Of Drugstores and Devices: Parsing the FDA's Evolving DTC "Policy"

by Dan Vorhaus

Andrew Pollack of *The New York Times* reports that, in an interview, OIVD Director Alberto Gutierrez indicated that the saliva collection kit Pathway had planned to sell through Walgreens may be a clearer case of a DTC genetic test subject to FDA oversight. According to Director Gutierrez, "Once you take a collection device and you are marketing through a drugstore, it is very easy for me to say whether something would fall under our policy."

Having never publicly announced any regulatory guidance with respect to DTC genetic tests, it's somewhat unclear what "policy" Director Gutierrez is referring to. However, if the relevant distinction between Pathway and other DTC genetic testing providers is the act of placing saliva collection kits on a drugstore shelf, it is not a distinction I find particularly persuasive—or clear—because it distinguishes tests on the basis of location (where the tests are marketed for sale) rather than substance (how the tests are described to consumers, which genetic variants are tested or how those variants are interpreted).

The fact that Walgreens is referred to as a "drugstore" is not much help, particularly when you consider that the number of products sold by Walgreens and similar chains that are *not* regulated by the FDA—everything from sandals and sunglasses to batteries and beach balls—dwarfs the number of products that *are* regulated. So what is it, exactly, about the Pathway/Walgreens partnership that prompted the FDA to act so quickly and publicly? Would the FDA's response have been different if Pathway had partnered with Wal-Mart? With Amazon.com? And if we get all the way to Amazon.com, how different is this from what Pathway was already doing: selling its test directly to consumers through a publicly accessible website?

Pollack and *The Times* report that, in addition to the letter it sent to Pathway, the FDA has sent similar letters "to a number of companies selling genetic tests directly to consumers, asking them to explain their tests and their business models," although Director Gutierrez "would not identify the companies or say whether any action had been taken." Case-by-case responses to company announcements that begin with statements to reporters do not provide current or prospective DTC companies with much guidance, so hopefully the FDA is in the process of formalizing an industry-wide policy that will provide clear(er) direction for what DTC genetic companies seeking to develop their businesses can and cannot do without the agency's approval. Barring a successful legal challenge, the FDA's regulatory policy, whatever it turns out to be, is what the DTC genetic testing industry will be forced to come to terms with. For that to happen, however, the industry must first understand what that policy is.