

23andMe effect: Sharper scrutiny ahead for personal genetic tests

A few weeks ago, the U.S. Food and Drug Administration halted the sale of 23andMe's personalized DNA test kits, claiming the company failed to sufficiently communicate with the regulatory body.

Many saw the FDA's action as their long-awaited entrance into regulating personalized genetic testing. According to a new article, this precedent could "signal stiffer oversight of thousands of tests in an industry predicted to increase fivefold in size."

"A large part of the industry isn't tightly overseen by the agency," writes John Lauerman and Anna Edney. "Genetic tests are in increasing demand to diagnose or determine disease risk and help make treatment decisions, especially in cancer. Increased regulation is needed to make sure tests like 23andMe's fulfill their claims, said James Evans, a geneticist at the University of North Carolina at Chapel Hill."

Read the full, original story: [Personal genetic tests face sharper scrutiny after 23andMe](#)

Additional Resources:

- "[FDA halt of 23andMe test kit could stall progress in personal genomics](#)," Genetic Literacy Project
- "[Do we need to be protected from our genomes?](#)" Pacific Standard
- "[23andMe founder pulls personal genomic service, pledges cooperation on FDA review](#)," 23andMe