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FDA Regulation of Laboratory-Developed Tests (LDTs)

Laboratory-developed tests (LDTs) are a class of in vitro diagnostic (IVD) device that is designed, manufactured, and used within a single laboratory. LDTs may be used in the context of identifying evolving diseases (e.g., new strains of infectious disease) or those subject to advancing scientific research (e.g., genomic cancer testing). LDTs increasingly incorporate complex technology (e.g., artificial intelligence [AI] software applications) and guide critical health care decisions. Experience with development of tests during the COVID-19 pandemic demonstrated the pivotal role LDTs play in facilitating rapid access to tests, and at the same time highlighted challenges with their regulation.

The regulation of LDTs has been the subject of ongoing debate in recent decades, driven in large part by the increase in the number and complexity of these tests. In general, the Food and Drug Administration (FDA) has maintained that it has clear regulatory authority over LDTs, as it does with all IVDs that meet the definition of *device* in the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA regulates the safety, effectiveness, and quality of the design and manufacture of IVDs pursuant to authority in the FFDCA. However, FDA traditionally exercised enforcement discretion over LDTs—choosing not to enforce applicable legal requirements with respect to such tests—meaning that most of these tests have neither undergone premarket review nor received FDA clearance, authorization, or approval for marketing. (For more information about FDA regulation of medical devices, see CRS Report R47374, *FDA Regulation of Medical Devices*.) Some representatives of clinical laboratories and manufacturers of LDTs have long asserted that LDTs are clinical services and not medical products, and therefore should be outside of FDA's regulatory purview.

Despite an absence of FDA guidance on broader LDT regulation, the agency had traditionally asserted authority over subsets of higher-risk LDTs, for example, direct-to-consumer (DTC) genetic tests that provide information about the risk of developing a disease. In 2024, FDA published a since-vacated final rule (89 *Federal Register* 37286, May 6, 2024) establishing a schedule that would have phased out FDA's traditional enforcement discretion policy for LDTs and clarified that IVDs are medical devices, including when manufactured by laboratories. This followed an October 2023 proposed rule (see CRS In Focus IF12628, *Regulation of Laboratory-Developed Tests: FDA's Proposed Rule*). The final rule would have required compliance with device regulatory controls for most LDTs over a period of four years.

Observers noted that FDA undertook rulemaking after Congress excluded authorizing legislation giving FDA explicit authority to regulate in vitro clinical tests, including LDTs, from user fee reauthorization in 2022. In March 2025, in two consolidated cases (*American Clinical Laboratory Association (ACLA) v. FDA and Association for Molecular Pathology (AMP) v. FDA*), the U.S. District Court for the Eastern District of Texas vacated the final rule. Specifically, the court held that LDTs are not "devices" under the FFDCA, and that FDA therefore exceeded its statutory authority in issuing the LDT final rule. This ruling, which was not appealed by FDA within the required timeframe, has the practical effect of removing most if not all LDTs from FDA's regulatory purview.

History of FDA Oversight: 2006-2021

FDA traditionally focused its enforcement on commercial IVDs (test kits) and has not generally enforced premarket or other regulatory requirements for LDTs. Over the past two decades, FDA indicated its intent to regulate LDTs using a risk-based approach due to their increasing number, significance, and complexity. In 2006 and 2007, FDA published and updated draft guidance on a subset of LDTs called In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). IVDMIAs were defined by the FDA as tests that, among other things, provide results that are not transparent and that the end user (usually a physician) could not independently derive. FDA never finalized this guidance and instead announced its intent to regulate all LDTs in a July 2010 public meeting, "Oversight of Laboratory Developed Tests."

October 2014 Draft Guidance

In July 2014, FDA notified Congress of its intent to begin regulating LDTs through draft guidance. The notification complies with a statutory requirement in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA, P.L. 112-144) that directed FDA to notify Congress at least 60 days before issuing any draft or final guidance on regulation of LDTs. In the October 2014 draft guidance, *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*, FDA presented the details of a risk-based framework for regulating LDTs. The framework generally identified classes of LDTs that would be (1) exempt from regulation entirely; (2) required to meet only registration and listing (or notification) and adverse event reporting requirements; or (3) required to meet registration and listing (or notification), adverse event reporting, applicable premarket review, and quality system regulation requirements. The determination to continue enforcement discretion—or to enforce certain or all applicable regulatory requirements—for an LDT would be based on risk evaluation. FDA collected comments on the draft guidance; however, in November 2016, the agency announced it would be delaying finalization.

