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Putting the brakes on home genetic testing: Four questions with geneticist Scott Diehl

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The Food and Drug Administration recently ordered an end to sales of the home genetic testing kit 23andMe. FDA medical experts said the kit's manufacturers had failed to prove their claim that the $99 test can help customers make informed decisions about their health, despite being asked for that proof for more than five years. 23andMe says that in 2013, more than 200,000 people have purchased its product.

According to the company's website, by analyzing DNA from a sample of a customer's saliva, "23andMe helps you know more about your health so you can take an active role in managing it." But the FDA says that customers may be risking their lives if they rely on test results to make important health-related decisions.

Scott Diehl is director of the Center for Pharmacogenomics and Complex Disease Research at the Rutgers School of Dental Medicine, and a longtime critic of tests such as 23andMe, which derives its name from the fact that human cells contain 23 pairs of chromosomes. Diehl says ordering the test off the market was the right decision.

What is wrong with letting consumers buy a product that tells them more about their DNA than they knew before?

The picture the test gives people is so incomplete as to make it useless. For years, 23AndMe has been telling unsophisticated consumers that

their risk of highly complex disorders such as diabetes, rheumatoid arthritis, Celiac disease, heart disease, stroke and schizophrenia is higher or lower based on just one or two inherited genetic variations. Most geneticists are convinced that risk of these diseases is determined by thousands of variants. Relying on these home testing kits is like predicting whether your car will break down during a long journey after you've only checked whether a couple of lug nuts on one of the wheels are sufficiently tight.

But even if the information is limited, is there any harm in it?

These incomplete tests for complex diseases may mislead people into thinking their risk is higher or lower than it really is, and they might fail to take important steps such as weight loss, improvements in diet or increased exercise because of a false report of low risk for a condition such as diabetes or heart disease.

What about tests for certain life-threatening illnesses?

Tests that predict a person's risk for deadly conditions like breast cancer or serious side effects of medications really have no place in the direct-to-consumer market. These tests require guidance and interpretation by doctors and trained genetic counselors because decisions can have major health consequences as well as psychological effects on the patient and family members. Few people without medical training have sufficient knowledge to understand what such tests really mean. The tests' limitations could scare some people unnecessarily while lulling others into a false complacency so that they fail to follow up with their doctors and get the far more rigorous and comprehensive testing that can be performed by a medical genetics laboratory.

Could further advances in testing technology, knowledge of genetics or added safeguards make home genetic testing acceptable to you in the future?

Although the cost of DNA assays has been coming down very rapidly, the challenge of interpreting the deluge of data has gotten far greater. Testing for diseases that have serious health consequences needs to be very carefully controlled. Today there are dozens of companies aggressively marketing tests for health conditions for which there is little or no clinical validation. It is in the public interest for the FDA to provide oversight of this growing industry so that consumers aren't paying for worthless information and so the test results have well-documented clinical validity just as the FDA requires for drugs and medical devices.

Provided by Rutgers University

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