FDA clears first DTC genetic test on cancer risk

March 16, 2018—23andMe received the first FDA authorization for a direct-to-consumer genetic test for cancer risk. The authorization allows 23andMe to provide customers, without a prescription, information on three specific BRCA1/BRCA2 breast cancer gene mutations that are most common in people of Ashkenazi Jewish descent. These three mutations, however, are not the most common BRCA1/BRCA2 mutations in the general population.

The test analyzes DNA collected from a self-collected saliva sample, and the BRCA1/BRCA2 (Selected Variants) Genetic Health Risk Report describes if a woman is at increased risk of developing breast and ovarian cancer and if a man is at increased risk of developing breast cancer or may be at increased risk of developing prostate cancer. The test detects three out of more than 1,000 known BRCA mutations; a negative result does not rule out the possibility that an individual carries other BRCA mutations that increase cancer risk.

“This authorization is incredibly valuable for those who might not be aware of their Ashkenazi Jewish descent or aren’t familiar with their family history of cancer,” Anne Wojcicki, 23andMe CEO and co-founder, said in a statement. “But it’s important to understand that the majority of cancer is not hereditary, our test does not account for all genetic variants that can cause a higher risk of cancer, and people should continue with their recommended cancer screenings.”

The FDA reviewed data for the test through the de novo classification pathway. As part of the review process in order to establish safety and effectiveness for this authorization, 23andMe demonstrated a high level of accuracy (greater than 99 percent concordance to Sanger sequencing) and precision (demonstrated by studies yielding greater than 99 percent reproducibility and repeatability).

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