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**PERSPECTIVE**

# Will the Wall Come Tumbling Down?

Erika Lutins and Sharon F. Terry

The company 23andMe was founded ''to help people access, understand and benefit from the human genome,'' and in turn transfer genetic information from the lab to the home (23andMe, n.d.). Their Saliva Collection Kit and Personal Genome Service (PGS) gave consumers health reports on over 200 diseases along with their ancestry information. That changed when, on November 22, 2013, the Food and Drug Administration (FDA) sent Anne Wojcicki, cofounder and CEO of 23andMe, a warning letter stating that the kit and PGS was ''collectively a device.'' Since it lacked the required premarket approval or *de novo* classification, it was ''in violation of the Federal Food, Drug, and Cosmetic Act.'' Therefore, the FDA stated that 23andMe must ''immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device'' (Gutierrez, 2013). This was not the end of 23andMe, but it threatened the company's main activity and perhaps the revolution it heralded in direct-to-consumer genomics.

However, on February 19, 2015, just 15 months after the warning letter, 23andMe and the aforementioned consumer revolution celebrated a victory; 23andMe was granted authorization by the FDA to market a carrier report for Bloom syndrome (U.S. Food and Drug Administration, 2015). Bloom syndrome is a rare inherited disorder that results in short-stature, increased skin sensitivity to the sun, and heightened risk of cancer (Genetics Home Reference, 2015). The company 23andMe established that the test accurately assesses Bloom syndrome carrier status as a result of two studies. The company also tested the usability of a saliva sample and how easy it was to follow the testing instructions. Wojcicki commented that this approval is a critical ''first step'' to providing consumers with their own health profiles. She also commented in the company blog, ''This is also the first-time the FDA has granted authorization to market a direct-to-consumer genetic test, and it gives 23andMe a regulatory framework for future submissions. While this authorization is for a single carrier status test only, we are committed to providing US customers with health information once more tests have been through this process and we have a more comprehensive product offering'' (Wojcicki, 2015). The FDA's motive behind this decision was to provide ''the least burdensome regulatory path for autosomal recessive carrier screening tests'' (U.S. Food and Drug Administration, 2015).

The implications here go beyond a single company or genetic test. ''The FDA believes that in many circumstances it is not necessary for consumers to go through a licensed practitioner to have direct access to their personal genetic information. Today's authorization and accompanying classification, along with FDA's intent to exempt these devices from FDA premarket review, supports innovation and will ultimately benefit consumers,'' said Alberto Gutierrez, PhD, director of the Office of In Vitro Diagnostics and Radiological Health, in the FDA's Center for Devices and Radiological Health. ''These tests have the potential to provide people with information about possible mutations in their genes that could be passed on to their children'' (U.S. Food and Drug Administration, 2015).

The FDA also announced that carrier screening tests are class II and are exempted from premarket approval. This refers to the classification system that was established by the Federal Food, Drug, and Cosmetic Act, which states that devices must be placed into one of the three categories, which reflect the regulation needed to monitor the device's capability to produce safe and accurate results. Class I is for minimal to moderate risk, class II for moderate to great risk, and class III for great risk. Class II regulations have ''general controls'' and ''special controls''; general controls are given to all medical devices, whereas special controls are specific to class II devices and supplement general controls (U.S. Food and Drug Administration, 2014). The special controls for this device include the following: if the test is sold over the counter, manufacturers must give information about clinical medical geneticists or counseling, before or after the test. Another control is clear labeling on the device that directs consumers to the manufacturer's website. Gutierrez also commented, ''Today's authorization and accompanying classification, along with FDA's intent to exempt these devices from FDA premarket review, supports innovation and will ultimately benefit consumers'' (U.S. Food and Drug Administration, 2015).

One could ask if this is a reversal of the FDA's stance with regard to direct-to-consumer genetic testing. It is certainly movement, but not a reversal. The carrier test that 23andMe chose to submit to the FDA is a wise choice, since it is for a very rare genetic condition usually discovered in childhood for which there is treatment or surveillance. For other kinds of tests, such as BRCA 1/2 testing for risk of hereditary breast or ovarian cancer, or pharmacogenomic tests, it will be much harder to obtain approval. This is a significant step, but a small one.

Genetic Alliance, Washington, District of Columbia.

President Obama specifically mentioned regulation of whole genome sequencing in the announcement of Precision Medicine in the White House in January 2015. He asked that new regulatory pathways that do not impede innovation be advanced (Obama, 2015). The FDA held a meeting on the topic, coincidentally the day after the Bloom DTC announcement (Terry, 2015). If we are to see the public engaged in their own health, while these are important steps, they are not enough. Access to information has revolutionized many industries. People are empowered when they have the right information to make informed decisions. The old ramparts around this information are crumbling—this is another hole in the wall.

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Address correspondence to:
*Sharon F. Terry, MA*
*President & CEO*
*Genetic Alliance*
*4301 Connecticut Avenue, NW*
*Suite 404*
*Washington, DC 20008*

*E-mail:* sterry@geneticalliance.org