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Wonkblog

Wondering if you have the gene linked to Alzheimer's? You may have to leave the U.S. to find out

By Peter Whoriskey December 7, 2015 Email the author

Suppose you want to know if you have the gene linked to Alzheimer's disease, or the one for breast cancer, or the one pertaining to how you handle caffeine.

If you live in Canada or in the United Kingdom or elsewhere in Europe, turns out, you can find out easily: Spit in a tube, send it off with about $200, and the testing company, 23andme, returns your personal genetics report with that information.

But if you live in the United States, those and other details of your genome are no longer offered, the result of a skirmish between the FDA and the industry.

The gap between the United States and other countries reflects the uncertainty over how to regulate consumer access to genetic information. Officials in other countries have allowed the company to offer a broader array of tests. In the UK, health officials require 23andme only to affirm that the "device" - the spit tube - is safe, but the agency said it does not regulate the test itself, according to a spokesperson for the Medicines and Healthcare Products Regulatory Agency. Officials at Health Canada, that country's agency, said that likewise, they do not regulate the tests.

In the United States, by contrast, the FDA officials require that any company offering a test that detects the immediate genetic risks of disease must submit evidence showing that the results are accurate and that they are presented to consumers in a way that ensures understanding. So far, no companies have done so, and it is unclear when U.S. consumers might get FDA-approved test results on these questions.

"We're not trying to block anyone's access to these tests," said Elizabeth Mansfield, of FDA's Center for Devices and Radiological Health. "This is important information. But we want to make sure that it's accurate and reliable and that people can understand it."

The company continues to offer U.S. consumers an array of genetic information, just not the information regarding gene variances that indicate a higher risk for diseases, which include breast cancer, celiac disease, Alzheimer's and Parkinson's diseases.

For example, the current 23andme tests in the U.S. offer information on the genes for hair color, lactose intolerance and ancestry. In addition, earlier this year, the FDA allowed companies to provide information regarding whether a person carries a gene that could cause disease in their children - the genes for cystic fibrosis, Tay-Sachs disease, and sickle cell anemia, for example.

A spokesman for 23andme said the company, the largest in the field, is working

with the FDA to offer the other tests but declined to offer a time-frame for when it might do so.

"We can't comment on any future submissions to the FDA," said 23andme spokesman Andy Kill. "More broadly, we want to provide as much information as we can to our customers and we are working through the FDA to do that."

Until two years ago, 23andme results in the United States, Canada, the U.K. and other countries were roughly the same. Then, in November of 2013, the FDA, citing compliance issues, ordered the company to shut down its testing. When the company relaunched its U.S. tests in October, the tests for genetic risks of disease were no longer part of the package.

One of the most significant hurdles for any company seeking to meet the FDA requirements is proving that the test results and their implications are fully understood by customers. Exactly how genes affect our health is complicated - some genes seem to determine whether a person gets a disease, while others only seem to be associated with disease.

For example, certain gene variants are associated with higher risks for Alzheimer's disease. But having that gene variant does not necessarily mean that a person will get Alzheimer's.

Experts in bioethics, even those who have generally favored broad consumer access to medical information, offered general support for the FDA requirements.

"To say there's information about yourself that you can't have - that's certainly a tough sell in the U.S.," said George Annas, chair of the Department of Health Law, Bioethics & Human Rights at the Boston University and the author of a new book on the subject, Genomic Messages. "But I think the FDA has made the right call here. If a company is going to make a health claim, they ought to be able to offer proof."

Robert Green, a medical geneticist and director of a genome program at Brigham and Women's Hospital and Harvard Medical School has argued that the FDA was "overcautious" in forcing 23andme to shut down two years ago. Based in part on his research with customers, he said, there was scant evidence that the test results had resulted in misunderstanding or harm.

But, he said, it was prudent for the FDA to issue more stringent requirements for tests that could indicate higher risks of disease.

"I don't think the FDA was wrong to insist on evidence," Green said. "In fact, I suspect that the entire industry will be better off for the regulation."

3 Comments

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