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In Landmark Ruling, Eastern District of Texas Strikes Down FDA's Final Rule Regulating Laboratory Developed Tests

In the never-ending saga over the battle to regulate laboratory-developed tests (LDTs), the Eastern District of Texas took the wind out of FDA's sails on Monday, vacating FDA's Final Rule that intended to regulate LDTs as medical devices similar to *in vitro* diagnostic (IVD) tests, which are commercially manufactured and undergo pre-market review by FDA.[1] Clinical laboratories can halt their plans, for now, to comply with the Final Rule's May 6, 2025, deadline to implement certain features of FDA's medical device quality system regulations.

As summarized in our May 6, 2024, client alert, FDA's Final Rule was set to dramatically alter the regulatory landscape for LDTs with major regulatory and financial implications to clinical laboratories, patients and health care providers.

Clinical laboratories will see the ruling as a major victory for the laboratory industry. The district court's ruling also comes as one of the first major checks on FDA's power in the post-*Chevron* world following last year's Supreme Court decision in *Loper Bright*.

Background and LDT Regulatory Timeline

In 1976, Congress enacted the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), granting FDA explicit authority to regulate medical devices, which included IVDs developed by manufacturers and sold for commercial purposes to laboratories, health care organizations and consumers.

Separate from FDA's authority, in 1988 Congress passed the Clinical Laboratory Improvement Amendments (CLIA), creating a statutory framework to certify clinical laboratories through quality, proficiency standards and personnel requirements. The Centers for Medicare and Medicaid Services (CMS) oversees CLIA certification and compliance for most laboratories in the country[2] that examine materials derived from the human body for the diagnosis, treatment or prevention of disease or to assess the health of human beings.

For decades, FDA did not attempt to assert authority or regulate laboratories or LDTs, which are defined as IVDs "intended for clinical use and that [are] designed, manufactured

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and used within a single laboratory that is certified under [CLIA]."[3] Starting in 1992, FDA claimed that it could regulate LDTs as medical devices through the issuance of a draft Compliance Policy Guide.[4] FDA declined to finalize the guidance, however, and assured laboratories that it did not intend to "routinely" exercise its authority over LDTs.[5]

FDA next asserted that it had jurisdiction over LDTs in a 1996 preamble to a proposed rule regarding device classification levels for certain active ingredients used for preparing LDTs.[6] FDA also recognized in the same preamble that "significant regulatory changes in this area could have negative effects" and that FDA would therefore only focus its oversight on "ingredients . . . that moved in commerce" and other tangible articles. FDA never took any final regulatory action to assert its authority over these tests.

In 2010, FDA held a two-day public meeting soliciting feedback on LDT regulation, hinting that it may consider formally regulating LDTs. Four years later, FDA formally released two draft guidance documents proposing a framework for LDT regulation.[7] The guidance documents were not well received by Congress, which criticized FDA for significantly shifting the way LDTs are regulated and directed FDA to suspend any efforts to finalize its guidance documents.[8] FDA complied and retreated from enacting any final guidance document.

A few years later, Congress considered two different pieces of legislation — The Verifying Accurate Leading-edge IVCT Development Act (VALID) of 2020 and the Verified Innovative Testing in American Laboratories (VITAL) Act of 2020.[9] Both bills proposed different approaches to regulating LDTs that would have created a new regulatory pathway under FDA premarket review or deemed LDTs as "services" to be regulated under CLIA. Both bills failed to pass even after being reintroduced in subsequent Congresses.

With failed attempts to regulate LDTs in Congress, FDA announced its attempt to move forward with regulating virtually all LDTs as medical devices in October 2023, which ultimately led to the Final Rule, effective May 6, 2024.

Shortly after the Final Rule went into effect, the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP) sued FDA in two separate lawsuits challenging that the Final Rule violated the Administrative Procedure Act (APA) because it exceeded FDA's statutory authority and was arbitrary and capricious. The two cases were consolidated into one.

Summary of Court Ruling

Explaining the storied history of LDT regulation, the district court found no question that Congress had considered the unique regulatory issues raised by clinical laboratories and the tests that they develop and perform, and that Congress chose to regulate these tests as "services" under CLIA. This contrasts with the authority Congress granted FDA to regulate "devices," which the district court concluded under the FDCA to mean "articles in commerce," not "services" performed by doctors and laboratories.

