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Anne Wojcicki Speaks Out About the F.D.A. Crackdown on 23andMe

By *CLAIRE CAIN MILLER*

Anne Wojcicki, co-founder and chief executive of [23andMe](#), the genetic testing company backed by Google, spoke Tuesday night for the first time about the [Food and Drug Administration's crackdown](#) on her company.

The service the company provides — using a saliva sample to analyze a customer's DNA for \$99 — is so novel that it does not fit into the F.D.A.'s framework, like “a square peg in a round hole,” she said. But she also said that 23andMe moved too slowly and failed to communicate with regulators.

Ms. Wojcicki spoke at a [Fortune Most Powerful Women](#) dinner in San Francisco. She was joined by her sister, Susan, Google's senior vice president of ads and commerce. They are two of the most prominent women working in Silicon Valley, which is also where they were raised.

Last week, [the F.D.A. ordered](#) 23andMe to stop marketing its genetic test because it said the company had not provided adequate evidence that the tests were accurate, and the agency was concerned about patients receiving genetic information without medical guidance. The warning [sparked controversy](#) among patients and people working in genomics.

23andMe has said it believes that people are entitled to information about their own DNA and has been working with the F.D.A. for several years to get regulatory approval for its tests. The problem, Anne Wojcicki said on Tuesday, is that the F.D.A.'s approval system is set up to approve individual tests, but 23andMe tests about a million components of a person's DNA. Filing for a million approvals would be impossible, she said.

The F.D.A. in May asked 23andMe for more information, Anne Wojcicki said, and the company did not respond quickly enough.

“We completely recognize we're behind schedule; we failed to communicate proactively,” she said. “They're a very important partner, and everyone is focused on resolving it.”

Her sister said that Google had struggled with the [same tension between](#) new technology and government regulators.

“In some ways, we’re in similar spaces, which is companies doing things that have never been done before,” Susan Wojcicki said. “So there are questions: ‘What are the implications of this?’ Lots of times these become more accepted as the technology gets used.”

Google and 23andMe also share another challenge — earning consumers’ trust as keepers of enormous amounts of their personal data. For instance, 23andMe earns money by sharing anonymous genetic information with scientists and researchers for medical studies, with customers’ permission.

In an [interview with The New York Times](#) last month, Anne Wojcicki, who is married to but [separated from](#) Sergey Brin, a Google co-founder, compared her mission to one expressed by Larry Page, the other Google founder.

“I remember in the early days of Google, Larry would say, ‘I just want the world’s data on my laptop,’” she said. “I feel the same way about health care. I want the world’s data accessible.”

On Tuesday, the sisters responded to [concerns about](#) 23andMe’s use of health data and whether Google, which financed 23andMe, could access it. The companies are right now completely separate, Susan Wojcicki said.

Her sister added that, at this point, the extent of the partnership was 23andMe’s using of [Google’s enormous computing power](#) to analyze genetic data, but that the data was proprietary to 23andMe.

Asked about achieving success in the [male-dominated tech business](#), the Wojcicki sisters credited their parents and their upbringing. Their mother, Esther, who was in the audience, is a journalism teacher, and their father, Stanley, taught physics at Stanford. Their three daughters were raised on campus.

“It wasn’t the finances and it wasn’t the business component,” Susan Wojcicki said of the career advice they received growing up. “It was, ‘Is it interesting and is it going to change the world in some way?’”