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Law Translation Statement

Title: Internal Company Alert: FDA Activity Concerning 23andMe

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Good afternoon, everyone! I hope everyone is doing well. My name is John Archibald. For those who don't know me, I am a senior Compliance Officer and Junior Counsel at Totally Real Medical Company (TRM). As employees of TRM, it is your responsibility to be aware of current events in your field and how said events affect you. Quite a stir has been made recently outside of the company that we thought needs to be addressed in an official alert in order to keep you, our valued colleagues, up to date.

In this alert, I will be summarizing the FDA's recent activity concerning 23AndMe using two important articles from the Journal of the American Medical Association (JAMA) and The New Yorker on the issue (if you would like to read these articles for yourself, please see the "Referenced Works" section of this blog post). After, I will go into the importance of these events within the medical industry and how this affects you as an employee of TRM.

On November 22rd, 2013, the FDA ordered 23AndMe, an independent genomics company, to cease marketing and sales of it's Personal Genome Service (PGS). The PGS is a product that, after analyzing a consumer's DNA, would output estimated risks "...for more than 250 diseases and health conditions by extrapolating from research studies." (Downing and Ross

2014). Despite being sold to over 500,000 customers, it never was approved by the FDA (Downing and Ross 2014). The reason being that, normally, a product such as the PGS would have to undergo low or high risk classification stages before being available for marketing and sales. Low risk products, according to JAMA, “...require only notification and registration with the FDA via the 510(k) process, which involves determination of whether the new device is ‘substantially equivalent’ to an existing device already available on the market,” (Downing and Ross 2014).

However, in 1997, the FDA Modernization Act created a loophole in which seemingly low risk devices that have no predicates that are “substantially equivalent” may be classified as such. Thus, even though 23AndMe’s 510(k) classification requests were denied, because the FDA identified the PGS as not being “substantially equivalent” to any predecessors in their report, this inadvertently qualified it for the FDA’s low risk classifications under the Modernization Act without needing approval (Downing and Ross 2014).

So, despite being warned by the FDA in an official letter, 23AndMe continued to sell and market the PGS. Issues arise, however, when we actually look at the effectiveness of the product. JAMA holds an anti-PGS standpoint: “Because 23andMe was able to market the PGS without regulatory approval, there is a paucity of data characterizing the accuracy of both its sequencing process and its estimates of disease risk. Obtaining accurate DNA sequences from the PGS requires multiple steps, including proper sample collection, transport, and storage, as well as precise sequencing,” (Downing and Ross 2014). This “paucity,” or scarcity, of data is extremely important in considering the long-term effects of a product such as PGS. The PGS has many steps before it can output its genetic data, and the amount of diseases and conditions it looks at

is grand in scale. At any point in the process, error may be introduced, thus producing an inaccurate result.

As mentioned, the PGS takes a look at a consumer's DNA and outputs estimated genetic risks for over 250 diseases and conditions. As the New Yorker puts it, "A 23andMe report might tell you that you carry, say, a gene variant that slightly elevates your risk of heart disease, another that protects you from celiac disease...or, in one of the company's most laden tests, that you have either zero, one, or two copies of a gene variant that increases the risk for Alzheimer's, and thus stand either a low, a modest, or a shockingly high chance of developing Alzheimer's." (Dobbs 2013). For example, considering the severity in condition one may go through suffering from Alzheimer's disease, one may completely change their lifestyle, their prescription intake, or interpret medical advice drastically differently after hearing about their new genetic discovery from the 23AndMe service. Now, imagine someone doing all this and the effect it would have on their mental health, but the PGS results weren't even accurate. It has the potential to significantly harm someone.

That being considered, 23AndMe eventually stopped all marketing and sales for its health-related genetic tests on December 6th, 2013. The potential for the FDA to pursue 23AndMe in court for inaccurate genetic results was too high. Although this may be interpreted as a good thing, what does this mean for the future of products like PGS? As the New Yorker explains from its more pro-PGS stance, "The F.D.A. has a point: genetic-risk information needs to be reasonably solid, and its recipients need to be properly served; there's a place for selective paternalism in genetic testing. Yet the agency seems like a poor candidate to strike this balance," (Dobbs, 2013). To analyze this quote, the FDA is right; the inherent risk that PGS has is great enough to warrant inspection and reassessment. However, 23AndMe puts forward a great

example around the possibility that life-changing discoveries about peoples' genetic health information are a simple, accessible, and affordable test away.

And, as some members of the public might perceive, the FDA is stretching on its concerns about the potential risk that comes with a PGS report. "If the F.D.A. indeed insists on making 23andMe prove beyond doubt the validity of every single correlation, no genetic-testing service will be able to economically deliver medically relevant genetic information directly to consumers. It will destroy the industry and leave medical genetics in the hands of a medical establishment that has already failed to give people an easy way to obtain and use the elemental information in their own spit," (Dobbs 2013). These strict regulations may result in a loss of accessibility to this kind of data in the future, or restrictions that permit only government approved testing sites.

It's an issue of government handling, accuracy, and ethical medical services. However, as producers of medical devices, this directly impacts our line of work. Certain products TRM may aim to produce in order to make DNA testing for genetic health-related diseases accurate and affordable may have to be put on the shelf until further policies are passed in government and certain cases are ruled upon. Thousands of dollars and hours of our lives spent to provide the public with more accessible health care products might be thrown away by these decisions. It is important that we as a company recognize our place in the industry; that we must continue to innovate and strive for medical excellency, while simultaneously providing affordable and reliable methods and products to diagnose and care for disease.

Thank you all for reading. Continue being great and doing great things!

Referenced Works

- 1.) Downing, Nicholas S., and Joseph S. Ross. "Innovation, Risk, and Patient Empowerment: The FDA-Mandated Withdrawal of 23andMe's Personal Genome Service." *JAMA : the Journal of the American Medical Association*, vol. 311, no. 8, American Medical Association, 2014, pp. 793–94, doi:10.1001/jama.2014.148.
- 2.) Dobbs, David. "The F.D.A. vs. Personal Genetic Testing." *The New Yorker*, Condé Nast, 27 Nov. 2013,
www.newyorker.com/tech/annals-of-technology/the-f-d-a-vs-personal-genetic-testing.