Considering the distinct legislative history of medical devices and laboratory services, the district court agreed with the plaintiffs that LDTs are "professional medical services that are qualitatively and categorically different from the tangible goods that FDA may regulate as a 'device,'" and that medical devices defined under the FDCA only refer to "tangible, physical products." The district court was further unpersuaded by FDA's argument that an LDT is an "IVD test system" made up of physical components that meet the definition of a medical device.

Rejecting FDA's argument on two grounds, the court found that (1) FDA had no statutory authority to alter the definition of a device under the FDCA to expand the definition to include laboratory services, and (2) FDA's self-created "IVD test system" conflates discrete tangible objects with an assortment of laboratory tools that professionals use to deliver a service. Relying heavily on last year's Supreme Court decision in *Loper Bright*, the court closely scrutinized the statute and made it abundantly clear that it was not deferring to FDA's interpretation of the statute and the authority that FDA was claiming from the statute. The court warned that should it accept FDA's position, it would lead to limitless implications of FDA oversight on all surgical procedures and physical examinations that use "devices," giving the term an "extraordinary, expansive meaning with far-reaching consequences."

The court further noted that, should it accept FDA's theory that an LDT does in fact meet the definition of a medical device under the FDCA, it would "render[] CLIA largely, if not entirely, pointless." For these reasons, the court determined that FDA's "asserted jurisdiction" over LDTs "defies the bedrock principles of statutory interpretation, common sense and longstanding industry practice." Therefore, the court concluded that the Final Rule exceeds FDA's authority, is unlawful and should be set aside pursuant to the APA.

Finally, in considering the appropriate remedy, the district court found that the circumstances in this case favor nullifying and revoking the Final Rule instead of remanding the Final Rule back to FDA to modify without vacating. In reaching this conclusion, the court considered the extreme financial impact the Final Rule would have on clinical laboratories as well as the unlikelihood that FDA could justify its decision on remand. Therefore, the Final Rule was vacated in its entirety.

What's Next?

With the Final Rule now vacated, FDA's "phaseout" policy to bring LDTs under the same regulatory scheme as IVDs is also terminated. Once the LDT Final Rule went into effect last year, laboratories were subject to a phaseout policy that would have required companies to begin complying with certain medical device requirements, such as medical device reporting and complaint handling, beginning on May 6, 2025.

While it is possible that FDA could appeal the decision, we do not expect the current Administration to do so. Experts had already predicted that President Trump was likely to order FDA to repeal, or not enforce, the Final Rule, as HHS under the first Trump Administration had revoked FDA's guidance document claiming authority to regulate LDTs as devices.

In light of the district court's ruling, it seems less likely that Congress, and in particular the Republican controlled House, will attempt to revive the bipartisan VALID Act.

In a town where we are taught to "never say never," we will keep a watchful eye on the Administration and Congress's reaction to the court's ruling.

[1] *American Clinical Laboratory Ass'n v. FDA*, Case No. 4:24-cv-00479 (E.D. Tex.).

[2] New York and Washington are exempt from CLIA, as they have their own state law regulatory oversight framework, which is enforced by the applicable state agency.

[3] LDT Final Rule, 89 Fed. Reg. 37286, 37289 (May 6, 2024).

[4] *See* FDA, Draft Compliance Policy Guide: Commercialization of Unapproved In Vitro Diagnostic Devices Labeled for Research and Investigation (Aug. 1992).

[5] Food & Drug Admin., *IVD Policy Will Not Include Exemptions for "Standard of Care" Tests*, The Gray Sheet (Oct. 11, 1993).

[6] 61 Fed. Reg. 10,484, 10,485 (Mar. 14, 1996).

[7] Food & Drug Admin., *FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)*, and *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* (Oct. 2, 2014).

[8] H.R. Rep. No. 114-531, at 72 (2016).

[9] VALID Act of 2020, H.R. 6102, 116th Cong. (2020); VITAL Act of 2020, S. 3512, 116th Cong. (2020).