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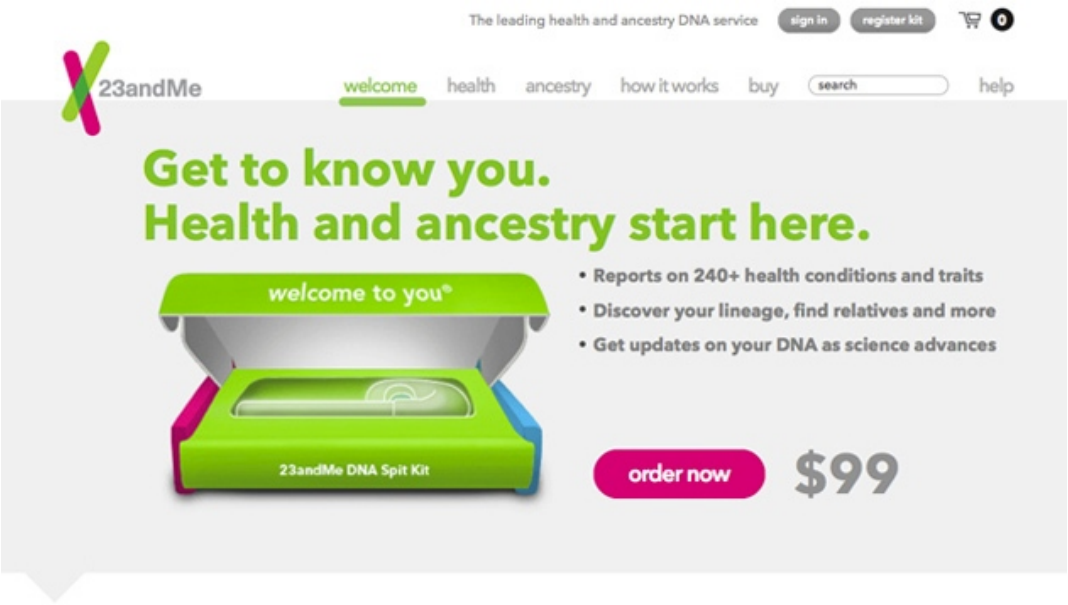
23andMe ordered to halt sales of DNA tests

US regulator seeks information on the safety and effectiveness of the company's analyses.

Sarah Zhang

25 November 2013



www.23andme.com

23andMe markets its DNA testing service direct to consumers.

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The US Food and Drug Administration (FDA) has ordered personal-genomics company 23andMe to stop marketing its DNA-testing service.

In a warning letter dated 22 November, the FDA of Silver Spring, Maryland, says that 23andMe has not provided information showing that its service is safe and effective. The agency expresses concern about the public-health consequences of supplying consumers with potentially inaccurate genetic information from testing with a product that has not been approved for use as a medical device.

23andMe, based in Mountain View, California, is the dominant player in the direct-to-consumer genomics market. The DNA analysis that it sells for US$99 purports to provide information on everything from the risk of breast cancer to a person's ancestry.

Long after it was founded in 2006, 23andMe maintained that its DNA tests provided general information rather than a medical service. Last year, however, the company reversed that stance, submitting paperwork for FDA clearance on its genetic tests.

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But the FDA says that 23andMe has still not provided any studies that validate the accuracy of DNA tests that it markets to consumers, despite “14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications”. The agency, which says that 23andMe stopped responding to its entreaties in May, has given the company 15 days to take corrective action before the FDA considers regulatory actions such as “seizure, injunction, and civil money penalties”.

John Conley, who specializes in technology law at the University of North Carolina in Chapel Hill and is editor of the *Genomics Law Report*, says that the FDA's letter is unusually stern. “It seems like the FDA is really irritated,” he says. “They think they’re getting the runaround.”

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In a statement released today, 23andMe says that it will cooperate. “Our relationship with the FDA is extremely important to us and we are committed to fully engaging with them to address their concerns.”

To those sceptical about the medical utility of direct-to-consumer genomics, the FDA’s action is a welcome intervention. “People shouldn’t be taking complex medical tests because they were seduced by clever ads,” says James Evans, a medical geneticist at the University of North Carolina School of Medicine.

But Misha Angrist, a genome policy analyst at Duke University in Durham, North Carolina, says that the FDA may be overstating the risks posed by 23andMe’s testing. He rejects the idea that a woman would elect to remove her breasts or ovaries on the basis of just the results of 23andMe’s breast-cancer-risk test, one scenario outlined in the FDA’s letter. Angrist also questions whether 23andMe really should be a priority for the FDA. “It just seems like a gratuitous killing of a mosquito with a sledgehammer,” he says.

As for the wider impact of the FDA’s scrutiny, Conley says that the agency’s move against 23andMe could further discourage companies from entering the already struggling direct-to-consumer genomics market. Since 2010, the FDA has sent letters of enquiry to more than a dozen such firms, suggesting that their tests need to be regulated as medical devices. Almost all of these companies have since folded or changed their business models.

Nature doi:10.1038/nature.2013.14236

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Nature ISSN 0028-0836 EISSN 1476-4687