Academics decry FDA crackdown on genome service companies

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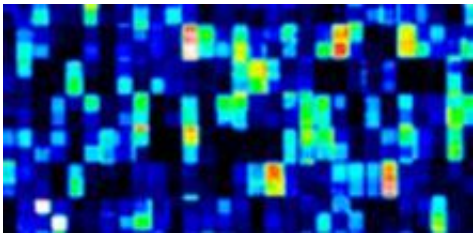

(Medical Xpress)—Dr. Robert Green, a medical geneticist with Brigham and Women's Hospital and Nita Farahany, professor of genome sciences and policy at Duke University, who also happens to be a lawyer have stepped into the "controversy" surrounding companies that provide genetic testing for anyone who wants it. Together the two have published a COMMET piece in the journal *Nature*, arguing against a recent order by the FDA, that 23andMe, a genome services company, cease offering services that offer medical advice.

As genome sequencing has come down in price, it's moved from research labs into the private sector with some companies now routinely offering genome services to the public. Such companies offer genealogy information, which is not considered controversial and/or quasi medical services such as letting people know if they have markers in their genes that make them more susceptible to certain diseases. This type of service

has become controversial chiefly because it hasn't become anywhere near foolproof—consumers report receiving different information from different testing companies. Because of this, the FDA chose to inject itself into the situation—last month they sent 23andMe a letter telling the company to stop offering such services. Now, Farahany and Green are responding to that letter and the possible impact it might have on genomic services in general.

Farahany, a onetime customer of 23andMe, and her colleague, argue that the FDA has overstepped its bounds in classifying genomic testing services as medical devices. They also accuse the agency of engaging in speculation rather than science in cracking down on such services and back up their allegations by listing several studies (some of which were conducted by 23andMe) that showed that consumers are not adversely impacted by such services. The FDA had suggested that some consumers may alter their medications or medical practices due to genome reports they receive. Farahany and Green also contend that the FDA's main reason for halting such services is out of fear of customer reaction should they be told they have a genetic predisposition to breast cancer. Farahany and Green cite more studies that have shown that the vast majority of consumers who receive such information immediately consult their physician and only take action if they are advised to do so by their doctor (as was the highly public case of celebrity Angelina Jolie.)

The FDA has yet to respond to the comment piece, but the article does shed light on the increasingly common practice of consumers seeking medical information by having their genes scrutinized—a practice that in the long run should be good for everyone. As more people have it done, more information becomes available which should over time help to improve the accuracy of such tests. Whether they should be held under the guidance of the FDA, however, is still unclear and may ultimately have to be resolved by the courts.

More information: Regulation: The FDA is overcautious on consumer genomics, Robert C Green& Nita A Farahany, *Nature*, DOI: 10.1038/505286a