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Wonkblog

23andMe gets FDA approval to report breast cancer risk without a doctor

By Carolyn Y. Johnson
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The direct-to-consumer genetic testing company, 23andMe, has received federal approval to inform people of breast cancer risk linked to three gene mutations — making it the first company allowed to test for cancer risk without a doctor's prescription in the United States.

The Food and Drug Administration decision is a step forward for the evolving world of consumer genomics. The company can report back the three mutations in the BRCA1 and BRCA2 genes that are the most common in the Ashkenazi Jewish population. Those mutations are not the most common BRCA mutations in the broader population.

Donald St. Pierre, acting director of the office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health, called the approval a step forward with "a lot of caveats" in a statement.

“Most BRCA mutations that increase an individual’s risk are not detected by this test,” St. Pierre said. “The test should not be used as a substitute for seeing your doctor for cancer screenings or counseling on genetic and lifestyle factors that can increase or decrease cancer risk.”

23andMe previously included breast cancer risk in its genetic tests in the United States but stopped in 2013 after the FDA sent the company a warning letter stating the company was marketing their test without approval. Anne Wojcicki, the co-founder and chief executive of 23andMe said the company's experience selling the test before 2013 in the United States and in the United Kingdom and Canada had provided insight into how useful the information can be, particularly to customers who did not realize they had Ashkenazi Jewish heritage.

“Since the FDA warning letter, it's been a high priority for me and the company to get this report back,” Wojcicki said. “I'm thrilled today.”

Wojcicki said although the company has not yet announced specific cancer risk mutations that it will add in the future, the approval surmounts a major hurdle.

Direct-to-consumer genetic tests have typically raised concern

because of fears people may not understand the information and panic or might be falsely reassured. Any person who comes back with a negative for these three gene mutations, for example, could still carry other mutations in the BRCA genes that elevate their cancer risk. They could also face elevated breast cancer risk because of other gene variations or other factors.

Robert C. Green, a medical geneticist at Brigham and Women's Hospital, said the FDA's decision was somewhat surprising but gratifying — and a step forward in democratizing genomic information.

Green has studied how people handle information about genetic disease risks, and he said that although the information can be upsetting, it can empower people to take actions.

“I don’t want to trivialize the potential for serious psychological burden that this risk information might provide; however, it is risk information that we know can lead to life saving interventions,” Green said. “So you have to balance that against the distress people might feel.”

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