Published on *The National Law Review* https://natlawreview.com

FDA Announces Intent to Issue Draft Guidance Documents Describing Regulatory Framework for Laboratory Developed Tests

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In a major announcement, on July 31, **FDA** notified **Congress** of its intent to issue two draft guidance documents that, if finalized, would implement a new regulatory system for **laboratory developed tests (LDTs)**. These guidance documents have been anticipated for several years, with the agency announcing over four years ago that it intended to change its regulatory policies for LDTs. FDA's draft guidance documents include the following:

- "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)."
- "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)."

As background, LDTs are diagnostic tests that are developed, validated, and performed by individual laboratories. These assays are developed for in-house use and are not commercially distributed to other laboratories. In contrast, commercially available in vitro diagnostic (IVDs) test kits are developed by diagnostic manufacturers and sold to clinical laboratories.

Clinical laboratories that develop and use LDTs are subject to oversight and regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and, historically, have not been regulated under the Federal Food, Drug, and Cosmetic Act (FDCA). Beginning in the 1990s, FDA adopted the position that LDTs are medical devices, but said that it would exercise its enforcement discretion and not impose FDCA medical device requirements on LDTs. That position changed in 2010, when FDA announced its intention to change its policy of enforcement discretion regarding LDTs and implement a risk-based approach to regulating LDTs. Subsequently, FDA stated that it would issue guidance documents to implement a regulatory system for LDTs. In the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Congress mandated that FDA give Congress at least 60 days' notice before issuing any guidance on the regulation of LDTs. In its July 31 notification to Congress, FDA stated that it would not publish the draft guidance documents or establish a docket for public comment until at least 60 days after the notification.

FDA's authority to regulate LDTs has been the subject of significant debate. At the same time that FDA issued its notification to Congress, it denied two citizen petitions (filed in 2006 and 2013), which

argued that FDA lacked jurisdiction over LDTs. Several bills have been introduced in Congress in the last several years proposing alternative regulatory systems for LDTs, including a proposal to amend CLIA.

Further analysis of the proposed framework will follow in a subsequent client alert.

Assuming FDA publishes the draft guidance documents as it has announced, it will accept comments from the public for 90 days.

National Law Review, Volume IV, Number 220