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23andMe CEO Responds to FDA Warning Letter

Anne Wojcicki Defends Genetic Tests, Acknowledges Company Late in Responding to Agency Concerns

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The head of genetic-test maker 23andMe Inc. responded to a Food and Drug Administration warning letter in a blog post Tuesday night, acknowledging the company was behind schedule in addressing FDA concerns but defending the accuracy and value of the company's tests.

The FDA ordered the Google Inc.-backed company to stop marketing its $99 genetic test in a Nov. 22 letter, saying the company hadn't secured marketing authorization and expressing concern that inaccurate results could lead consumers to undergo unnecessary health procedures such as breast-cancer surgery. The FDA said 23andMe hadn't responded to numerous requests for more information, even as the company was launching a national television advertising campaign for the product, which analyzes genetic information from a person's saliva for clues about disease risk and ancestry.

The company began marketing its tests in late 2007. In a post on the company's website, Chief Executive Anne Wojcicki said 23andMe began discussions with the FDA in 2008, and submitted its first application for FDA clearance last year. "We received feedback on those submissions and acknowledge that we are behind schedule with our responses," she wrote in the post.

She said the company has "worked extensively with our lab partner to make sure that the results we return are accurate. We stand behind the data that we return to customers—but we recognize that the FDA

needs to be convinced of the quality of our data as well."

An FDA spokeswoman declined to comment Wednesday on Ms. Wojcicki's statement.

The FDA's move against 23andMe is a blow to the burgeoning genetic-testing industry, which has capitalized on consumers' desire to learn more about their genetic profiles.

Some consumers rallied to 23andMe's defense in posts on the company's Facebook FB -0.55% page, saying the FDA move amounted to government interference with their right to obtain their own genetic information. Online petitions at change.org and Whitehouse.gov asking the Obama administration to reverse the FDA order had gathered more than 5,100 supporters as of Wednesday morning.

Some called the scenarios raised by the FDA in its warning letter unrealistic, such as the possibility that inaccurate test results about genetic mutations linked to breast and ovarian cancer could cause women to undergo unnecessary surgery. Supporters said the test results were a guide, and that people would still have to go through a doctor to undergo such procedures.

"I am crestfallen," Diana Cleaveland, a 51-year-old with Ehlers-Danlos syndrome, an inherited connective-tissue disorder, said in a phone interview. Ms. Cleaveland said she purchased information about her genetic profile from 23andMe last year in an effort to learn more about her disease. "I felt it was my last hope for self-empowerment and being able to research my own disease process," she said, adding that she'd been hoping to purchase a kit for her daughter, who may be susceptible to Ehlers-Danlos syndrome.

Other 23andMe customers were confused about the status of their product orders in light of the FDA's letter. Some asked whether they would receive the "spit kits" they ordered, whether they should send saliva samples back to the company in kits they've already received, or whether they would receive test results.

Several expressed frustration over what they described as a dearth of information from the company. Some said they couldn't get through to customer-service representatives on the phone, or received automatic replies to emails. In an email to customers Wednesday, Ms. Wojcicki apologized for the "limited response" to customer questions. "We don't have the answers to all of those questions yet, but as we learn more we will update you," she wrote.

The FDA gave 23andMe 15 working days to respond to its letter and outline the steps it has taking to address FDA concerns.

Evidence on the use and value of such genetic information is limited, and researchers are just beginning to address the question. Results may indicate, for instance, that a person's risk of a certain disease is 2% compared with a general prevalence in the population of 1%. While that's a doubling of risk, the absolute difference "isn't very meaningful," said Robert Green, a genetics medicine researcher at Harvard-affiliated Brigham and Women's Hospital, Boston.

But some believe that just being aware of disease risks may encourage the adoption of healthier diet and exercise habits. "There is anecdotal evidence that this is one more way people motivate themselves to do what they ought to do anyway," Dr. Green said.

Proponents say the tests can also identify potentially important risks for both common and inherited diseases that could lead consumers to discuss the findings with their doctors.

Funded by grants from the National Institutes of Health, Dr. Green and his colleagues have conducted surveys among users of the tests. Among 1,057 consumers who responded to a survey six months after taking either a 23andMe test or one from another company, 28% had discussed the results with a doctor, 11% had undergone additional tests or procedures and 3% had discussed results with a genetic counselor, according to the researchers' preliminary findings presented at a recent meeting of the American Society for Human Genetics.

Whether such doctor visits and additional tests reflect smart or wasteful use of medical resources or lead to improved health for patients isn't known, but researchers are looking at such questions, said Dr. Green, who doesn't have financial ties to any makers of personal genetic tests.

Dr. Green said he isn't aware of any cases of harm from the tests.

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