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District Court Vacates FDA LDT Rule; What's Next for Regulation of Lab Testing?

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On March 31, 2025, Judge Sean D. Jordan of the U.S. District Court for the Eastern District of Texas issued an opinion and judgment in *American Clinical Laboratory Association v. FDA*. Judge Jordan's decision vacates and sets aside the Food & Drug Administration's (FDA) final rule, Medical Devices; Laboratory Developed Tests (the LDT Rule).[1] The LDT Rule would have required laboratories offering LDTs to meet medical device requirements. The preamble to the LDT Rule provided a multi-stage phase out of FDA's enforcement discretion policy, under which the first set of regulatory requirements would have been actively enforced beginning May 6. While many labs are breathing a sigh of relief after the publication of this order, questions remain as to how the agency will proceed and the broader implications for regulation of lab tests and in vitro diagnostics generally.

In his decision, Judge Jordan concluded that the definition of "device" in the Food, Drug and Cosmetic Act did not, as the plaintiffs argued, extend to LDTs, which he characterized as "laboratory-developed test services." He found that this definition, as well as those included in 1973 and 1977 device-related rulemakings, indicated that the term "device" applies to "tangible, physical products" and could not be read to extend to the kind of professional services involved in the development and running of LDTs. He also interpreted the concept of an "IVD test system" as an improper expansion of the device definition. The court distinguished software as a medical device, which *is* regulated by FDA, explaining in a footnote that "while it is possible to conceive of "software in the abstract: the instructions themselves detached from any medium," "[w]hat retailers sell, and consumers buy," are "tangible," "physical cop[ies] of the software" that, whether "delivered by CD-ROM" or "downloaded from the Internet," are ultimately "contained in and continuously performed

by" a piece of physical hardware such as a computer." *See American Clinical Laboratory Assoc. v. FDA*. (quoting *Microsoft Corp. v. AT&T Corp*., 550 U.S. 437, 446–48, 449–51, 127 S.Ct. 1746, 167 L.Ed.2d 737 (2007)).

The court also pointed to Congress' passage of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as its decision not to enact the VALID Act or the VITAL Act (both of which were intended to clarify FDA's role in regulating LDTs), as further evidence that FDA lacks authority over LDTs. In addition, the court noted that the projected economic impact of the LDT Rule on laboratories was such that congressional action would be required to implement such a change.

The government has 60 days to appeal the decision, although whether it will do so is unclear. In the meantime, FDA will have to contend with a variety of key questions emanating from the decision, such as how to define the line between the type of "service" that the court held is not a device, whether and to what extent the agency can re-focus its regulatory and compliance resources on tangible device components of "test systems" (including software) used by labs, and the implications for those LDTs for which labs were actively seeking clearance or approval as a device. More broadly, FDA's consideration of these questions will take place against the backdrop of an actively changing landscape at FDA as the agency undergoes significant workforce changes under new leadership. While members of Congress have offered a number of reform proposals for in vitro diagnostics, there are no immediate prospects for legislative action.

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1 For more information about the LDT Rule, click here.

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