Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

District Court Rules FDA Lacks Authority to Regulate Laboratory Developed Tests

Updated May 19, 2025

On March 31, 2025, the U.S. District Court for the Eastern District of Texas ruled—in two consolidated cases, *American Clinical Laboratory Association (ACLA) v. FDA* and *Association for Molecular Pathology (AMP) v. FDA*—that the Food and Drug Administration (FDA) lacks statutory authority under the Federal Food, Drug and Cosmetic Act (FD&C Act) to regulate laboratory developed tests (LDTs). LDTs are diagnostic tests that examine specimens derived from the human body such as blood or tissue and are designed, manufactured, and used within a single laboratory, as opposed to being commercially available as "test kits." Examples of LDTs include some forms of COVID-19 tests, genomic testing for cancer, and most newborn screening tests. As LDTs increased in complexity over the years—and as the earlier phases of the COVID-19 pandemic shined a spotlight on them—their regulation has been a subject of ongoing debate, including by Congress.

Historically, FDA has maintained that it has clear regulatory authority over LDTs because they are medical devices. At the same time, the agency had, until May 6, 2024, claimed to exercise enforcement discretion over LDTs—i.e., the agency had chosen not to enforce applicable device regulations for LDTs. On May 6, 2024, however, FDA issued a final rule (final LDT rule) that generally subjected LDTs to regulation under the FD&C Act. Members of the laboratory industry challenged the rule. Siding with the plaintiffs, the district court—in a case closely watched by industry—held that the final LDT rule exceeds FDA's statutory authority because LDTs are medical test services rather than devices. This Legal Sidebar provides background on FDA's final LDT rule and related legal issues, an overview of the district court's decision, and certain considerations for Congress.

Background

The regulation of LDTs implicates two existing federal laws: (1) the FD&C Act, which regulates various products including medical devices; and (2) the Clinical Laboratories Improvement Act of 1967 (CLIA), which, as amended by the Clinical Laboratory Improvement Amendments of 1988, provides the regulatory framework for clinical laboratories.

Congressional Research Service
https://crsreports.congress.gov
LSB11312

Medical Device Regulation

Under the FD&C Act, a "device" subject to FDA regulation is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" that is "intended for use in the diagnosis of disease or other conditions . . . in man or other animals." Historically, FDA has maintained that LDTs are a subset of in vitro diagnostic (IVD) devices, which are devices used in the analysis of human samples for diagnostic purposes, and include reagents, instruments, and systems used in the testing. As with other medical devices subject to regulation under the FD&C Act, FDA uses a risk-based regulatory approach for IVDs. Depending on their intended use and risk relative to that use, IVDs receive one of three risk classifications with different degrees of control. Class I devices are considered low risk. Such devices are only subject to general controls, which include, for example, requirements regarding establishment registration, device listing, good manufacturing practices, and labeling. Although premarket notification is a general control, Class I devices are generally exempt from this requirement, meaning they do not usually need to receive FDA clearance before being marketed. Moderate risk devices (Class II) must comply with general controls, are generally subject to the premarket notification requirement, and may be subject to additional device-specific special controls. Class III devices are high risk; in addition to complying with general controls, they are generally required to receive a premarket approval (PMA) prior to marketing, which is the most rigorous form of premarket review for devices.

Although FDA has long asserted authority to regulate LDTs as a type of IVD, the agency has, up until 2024, exercised enforcement discretion with respect to LDTs. This meant that FDA had historically focused its oversight of IVDs on diagnostic test kits that are broadly marketed to laboratories or the public—for example, some clinical genetic assays and over-the-counter pregnancy tests. With respect to LDTs that are developed, validated, and utilized within a single laboratory, FDA had opted not to enforce IVD requirements on LDTs.

