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FDA resumes enforcement relating to laboratory developed tests

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On April 4, 2019, the U.S. Food and Drug Administration's (FDA or the agency) Office of In Vitro Diagnostics and Radiological Health issued a Warning Letter to Inova Genomics Laboratory in one of the first FDA enforcement actions against a clinical laboratory for services offered as laboratory developed tests (LDTs) in more than five years, and certainly the first such action of which we are aware since FDA announced in late 2016 that it would not finalize the proposed framework and guidance documents for the regulation of LDTs. At that time, FDA elected to revert to the enforcement discretion approach the agency had employed for LDTs between 1998 and 2014 where FDA refrained from enforcing its requirements for assays that were developed, validated and performed in a single CLIA laboratory with a physician order. While FDA and stakeholders have proposed legislation (e.g., The Diagnostic Accuracy and Innovation Act) to provide FDA greater explicit authority over LDTs, FDA has long held that the agency already has authority to regulate these services.

Briefly, the question of whether and to what extent FDA and the Centers for Medicare and Medicaid Services (CMS) have overlapping and distinct oversight over laboratory services developed and offered by high complexity clinical laboratories and offered on the order of healthcare providers has been debated (sometimes heatedly) for more than 20 years, especially following FDA's general assertion in1998 that the agency had the authority and intended to regulate such services. Over the intervening years, however, FDA maintained that the Agency was exercising its discretion and refraining from enforcing the Agency's requirements (i.e., exercising enforcement discretion) for most LDTs (as outlined below), while also selectively taking enforcement action against individual entities offering LDTs as services or providing supporting reagents, components or collection devices when FDA concluded that: (1) the LDT raised significant public health risks; (2) it was not developed by the clinical laboratory where it was offered; (3) the technology used in the LDT presented specific risks to the test's validation or performance; or (4) the LDT was offered directly to consumers or included claims of specific clinical benefit or diagnostic outcome such as being marketed for a specific diagnostic or prognostic, clinical outcome where FDA perceives a high risk if there is a misdiagnosis or error.

While the Agency issued numerous warning letters prior to 2016 to laboratory companies, principally those offering DTC genetic tests, this recent Warning Letter is the first instance in several years of the Agency taking action in relation to an LDT. In the letter, FDA focuses on clinical utility of the claims made for the LDTs. This enforcement action also suggests a renewed willingness at FDA to focus on LDT issues. Coupled with FDA's recent enforcement actions with respect to various human tissue and cellular products, especially in the area of stem cells and therapeutic claims for such products, this Warning Letter may suggest a renewed interest in enforcement by the Agency, especially in areas where FDA perceives newly emerging or elevated risks.

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