FDA Continues Scrutiny of DTC Genetic Testing by Clinical Labs

The U.S. Food and Drug Administration (FDA) recently released three untitled letters from the Office of In Vitro Diagnostics and Radiological Health (OIR) to clinical laboratories offering direct-to-consumer (DTC) genetic tests, and a report of case studies purporting to provide public health evidence for FDA oversight of all laboratory-developed tests (LDTs). The three letters allege that the laboratories in question were offering medical devices that required premarket review by FDA. The letters came less than two months after a similar letter in late September. This all shows that OIR is still actively engaged in its effort to assert greater control over clinical laboratories generally, and genetic testing in particular, despite recent legislative efforts to limit this authority and FDA’s recent authorization of a DTC genetic test offered by 23andMe.

The three letters, sent to DNA4Life, DNA-Cardiocheck, Inc., and Interleukin Genetics, Inc., all concerned tests intended to identify patients at increased risk for certain medical conditions or drug responses. The September letter to Pathway Genomics, Inc. alleged that the company’s genetic tests for early cancer detection and the blood collection tubes mailed to consumers were medical devices requiring premarket review.

FDA has not traditionally regulated LDTs — in vitro diagnostics intended for clinical use and designed, manufactured and used within a single laboratory. But FDA has long maintained that the unregulated status of LDTs is a result of the agency’s decision to refrain from invoking its medical device authorities, rather than a consequence of the agency’s lack of statutory authority over LDTs.

FDA has taken steps in recent years to assert authority over LDTs, particularly those that are DTC genetic tests. In 2010 and 2011, FDA issued at least 20 untitled letters targeting DTC genetic tests. In 2014, FDA further proposed a framework for regulatory oversight of all LDTs, which stated that LDTs marketed DTC are subject to regulation as medical devices and not eligible for enforcement discretion.1 On November 16, FDA’s Office of Public Health Strategy and Analysis released a report calling for additional oversight of LDTs, describing 20 examples of tests that “may have caused or have caused actual harm to patients” due to the absence of compliance with FDA requirements. More than half of the examples involve genetic testing.2

A coalition of manufacturers and two physician specialty societies have responded by proposing legislative text that would limit FDA’s authority over LDTs, and the House of Representatives Committee on Energy and Commerce recently issued a discussion draft of such legislation. “Precision medicine” proposals, focused on the

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development of personalized therapies and diagnostics, have also been included in several bills introduced in Congress. Finally, FDA itself issued a *de novo* decision letter authorizing 23andMe to market genetic carrier tests DTC after asking the company to stop marketing those and other genetic tests in a November 2013 warning letter.

Some clinical laboratories seeking to offer DTC genetic tests might have viewed these developments as evidence that FDA’s approach has softened in light of uncertain federal policy. The recent letters and report signal that FDA remains focused on such tests and willing to assert authority over them.

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Sidley Austin LLP has an internationally recognized food and drug practice, representing major pharmaceutical, biological, medical device and food/dietary supplement clients on matters relating to the development, manufacture and marketing of products regulated by the Food and Drug Administration (FDA) and other related government authorities.

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