Clinical Laboratory Regulation

Clinical laboratories offering LDTs are subject to CLIA, which is administered by the Centers for Medicare & Medicaid Services (CMS). Under CLIA and its implementing regulations, clinical laboratories must be certified by CMS or accredited through certain CMS-approved accreditation organizations. In addition, testing performed by a laboratory must be provided by skilled and credentialed professionals with certain oversight by a laboratory director, who must ensure that the laboratory's test methodologies are "capable of providing the quality of results required for patient care." Laboratory testing services are subject to certain quality controls, including maintenance and function checks, calibration and control procedures, and ongoing quality monitoring. CLIA requires laboratories to demonstrate the proficiency of their tests multiple times a year. In response to FDA's assertion of regulatory authority over LDTs, some representatives of clinical laboratories and manufacturers of LDTs, such as the ACLA, had asserted that LDTs are professional clinical services that are regulated by CMS under CLIA and fall outside of FDA's jurisdiction.

FDA's Final LDT Rule

As LDTs grew in complexity, and as COVID-19 test development and deployment during the pandemic shined a spotlight on LDTs, both Congress and FDA focused on LDT regulation leading up to 2022. The Senate, in 2022, incorporated into the FDA user fee reauthorization bill a legislative proposal—the Verifying Accurate, Leading-edge, In Vitro Clinical Tests Development (VALID) Act—that would have imposed a comprehensive regulatory regime for both IVDs and LDTs. The VALID Act was not, however, included in the enacted law.

In October 2023, FDA published a proposed rule to make explicit that LDTs are included as IVDs subject to FDA regulation. The agency finalized the rule on May 6, 2024. Under the final rule, FDA amended the regulatory definition of "in vitro diagnostic products" to include LDTs by adding to the definition that IVDs "includ[e] when the manufacturer of these products is a laboratory." The final LDT rule additionally outlines how FDA plans to phase in the relevant device regulatory controls over a period of approximately four years, starting with requirements related to adverse event reporting and reports of corrections and removals.

The District Court Order in *ACLA v. FDA* and *MPA v. FDA*

In two separate lawsuits, certain trade and professional organizations, laboratories, and physicians sued to challenge the final LDT rule, and the cases were consolidated before the U.S. District Court for the Eastern District of Texas. In the suits, the plaintiffs argued that FDA exceeded its statutory authority in regulating LDTs as IVDs because LDTs are professional clinical services that are not "devices" subject to the FD&C Act. In response, FDA argued that LDTs meet the FD&C Act's definition of "device" because LDTs are test systems that consist of "apparatus[es]," "contrivance[s]," and articles that are "similar or related" to "instrument[s]" and "in vitro reagent[s]," and that are intended for use in the diagnosis of disease. Siding with the plaintiffs, the district court—adopting the plaintiffs' characterization of LDTs as "laboratory test services" that are performed "on blood, urine, tissue, or other types of specimens at the request of an individual physician"—held that such services are not "devices" within the meaning of the FD&C Act. This conclusion, in the court's view, is supported by the statutory text, canons of statutory construction, and the context and history of the FD&C Act and CLIA.

With respect to the statutory text, the court concluded that both the ordinary meaning of the terms included in the "device" definition, as well as other relevant FD&C Act provisions, exclude intangible services from the definition of a device. In particular, in the court's view, the ordinary meanings of the terms "instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent" all refer to tangible or physical objects, and would therefore not have included an intangible testing service. According to the court, this conclusion is consistent with the FD&C Act's provision directing FDA to regulate "any food, drug, device, tobacco product, or cosmetic" that is "introduc[ed] into interstate commerce"—language that reflects a congressional intent to authorize FDA to regulate "only commercially distributed medical 'devices,'" or test kits, and not "professional medical services that are qualitatively and categorically different from the tangible goods." This distinction, in the court's view, is further reflected in the final LDT rule, which untenably stretches the meaning of "manufacturer"—which the court found, in common parlance, refers to an entity that makes physical objects—to include a laboratory that provides testing services. In concluding that LDTs are not devices, the court rejected FDA's argument that certain definitions of the terms "apparatus" and "contrivance" encompass intangible processes.

