Case 14: 23andMe (and the FDA)

International scientists working on the Human Genome Project worked for nearly a decade to decode the sequences of chemical base pairs of our DNA and learn what our genes have to say about us.[63] One of the goals was to use genetic data to better understand the keys to disease and prevention,[64] in addition to other scientific applications of the research in areas such as energy,[65] anthropology, evolution,[66] and food consumption.[67] While we have made huge advances in genetic testing and are now able to look at our genes to determine parental lineage and the causes of miscarriage, some more predictive analyses are still in progress.[68]

Take, for instance, the tests provided by Silicon Valley-based tech company, 23andMe. This company has made news in the past year because of its direct-to-consumer (DTC) genetic testing, which it marketed as able to predict gene variants "linked to traits ranging from ancestry and earwax to warfarin sensitivity and Alzheimer's disease."[69] The company came under pressure from the Food and Drug Administration (FDA), and was ordered on November 22, 2013, to stop some of its marketing because of concerns about the reliability and applications of the information the company provided.[70] The company since complied with the demands of the FDA and has been permitted to continue marketing its product.[71] But the concerns still persist about the propriety of using such easily-accessible genetic testing to learn more about one's genetic history and propensities.

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[63] Robert Krulwich, Cracking the Code of Life (television show), PBS, April 17, 2001.
[64] Stephen S. Hall, "Revolution Postponed: Why the Human Genome Project Has Been Disappointing," http://www.scientificamerican.com/article/revolution-postponed/, Scientific American, October 2010.
[65] National Human Genome Research Institute, "What's Next? Turning Genomics Vision Into Reality: Genomes to Life," www.genome.gove/11006944, National Institutes of Health and U.S. Dept. of Energy, September 2006.
[66] Shannon Biello, "Genome Advance of the Month: The X and Y of human origins: Using Y chromosome sequencing data to explore human evolution," http://www.genome.gov/27555170, National Human Genome Research Institute, National Institutes of Health, September 30, 2013.
[67] Joy Yang, "Genome Advance of the Motion: Food for Thought," http://www.genome.gov/27551968, National Human Genome Research Institute, National Institutes of Health, June 20, 2013.
[68] Stephanie M. Lee, "Anne Wojcicki discusses future of 23andMe," http://www.sfgate.com/technology/article/Anne-Wojcicki-discusses-future-of-23andMe-5502875.php, SFGate (San Francisco Chronicle online), May 24, 2014.
[69] Benjamin Cohn and Dalga Surofchy, "Regulating Direct-to-Consumer Genetic Testing vs. The Right to Know," http://synapse.ucsf.edu/articles/2014/05/22/regulating-direct-consumer-genetic-testing-vs-right-know, Synapse, May 22, 2014.
[70] See Warning Letter to Ann Wojcicki, CEO, 23andMe, Inc. at http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm, U.S. Food and Drug Administration, Dept. of Health and Human Services, November 22, 2013.
[71] See Close Out Letter to Anne Wojcicki, Co-Founder and Chief Executive Officer, 23andMe, Inc. at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm391016.htm, U.S. Food and Drug Administration, Dept. of Health and Human Services, March 25, 2014.

For instance, one journalist took the challenge and submitted her genes for analysis to 23andMe, Inc., and detailed her reaction to the information she received.[72] Most prominent was the paranoia that some results caused her with regard to predisposition to diseases she had never even imagined, as well as concerns about whether she would be required to disclose her results to insurers, and a generalized sense that the information was not easily digested or accessible to the average consumer due to the complexity of the science behind the results.

Another journalist, however, found the results both entertaining and relieving, as he found that his genetic profile showed rather low propensities to many common diseases. He also encouraged others to take the test, with the warning that, "the shorter the genetic straw you draw, the more important it is for you to be aware of it."[73] He argued that the results could help people become more proactive about their health and wellbeing. Samples of the information obtained from this journalist's report can be reviewed on his blog review of 23andMe.

Some have wondered why the FDA was involved at all. After all, 23andMe just takes a little saliva - one sends the test tube to the 23andMe lab, where it is analyzed and a report is generated. Users don't consume anything, and the procedure is completely non-invasive. However, the FDA regulated the tests as a "medical device" and demanded that the information provided to users be scientifically tested and verified.

[72] Elly Hart, "Why 23andMe Genetic Testing Is A Waste Of Time And Money," http://www.gizmodo.com.au/2011/04/why-23andme-genetic-testing-is-a-waste-of-time-and-money/, Gizmodo Australia, April 7, 2011.
[73] Nikola Danaylov, "23andMe DNA Test Review: It's Right For Me But Is It Right for You?," http://www.singularityweblog.com/23andme-dna-test-review-its-right-for-me-but-is-it-right-for-you/, SIngularityweblog.com, 2011.