23andMe founder pulls personal genomic service, pledges cooperation on FDA review

After last week's cease-and-desist order from the Food and Drug Administration regarding the selling of 23andMe's personal genomic kits, the company continued to air advertisements promoting the $99 introductory service. Apparently fearing repercussions for appearing intransigent, and after discussions with government officials, founder Anne Wojcicki announced "23andMe will comply with the FDA's directive and stop offering new consumers access to health-related genetic tests while the company moves forward with the agency's regulatory review":

> I am highly disappointed that we have reached this point and will work hard to make sure consumers have direct access to health information in the near future. Our goal is to work cooperatively with the FDA to provide that opportunity.

In her post, Wojcicki appeared stung by a stream of articles that questioned the reliability of the 23andMe data, which most experts believe are state-of-the art.

> We also want to make clear that we stand behind the data we have generated for customers. Our lab partner adheres to strict quality standards that are part of the Clinical Laboratory Improvement Amendments of 1988 — known as CLIA. These are the same standards used in the majority of other health and disease-related tests. We decided several years ago to comply with CLIA guidelines to be consistent with other types of laboratory testing and to assure customers about the quality of data. Our testing has shown a greater than 99.9 percent accuracy rate.

When or if the FDA will lift its ban is not known, and the company's prospects, and the the direct-to-consumer personal genomics industry itself, is hanging by a thread.

Read the full, original post: 23andMe Provides An Update Regarding FDA's Review