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FDA's Message to Medical Device Company: Stop

All About Advertising Law Blog

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The widely publicized start-up company 23andMe, Inc. markets its "personal genome service product" as providing reports on hundreds of diseases and conditions that enable users to "take steps toward mitigating serious diseases," including diabetes, coronary heart disease, and breast cancer. This all sounds good. As an **FDA Warning Letter** issued on November 22, 2013, makes clear, however, 23andMe was marketing its product – a medical "device" under the federal **Food, Drug & Cosmetic Act** – without benefit of FDA approval. FDA thus ordered the company to immediately discontinue marketing.

The FDA's Warning Letter to 23andMe is of interest on several levels. First, there is the interest in the cutting-edge technology of the very personalized medical information which the product offers. The promise to "learn more about [one's] health and ancestry" that the company makes on its website is exciting and enticing.

Similarly, it is impressive that existing technology makes it possible to order a test kit online, collect a sample in the privacy of one's own home, and return the sample to the company's laboratory and then receive a report which promises to "provide specific health recommendations."

The FDA's Warning Letter is also of interest for the record of noncooperation on the part of the company which it recounts. The FDA states that it "do[es] not have any assurance that [23andMe] has analytically or clinically validated [its product] for its intended uses." In the FDA's telling, the company has not completed studies the company agreed to conduct or "even started other studies necessary to support" the product. We must await the company's response to the Warning Letter to hear its side of this story.

And finally, the Warning Letter is of interest as a current example in the ongoing debate regarding personal freedom and regulation in the interest of public health and safety. Movie theatres across the country are showing ***Dallas Buyers Club***, the story of Ron Woodroof's battle with AIDS and the FDA, in which he sought to use and to make available to others with AIDS unapproved drugs. 23andMe is no Ron Woodroof, but there are some similarities.

After watching *Dallas Buyers Club*, one wonders, why did the FDA seek to prevent AIDS patients from taking medicines merely because they were unapproved, particularly given the absence of any then known effective therapy? 23andMe's less poignant versions of those questions are why shouldn't a person be free to obtain a report on his/her DNA, or why is it a legitimate subject of government interest to prevent this?

FDA has a long history of addressing these types of questions and has its ready response. The FDA told 23andMe that "the main purpose of compliance with FDA's regulatory requirements is to ensure that the tests work" and, again, in the FDA's telling, the company failed to provide the FDA with proof that 23andMe's tests work as intended. False negatives or false positives potentially pose public health risks because, again in the FDA's words, "patients relying on such tests may begin to self-manage their treatments through dose changes or even abandon certain therapies." If people are going to "self-manage their treatments," they should do so using accurate information from tests which work.

There is, of course, tension between the libertarian impulse, which is rather deeply ingrained in most Americans, and the reality of regulation. That debate will never be settled or perfectly resolved, nor should it be. The case for regulation – that is, the case for demonstrating to the satisfaction of the

government that a product is what it says it is, that it works as intended, and is safe and effective – is strongest in the context of drugs and medical devices. The FDA has called upon 23andMe to demonstrate that its tests work. That question must be answered before the product can be marketed.