The court also concluded that two canons of statutory construction—*ejusdem generis* and *noscitur a sociis*—bolstered its interpretation that the plain language of the FD&C Act excludes LDTs from the definition of devices. Canons of construction are guiding principles developed by courts that supply default assumptions about the way Congress expresses meaning, and are sometimes used by courts to resolve statutory ambiguities. Under the *ejusdem generis* canon, a general, catchall term that follows an enumerated list of specific ones is limited in meaning to matters similar to those specifically identified. According to the court, this canon is relevant to the FD&C Act's definition of "device" because the definition lists seven examples (instrument, apparatus, implement, machine, contrivance, implant, and in vitro reagent), followed by the catchall phrase "or other similar or related article." The application of this canon, the court reasoned, means that the catchall phrase includes only materials similar to the preceding list of specific, physical items, and forecloses FDA's expansive reading of the catchall phrase to include intangible testing services. Similarly, the canon of *noscitur a sociis* provides that a word is "given more

precise content by the neighboring words with which it is associated." The application of this canon, the court reasoned, further supports interpreting "apparatus" and "contrivance" in this context in a manner consistent with the neighboring words in the statute. Because the other words in the statutory definition of device (instrument, implement, machine, implant, and in vitro reagent) are all physical objects, the court declined to read "apparatus" or "contrivance" to cover "methodologies, processes, or professional services."

The court further concluded that the broader context of the statutory scheme and the history of the FD&C Act and CLIA support its conclusion that LDTs are not devices. In the court's view, Congress enacted the FD&C Act to address concerns with "faulty manufactured products," not laboratory test services. To regulate clinical laboratories engaged in interstate commerce and their test services, the court observed, Congress enacted CLIA. Under CLIA, CMS oversees the regulation of clinical laboratories and their tests, and requires clinical laboratories to be certified, to comply with quality control standards, and to participate in regular proficiency testing. In concluding that LDTs are federally regulated only by CLIA, the court rejected FDA's argument that, when Congress amended CLIA in 1988, FDA already had authority to regulate LDTs but was exercising enforcement discretion in not applying the relevant medical device requirements to LDTs. The court observed that, whereas CLIA's legislative history is "replete with references to the overlapping standards of CLIA, the Medicare statute, and of state regulations," any reference to FDA was "[c]onspicuously absent." This silence, in the court's view, provided "no indication that [CLIA's] changes contemplated a role for FDA."

Based on its conclusion that LDTs are not "devices" under the FD&C Act, and that FDA therefore exceeded its statutory authority in issuing the final LDT rule, the court vacated the rule and remanded the matter to FDA. The court issued its opinion on March 31, 2025.

Considerations for Congress

It is unclear what, if any, additional actions FDA will take following the district court's decision. The agency may seek to appeal the district court's decision and continue to defend the final LDT rule. The agency may also opt not to appeal and decide to take no further action following remand. Taking no further action could effectively mean that, as was the case before the issuance of the final rule, most if not all LDTs are subject only to indirect federal regulation through CLIA, which regulates the clinical laboratories in which LDTs are performed, and not to direct federal regulation under the FD&C Act. FDA may also further clarify its policy with respect to LDTs through guidance.

The regulation of LDTs has been of interest to some Members of Congress. Bills that would have established a regulatory framework for both IVDs and LDTs were introduced in the 116th, 117th, and 118th Congresses. Depending on what Congress determines to be the appropriate regulatory framework for LDTs, Congress could decide that no further legislative action is needed at this time because LDTs, notwithstanding the dispute regarding FDA's jurisdiction over them, are regulated through CLIA's regulation of clinical laboratories. Alternatively, Congress could respond to the vacatur of the final LDT rule by enacting legislation that expressly provides for direct regulation of LDTs.

Author Information

Dorothy C. Kafka
Legislative Attorney

Wen W. Shen
Legislative Attorney

Disclaimer