

Laboratory Developed Tests Rule Vacated Ahead of FDA's First Compliance Deadline

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On March 31, 2025, Judge Jordan of the Eastern District of Texas vacated FDA's final rule regulating Laboratory Developed Tests (LDTs) just shy of the FDA's first compliance deadline under the rule, which would have become effective on May 6, 2025. For more information about the LDT Rule, its requirements and deadlines, as well as the surrounding uncertainty and controversy leading up to this decision, see our December 2024 article, "[A Closer Look at FDA's Controversial Rule on Laboratory Developed Tests.](#)"

What Did the Court Have to Say About the LDT Rule?

Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA has the authority to regulate medical "devices." FDA's LDT Rule was promulgated on the theory that LDTs have always met the definition of devices under the FDCA, but that FDA had merely declined to exercise its statutory authority to regulate them prior to its enactment of the LDT Rule. The court, however, disagreed with this contention, ruling, instead, that the FDA's attempt to regulate LDTs exceeded the agency's statutory authority under the FDCA, citing as support: the statutory text of the FDCA, the historical context underlying its enactment (and the distinguishable enactment of CLIA), Congressional intent, and applicable canons of construction.

As expected, the Loper Bright case played a vital role in the court's assessment, as such case (which overturned the longstanding policy of judicial deference to agency decisions under Chevron) mandates that courts "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority." Thus, the court must determine the "best reading of a statute," and an agency's "merely 'permissible' reading is not enough."

1. FDCA's Definition of Device

The FDCA defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory." In interpreting the "device" definition, the court considered the plain meaning of the listed items, which "ordinarily refer to tangible, physical products." This is distinguishable from LDTs, which the court deemed to be professional services performed by clinical labs, consistent with the longstanding argument against FDA's jurisdiction over LDTs. Thus, the court reasoned, while FDA may regulate certain equipment that may be utilized in the performance of LDTs, the LDTs, themselves, are not tangible products, but rather "process[es] and methodolog[ies]."

In addition, the court found that interpreting "device" under the FDCA to include LDTs "sits uncomfortably with" other FDCA provisions. For instance, the court highlights that an application for premarket approval of a device requires a description of: (1) components and ingredients, and (2) methods, facilities, and controls used in manufacturing and processing. These requirements, according to the court, distinguish devices from LDTs because LDTs do not have "ingredients, properties, or components," nor are they "manufactured [or] processed."

2. FDCA v. CLIA – Legislative History and Congressional Intent

The court pointed to the distinct legislative histories of the FDCA and CLIA to discredit FDA's asserted authority over LDTs, noting that the FDCA was enacted in 1938 and amended by the Medical Device Amendments (MDA) in 1976 to give FDA the authority to regulate medical devices as needed to ensure their safety and effectiveness. In contrast, CLIA was enacted in 1967, as amended by the Clinical Laboratory Improvement Amendments in 1988, to provide CMS the necessary oversight to ensure the accuracy and reliability of clinical laboratory testing. The court explained that Congress never indicated any overlap between these two regulatory schemes, but rather viewed ensuring medical device safety and efficacy and ensuring laboratory-testing accuracy and reliability as two "distinct problems requiring different regulatory solutions." Further, the court found the absence of any reference to FDA's alleged preexisting authority over LDTs in the statutory text of CLIA or related legislative history to be a clear indication that Congress never intended for LDTs to fall within the scope of the FDCA, especially since (1) Congress's stated objective in amending CLIA in 1988 was to establish a "unified regulatory mechanism" to replace the "patchwork of inconsistent and overlapping standards" to which clinical labs were then-subject, and (2) the various "references to the overlapping standards of CLIA, the Medicare statute, and [] state regulations" in legislative documents. Considering these circumstances, the court found that "[t]his legislative silence" spoke volumes.

While the court expressly noted that the "FDCA's text, alone, is enough to conclude that FDA lacks authority to regulate [LDT] services as medical 'devices'," it addressed the historical context surrounding the enactment of the MDA in 1976 and the subsequent CLIA amendments in 1988 to reinforce its court's conclusion that the enactment of the LDT Rule was FDA's attempt to assert authority that Congress never granted to the agency. Turning to common sense, the court explained that there would have been no practical reason to enact the CLIA amendments in 1988 if FDA already had the authority to regulate "those same tests." In other words—more specifically, the court's words—FDA's argument that the MDA authorized FDA to regulate LDTs "cannot be sustained without rendering CLIA largely, if not entirely, pointless."

So . . . What Now?

Following the court's decision to vacate the rule, LDT manufacturers are effectively relieved from any obligation to comply with FDA's device regulations in accordance with the "phaseout policy," the first stage of which was set to take effect next month (May 2025). Thus far, the government has not indicated whether it intends to appeal this decision. However, an appeal at this point would come as a surprise given the policies and statements that the current administration has made to-date in relation to the LDT Rule, as well as its promises to overhaul any FDA policies viewed as unduly restrictive.

Importantly, the court reaffirmed the FDA's authority to regulate other in vitro diagnostics (IVDs), which are squarely within the definition of "device" under the FDCA. Accordingly, as noted in our [prior article on the LDT Rule](#), any companies that currently believe the IVDs they make, distribute, and/or sell are not subject to FDA oversight because they meet the definition of an LDT should consider consulting with legal counsel to confirm, as the current period of confusion and uncertainty in relation to FDA amid the transition to the new administration could serve as a useful time for industry to check in on, update, and/or improve compliance-related policies.

We will continue to monitor this area for further developments, including whether the government files an appeal before the 60-day window for doing so expires. For more FDA-related news and insights in the meantime, visit [HB At The Counter](#) or contact a member of our [FDA Regulatory and Compliance Team](#).