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A Texas Federal Court Sides with Laboratories, But There May Be Unintended Consequences for FDA

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The obvious result of the legal shootout between the U.S. Food & Drug Administration (FDA) and clinical laboratory trade associations, the American Clinical Laboratory Association and the Association for Molecular Pathology, in the Eastern District of Texas to determine whether the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits the agency to regulate laboratory developed tests (LDTs) is a complete victory for clinical laboratories. The U.S. district judge's decision, issued on March 31, 2025, vacated the May 2024 final rule through which FDA sought to specify that LDTs are agency-regulated in vitro diagnostic products (IVDs) and to describe a plan for phasing-in enforcement of existing medical device regulations for such products over four years (see our previous posts on the LDT final rule here and here). In adopting the plaintiffs' arguments wholesale, however, the judge created some incongruities in the relevant regulatory frameworks, as well as several quandaries for FDA and the clinical laboratory industry going forward. These inconsistencies could have greater consequences down the road if the Trump administration decides not to appeal the ruling.

The key issue at the core of the *ACLA v. FDA* litigation was whether LDTs are "devices" as defined in the FD&C Act and thus subject to FDA's regulatory authority under the Act. The answer to this question could have been decided on much more narrow grounds than it ultimately was. In particular, the judge could have decided that the distinction between the design and manufacture of a laboratory-based diagnostic assay – which is, essentially, an assembly of individual medical devices and equipment and a predetermined methodology for specimen collection and analysis – and the performance of the assay by lab professionals is too vague to support the argument that such diagnostic assays are definitively medical devices under the statute. Instead, the judge's opinion broadly held that LDTs cannot be medical devices because they are not physical, tangible products and because "no article of personal property is transferred such that title passes from one party to another" in the commercialization of an LDT.

By framing his determination in the broadest way possible, the judge implicates other aspects of FDA's regulatory authority, which could be used to challenge the agency in the future. Some of these potential future consequences include:

1. The court concluded that only LDTs (diagnostic assays that are designed, manufactured, validated, and used within a single laboratory that is CLIA-certified for high-complexity testing) are not subject to FDA regulations because they are clinical laboratory professional services rather than products and that the agency was only authorized by Congress to oversee "material things or products, not medical methodologies, processes, or services." But FDA presumably continues to regulate any diagnostic assay developed by multiple entities and performed by one or more laboratories as an IVD subject to medical device regulations, because such an assay would not fall within the agreed-upon definition of an LDT. The outcome of this dichotomy is that, for the moment, FDA cannot regulate a diagnostic assay designed and performed by a single laboratory because that is a service rather than a product, but it can regulate as a product a diagnostic assay designed and performed by multiple laboratories. A plain text reading of the statutory definition of "device" does not provide support for such an interpretation, so it would be unlikely to prevail. Such an inconsistent outcome is likely to become the subject of a future lawsuit, due to the arguably unfair application of the FD&C Act to clinical laboratories performing multi-lab versus single-lab diagnostic assays.
2. The judge's opinion implies that software cannot be a medical device because it is intangible and not a physical product that could meet one of the terms listed in the Act's definition of device. In addition, when software is commercialized, the customer typically accepts a license to use the software (especially for software as a service arrangements, in which all or much of the software is cloud-based), so no "title" for an item of personal property passes from the seller to the customer. Such an interpretation of the ACLA v. FDA district court decision could trigger massive lawsuits seeking to liberate software intended for medical uses from FDA's jurisdiction, even though Congress has recognized through recent amendments to the FD&C Act – such as in the 21st Century Cures Act from 2016 and the Food and Drug Omnibus Reform Act of 2022 – that standalone software can be a medical device depending upon its intended use.
3. In addition, due to the district judge's determination that LDTs are not devices, our expectation is that FDA will no longer accept submissions for device pre-market review of LDTs—even voluntary submissions, which the agency previously accepted from any clinical laboratory interested in obtaining regulatory authorization for its assays—because the agency cannot provide authorization to "professional services" that fall outside of its statutory authority. This outcome denies clinical laboratories access to FDA device authorization pathways, which are widely recognized by payors and customers as official confirmations of a diagnostic assay's safety and quality. Furthermore, LDTs will no longer qualify for Breakthrough Device designation and the potential expedited pathways to coverage and reimbursement (a prior post discusses that topic, here). The loss of such regulatory options may have a significant impact on clinical laboratories that have already committed resources toward obtaining pre-market authorization from FDA in anticipation of the final rule becoming fully effective or that may have been depending on a Breakthrough Device designation to attract investors. It is also unclear what may happen to LDTs that have already been granted such a designation from FDA's Center for Devices and Radiological Health.

Although clinical laboratories have hailed the decision in the case as a return to the status quo (presumably of LDTs not being subject to active FDA regulation), the reality is much different—it creates a striking vacuum in the U.S. regulatory framework for LDTs. Before ACLA v. FDA was decided, the agency exerted some oversight over the design, safety and efficacy of LDTs and could issue warning letters or initiate investigations into laboratories developing tests that could harm patients or adversely affect public health, even though clinical laboratories historically denied that FDA had any such authority. According to the district court, however, FDA does not have any

oversight role in the safety and efficacy of LDTs due to the unambiguous holding that they are not and have never been “devices.” The Centers for Medicare & Medicaid Services (CMS), which regulates laboratory professionals and operations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), previously stated in the context of the litigation that it has no authority over the safety and efficacy of LDTs so it seems unlikely that CMS would attempt to fill the new regulatory gap. It is important for labs to keep in mind, however, that even though the limited oversight authority that FDA had to mitigate or address potential harm to patients from LDTs is now gone, the agency has alternative methods of monitoring clinical laboratories with respect to FD&C Act compliance as we discuss here.

This is just a brief look at the potential fallout from ACLA v. FDA if the Trump administration’s FDA and Department of Justice decide not to appeal the ruling; while any previous administration definitely would file an appeal, given the breadth and possible unintended consequences of this ruling, but the actions of the current administration are difficult to predict. The district court’s decision in this case is a new major inflection point in the regulatory history of IVDs, and stakeholders should pay close attention to how the laboratory and IVD industries, medical professionals, regulatory agencies, and politicians respond. We will continue to monitor and report on key developments in this space.

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