'23andMe' Gets the Green Light For Disease Gene Tests

By Julianna LeMieux — April 6, 2017

23andMe [1], founded in 2006, is a personal genetics company with the mission to "help people access, understand and benefit from the human genome."

Up until 2013, 23andMe was selling home DNA testing kits that gave genetic information to consumers. After submitting a sample of saliva, customers could have access to their genetic results online - related to both ancestry and health information. However, after years of back and forth with the FDA, 23andMe was told to stop selling their kits that allow disease detection. The letter from the FDA stated,

"because you are marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act." "Therefore, 23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device."

Now, just four years later, because 23andMe went through the proper channels, the FDA has changed its tune. A press release [2] stated that they will allow the sale of the kit that tests for ten different genetic conditions. The ten are listed below - as noted in the press release.

- Parkinson's disease [3], a nervous system disorder impacting movement;
- Late-onset Alzheimer's disease [4], a progressive brain disorder that destroys memory and thinking skills;
- Celiac disease [5], a disorder resulting in the inability to digest gluten;
- **Alpha-1 antitrypsin deficiency** [6], a disorder that raises the risk of lung and liver disease;
- **Early-onset primary dystonia** [7], a movement disorder involving involuntary muscle contractions and other uncontrolled movements;
- **Factor XI deficiency** [8], a blood clotting disorder;
- **Gaucher disease type 1** [9], an organ and tissue disorder;
- **Glucose-6-Phosphate Dehydrogenase deficiency** [10], also known as G6PD, a red blood cell condition;
- **Hereditary hemochromatosis** [11], an iron overload disorder; and
- **Hereditary thrombophilia** [12], a blood clot disorder.

But, what is this information really worth?

At most, the information from the company can give you a sense of how likely you may or may not be to have the disease. For an example, let's look at celiac disease. The genetic component of celiac disease is the human leukocyte antigen (HLA) genes. There are two that give a predisposition for celiac disease - the DQ2 or DQ8 haplotype. So, if you have the DQ2 or DQ8 version, you may (or may not) have celiac disease. If you don't have DQ2 or DQ8, you are extremely unlikely to have celiac disease.

So, in that sense, the information from 23andMe can tell you that you do not have celiac disease, but, it cannot tell you if you do have it.

The DQ2 or DQ8 are required, but not sufficient. Meaning that you need to have them in order to have celiac disease, but, you also need some other, unknown factor - an environmental factor or another genetic component. The disease is diagnosed only through bloodwork and an endoscopy, not the presence of these HLA genes.

So, the genetic testing offered from 23andMe is not worthless as it can give an indication of likelihood. But, it cannot and should not be used for diagnosis. Diseases are not that simple, and our genes are not the only factor at play.

The question as to whether people should have access to this information without professional support is another one. But, as genetic sequencing gets cheaper and these boundaries are pushed, 23andMe is certainly paving the way for increased access to our own genetic information. What we do with that information remains to be seen.

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**Links**

[1] https://www.23andme.com/
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1592479/