23andMe Seeks FDA Approval for Personal DNA Test

Matthew Perrone, AP Health Writer

WASHINGTON (AP) — Genetic test maker 23andMe is asking the Food and Drug Administration to approve its personalized DNA test in a move that, if successful, could boost acceptance of technology that is viewed skeptically by leading scientists who question its usefulness.

23andMe is part of a fledgling industry that allows consumers to peek into their genetic code for details about their ancestry and future health. The company's saliva-based kits have attracted scrutiny for claiming to help users detect whether they are likely to develop illnesses like breast cancer, heart disease and Alzheimer's.

The biology of how DNA variations actually lead to certain diseases is still poorly understood, and many geneticists say such tests are built on flimsy evidence.

For years, the Silicon Valley company has resisted government regulation, arguing that it simply provides consumers with information, not a medical service. But now company executives say they are seeking government approval — and the scientific credibility that comes with it.

"It's the next step for us to work with the FDA and actually say, 'this is clinically relevant information and consumers should work with their physicians on what to do with it,' " said CEO and co-founder Anne Wojcicki, who is married to Google co-founder Sergey Brin. Google and Brin have invested millions in the privately held company, which is based in Mountain View, Calif.

Wojcicki says the shift in strategy reflects the growing scope of the company's test kit, which now measures the risks of developing more than 115 different diseases.

23andMe said Monday it submitted an initial batch of seven health-related tests to the FDA for review. The company plans to submit 100 additional tests in separate installments before the end of the year. Tests involving family history and nonmedical traits will not be reviewed, since they don't fall under FDA oversight.

Even some of the harshest critics of the genetic testing industry say 23andMe is taking the right approach.

Dr. James Evans of University of North Carolina said he considers much of the information reported by 23andMe, "relatively useless," and "in the realm of entertainment." He believes patients benefit more from pursuing a healthy lifestyle

than parsing the potential risks of developing various diseases.

But as test makers begin analyzing larger portions of genetic code, there are rare cases when the findings may help doctors identify patients with a higher risk of treatable health problems, such as aneurysms or colon cancer.

"I think we've now entered an era where these direct-to-consumer offerings are beginning to have real medical relevance, and therefore I am in favor of them being done within some regulatory context," said Evans, a professor of genetics and medicine at UNC's Medical School.

The move may also give 23andMe a competitive edge over rivals like deCODE Genetics and Navigenics, which market similar tests. Those companies did not respond to requests for comment Monday.

"We really want to take a leadership role in this industry," said 23andMe's chief legal officer, Ashley Gould. The company says more than 150,000 people worldwide have used its test, which sells for $299 online.

The FDA already regulates a variety of genetic tests administered by health care providers, such as those given to pregnant women to detect cystic fibrosis in a developing fetus.

But it remains to be seen whether the FDA will endorse 23andMe's commercial approach, which sidesteps doctors by sending results directly to consumers. 23andMe and its peers believe there is a mainstream market for personalized genetic information, though it is still very much a niche field.

23andMe executives point out that they first contacted the FDA in 2007, before launching their product. The agency did not take an interest in the technology until 2010, when it issued letters to several testing companies, stating that their products are considered medical devices and must be approved as safe and effective.

Washington's pressure on the industry intensified a month later, when federal investigators issued a scathing report saying that companies like 23andMe produced misleading information of little to no use.

An undercover investigation by the Government Accountability Office found that four genetic testing companies delivered contradictory predictions based on the same person's DNA, which often contradicted the patient's actual medical history.

Proponents of genetic testing say 23andMe's bid for FDA approval is an important step in regulating an emerging application for genetic information.

"Many consumers are going to want to know this information, and you don't need a hospital to obtain it, so it's important to make sure it's well regulated," said Dr. Eric Lander, president and director of the Broad Institute, a genomic research center affiliated with Harvard University and the Massachusetts Institute of Technology. "I

think 23andMe is taking a very forward-leaning step."

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