (FDA) announced Wednesday that it has approved the marketing of 23andMe's reports on pharmacogenetics, which the genetic-testing company claims are designed to assess whether genetics may affect an individual's ability to metabolize certain drugs including antidepressants.

The company is [characterizing](#) the move as the "first authorization of a direct-to-consumer report on pharmacogenetics." But with the approval of 23andMe's Personal Genome Service test also come a number of caveats, the most glaring of which being that the test is meant to facilitate conversations with healthcare professionals rather than inform any kind of final word on medications or treatments.

"This test should be used appropriately because it does not determine whether a medication is appropriate for a patient, does not provide medical advice and does not diagnose any health conditions," Tim Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health, said in a [statement](#). "Consumers should not use this test to make treatment decisions on their own. Any medical decisions should be made only after discussing the results with a licensed health care provider and results have been confirmed using clinical pharmacogenetic testing."

The FDA says the tests aren't meant to be used to inform the recommendations for treatment by a provider, assess a patient's ability to respond to medications, or even be interpreted without additional "independent pharmacogenetic testing." The genetic-testing startup [said](#) Wednesday that the special controls associated with the authorization for 23andMe to market the tests are meant to "ensure safety, effectiveness and accuracy."

"We've continued to innovate through the FDA and pioneer safe, effective pathways for consumers to directly access genetic health information," 23andMe co-founder and CEO Anne Wojcicki said in a statement.

"Pharmacogenetic reports are an important category of information for consumers to get access to and I believe this authorization opens the door for consumers to work with their health providers to better manage their medications."

23andMe is only the latest in gene-testing companies to get in on pharmacogenetics reports. [Business Insider](#) reported earlier this month that more than two dozen Albertsons pharmacies in Chicago, Philadelphia, and Boise were offering such tests as part of a pilot program with the company Genomind. It also said 23andMe competitor Color Genomics recently began offering its own pharmacogenomics product with its \$250 test. But the tests do have their critics, some of whom told Business Insider that the tests may not be better than the trial-and-error method.

“I don’t necessarily need to know up front if a person is a poor drug metabolizer. I need to know which specific drug to use where I will get the positive effect with less side effect burden,” Alan Schatzberg, a Stanford University psychiatrist and the director of the Stanford Mood Disorders Center, told the site. “These tests don’t do that.”

The other reason genetic-testing kits—and particularly straight-to-consumer kits—can be problematic are because they can lead to confusion when it comes to assessing potential risks.

“Even if you test negative for all known [disease] genes, your risk for that disease may still be increased based on your family history,” Mary Freivogel, president of the National Society of Genetic Counselors, told [Stat](#) last year. “A negative 23andMe test might provide false assurance.”

As appears to be the indication from the FDA, it may be best to take any genetic-testing kit with a [grain of salt](#).