January 2017 Discussion Paper

FDA summarized the comments it received on the 2014 draft guidance in a January 2017 *Discussion Paper on*

Laboratory Developed Tests (LDTs), noting that it would not be issuing "a final guidance on the oversight of [LDTs] at the request of various stakeholders to allow for further public discussion … and to give our congressional authorizing committees the opportunity to develop a legislative solution." The discussion paper included a proposed framework for LDT oversight that would focus on "new and significantly modified high and moderate risk LDTs." Previously marketed LDTs would be grandfathered and would not be expected to comply with most or all FDA regulatory requirements, such as premarket review, unless necessary to protect the public health. In addition, new and significantly modified LDTs in several specified categories (e.g., LDTs for rare diseases) would generally not be expected to comply with FDA regulatory requirements.

COVID-19 Pandemic

The COVID-19 pandemic highlighted issues with LDT regulation, specifically how the enforcement discretion policy interacted with a public health emergency and its related requirements. Many LDT developers, for example, did not recognize that COVID-19 LDTs had to have an Emergency Use Authorization (EUA) prior to test marketing or clinical use. This requirement was unfamiliar to many LDT developers, and in an effort to facilitate access to testing, FDA developed a COVID-19 test policy allowing certain laboratories to clinically use their LDTs after notification to the agency but prior to FDA granting an EUA for the test. Subsequently, FDA reported that this modification, in combination with the EUA's lesser evidentiary standard, resulted in the use of LDTs that "proved to have performance problems or to be poorly validated."

In August 2020 the Department of Health and Human Services (HHS) announced that, during the height of the COVID-19 pandemic, it was rescinding all guidance, compliance manuals, website statements, or other informal issuances concerning FDA premarket review of LDTs. This announcement applied to all LDTs—including COVID-19 LDTs—and stated that FDA could not require premarket review for these tests absent a notice-and-comment rulemaking process. Although this policy was eventually rescinded in November 2021, it highlighted potential challenges for the agency proceeding with oversight of LDTs through agency level guidance rather than formal rulemaking.

Recent FDA Oversight: 2023-2025

As noted, in May 2024, FDA published a final rule to phase out its policy of enforcement discretion over LDTs, and that rule was subsequently vacated by the district court. The LDT final rule would have adopted a single amendment to the existing regulatory definition for *in vitro diagnostic products* to clarify that IVDs, where the manufacturer is a clinical laboratory, meet the definition of *device* under the FFDCA (21 C.F.R. §809.3). In September 2025, FDA published a final rule to revert "to the text of the regulation as it existed prior to the effective date of the May 2024 final rule."

The phaseout policy for FDA's enforcement discretion approach for LDTs outlined in the final rule would have required compliance with device regulatory controls (e.g., adverse event reporting, labeling, premarket notification) to be phased in over a period of approximately four years with respect to IVDs manufactured and offered as LDTs. The timing of the policy was to have been based on time from publication of the final rule. The phasing out of FDA's enforcement discretion approach, in addition to being viewed as addressing FDA's stated public health concerns with LDTs, was viewed by some stakeholders as a way to level-set regulation of LDTs and traditional commercial IVDs. The different regulatory approach for these tests has been highlighted as a concern by IVD manufacturers.

The phaseout policy would have included five stages. For example, one year after publication of the final rule, manufacturers of IVDs offered as LDTs were to have complied with medical device adverse event reporting (MDR, 21 C.F.R. Part 806), reports of corrections and removals (21 C.F.R. Part 803), and quality system (QS) requirements regarding complaint files (21 C.F.R. §820.198). Two years after publication of the final rule, manufacturers of IVDs offered as LDTs would have been required to comply with additional regulatory controls *other than* QS regulation and premarket review requirements, for example, labeling (21 C.F.R. Parts 801 and 809), registration and listing (21 C.F.R. Part 807 other than Subpart E), and investigational device requirements (21 C.F.R. Part 812). Three and a half to four years after the rule's publication, manufacturers of IVDs offered as LDTs would have had to come into compliance with premarket review requirements (e.g., premarket notification, De Novo classification request, PMA).

Discerning the applicability of the final rule would have been complex, as certain categories of LDTs would have fallen outside the scope of the phaseout policy (e.g., tests developed for emergencies under FFDCA Section 564) whereas certain categories would have remained under a policy of complete enforcement discretion (e.g., 1976-type LDTs).

Issues for Consideration

The 2025 district court ruling vacating FDA's final LDT rule and holding that LDTs are not devices raises considerations, which may include, for example:

- What is the specific scope of the district court's definition of LDT? How does that relate to FDA's definition of the term?
- Will, and if so how might, FDA's expertise and experience with LDTs be leveraged?
- Will LDT developers lack access to policies predicated on FDA marketing authorization? Will developers be able to seek authorization voluntarily?
- How will existing premarket authorizations for LDTs be considered?
- Are there implications for FDA's regulation of other products, particularly those that are not tangible, such as software as a medical device (SaMD)?

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