FDA action against 23andMe doesn't signal the end for personal genomics

Last Monday, the U.S. Food and Drug Administration posted a letter on its website demanding that genetic testing company 23andMe stop marketing its popular home genome testing kit until it receives marketing clearance from the agency.

Since then, many have wondered if this was the FDA's long-awaited first step in the regulation of direct-to-consumer genetic testing. But the FDA's cease and desist letter doesn't signal the end of personal genomics, as many have speculated. Rather, their action marks a new era for regulating fast-moving technologies, the rules of which are likely to be written as a result of this particular case.

"But inconsistencies are not just a problem for 23andMe," writes the Genomics Law Report's Jennifer K. Wagner. "They plague the FDA in this area too. Because the FDA has been ignoring personal genetic/omic analyses for ancestry (*e.g.*, Ancestry.com DNA, LLC uses the same basic chip as 23andMe, Inc. as part of their ancestry analysis), the spit kit itself cannot be used as the basis for claiming the PGS service is within FDA oversight of 'medical devices.' Some have said that the FDA has no interest in regulating return of raw data results, interpretations for ancestry purposes, or traits like earwax. Yet on what basis is that decision being drawn and by whom?"

Read the full, original story here: The Sky is Falling for Personal Genomics! Oh, nevermind. It's just a cease & desist letter from the FDA to 23andMe.

Additional Resources:

- "FDA halt of 23andMe test kit could stall progress in personal genomics," Genetic Literacy Project
- "FDA v. personal genetic testing," New Yorker
- "Should hoarding of genetic info cause FDA to fear 23andMe?" Scientific American