CAPITOL STREET

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Lab Developed Test Rules Gone

Positive for Clinical Labs

Relevant Companies

Our Take & Next Up

The Court ruling strikes down the LDT guidance in its entirety, good news for the clinical lab industry. Today, the Eastern District Court of Texas vacated entirely the FDA's Final Rule on laboratory developed tests here. The FDA will likely choose to accept the ruling and rescind the guidance, which lightens the potential regulatory burden at a time of new leadership with likely similar ideology and extreme staffing cuts. However, if the agency believes that the ruling may have implications for the agency's ability to regulate medical devices at large, the FDA (under Commissioner Makary) could choose to appeal the decision made by the court. We think the latter is less likely.

Key Points

A District Court struck the LDT guidance, citing violation of the *Administrative Procedure Act (APA)*.

- District Judge Sean Jordan agreed with ACLA (American Clinical laboratory Association) and AMP (Association for Molecular Pathology) that the agency overreached their statutory jurisdiction and authority because it treats laboratory testing services as medical devices. However, the judge disagreed that the rule was arbitrary and capricious, an abuse of discretion.
- ACLA & AMP argued that the FDCA make clear that a "device is a physical product, not a professional service". They also stated that CLIA (Clinical Laboratory Improvement Amendments) provides the "distinct and uniform system of regulation for clinical laboratories".

The FDA will likely accept the ruling and rescind the LDT guidance. The agency is facing severe staffing cuts and may accept the loss in light of the potential regulatory burden of adding LDTs onto their reviews. It is also in the agency's interest to maintain focus and stability at the FDA which may lead to the agency rescinding the rule to focus on the quality of their current reviews.

Could legislation be back? Yes, but the *VALID Act* is likely dead (our prior *VALID Act* analysis here). We would expect an IVD (In-vitro diagnostics) model. We could see IVD reform and perhaps a CLIA-type model endorsed by Congress in the future.

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