

CAPITOL STREET

April 29, 2024

FDA Will Regulate Lab Developed Tests

Four Year Phase In; Lawsuits Likely Ensnare

Relevant Companies



»» Our Take & Next Up

Today, FDA released final guidance ([here](#)) on regulating LDTs as medical devices ...Lawsuits are expected next from industry stakeholders as FDA doubles down on its assertion that LDTs are potentially inaccurate. FDA notes that today's LDTs are, among other things, used more widely by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions. In this regard, today's LDTs are similar to other IVDs that have not come within FDA's general enforcement discretion approach. We look to a potential legal showdown as putting the ball back in Congress's court, post-election, with the potential for a revived VALID Act type phased-in framework (and user fees for FDA) coming back into play. As a reminder, VALID was deemed as more palatable to industry as a way to regulate LDTs.

»» Key Points

FDA will regulate Laboratory-Developed Tests (LDTs) as medical devices. The FDA asserts that the new regulatory framework is needed as the risks associated with LDTs are much greater today and lie beyond what an 'enforcement discretion' can provide. And while the agency acknowledges that the laboratories occupy a distinct role in diagnostic testing (they are the entities that generally perform the tests), the agency argues that a device that is manufactured in connection with a medical service or procedure still fall under FDA's jurisdiction.

- **FDA notes IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory.**
- **FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs (i.e., FDA's expectations for compliance will generally be the same).** This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs.

- **FDA will be doing targeted enforcement for several categories of IVDs manufactured by a laboratory.** FDA may update any of these enforcement discretion policies as circumstances warrant or if the circumstances that inform these policies change, consistent with FDA's good guidance practices.

Recall the FDA sought comment on how to handle tests by smaller laboratories that fall below a certain threshold (<\$150 K a year) & on academic medical centers (AMCs). For AMCs, the FDA will allow for an "unmet need" exemption and not enforce premarket review and QS requirements for LDTs where there is no available FDA-authorized IVD that meets the patient's needs manufactured and performed by a laboratory integrated within a healthcare system. FDA will continue enforcement discretion on LDTs that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYSDOH CLEP).

The rule is economically "significant" with a ~\$1.33 B cost to FDA/industry, FDA asserts the savings (averted health losses) will outweigh the costs.

- The annualized costs (to labs) range from \$566 M to \$3.56 B at a 7% discount rate, with a primary estimate of \$1.29 B, and from \$603 M to \$3.79 B at a 3% discount rate, with a primary estimate of \$1.37 B. *FDA quantifies costs to affected laboratories for complying with statutory and regulatory requirements. Additional costs include costs to FDA, which we include in our estimates*
- FDA estimates that the annualized benefits over 20 years range from \$1 B to \$11 B at a 7% discount rate, with a primary estimate of \$3.51 B, and from \$1.24 B to \$13.62 B at a 3% discount rate, with a primary estimate of \$4.34 B. *FDA quantifies benefits to patients from averted health losses due to problematic IVDs offered as LDTs and focuses mainly on certain broad disease categories associated with the majority of misdiagnosis-related harms in the US. Additional benefits include averted non-health losses from reduced spending on problematic IVDs offered as LDTs and unquantified reduction in costs from lawsuits.*

There will be a 4-year phase out period (unchanged from proposed) for all LDTs manufactured and offered by labs that are CLIA certified (even if they are not designed and used within a single lab). The FDA noted that many IVDs manufactured by labs are currently being marketed as LDTs, and that a sudden change could negatively impact the public. As a result, the agency is offering a phase out period of several years that will end no earlier than 2028.

- **Stage 1 (1 year after final guidance):** End the general enforcement discretion approach for medical device report (MDR) requirements and correction and removal reporting requirements 1 year from publication of this final rule.
- **Stage 2 (2 years after final guidance):** End the general enforcement discretion approach for requirements other than MDR, correction and removal reporting, quality system, and premarket review 2 years from publication of this final rule.
- **Stage 3 (3 years after final guidance):** End the general enforcement discretion approach for quality system requirements 3 years after FDA publishes a final phaseout policy.
- **Stage 4 (3.5 years after final guidance):** End the phaseout for the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs offered as LDTs should occur 3½ years from publication of this final rule. This timeline aligns the phaseout for the general enforcement discretion approach with the start of FY 2028 (Fall 2027), the beginning of a new user fee cycle. FDA highlights that this alignment allows for industry participation in negotiations for the next user fee cycle with the knowledge that laboratory manufacturers will be expected to comply with premarket review requirements.
- **Stage 5 (4 years after final guidance):** End the general enforcement discretion approach for premarket review requirements for moderate risk and low risk IVDs 4 years from publication of this final rule.

The FDA also highlights exceptions to the new pathway including blood donor screening tests, tests intended for emergencies, and direct-to-consumer tests. These tests will still be regulated as before as donation testing centers have generally complied with FDA registration requirements. FDA will also exclude Human Leukocyte Antigen (HLA) tests that are used with transplants. The agency will also continue to allow enforcement discretion on “1976-Type LDTs”, which use manual techniques (without automation) by laboratory personnel with specialized expertise, and use components legally marketed for clinical use.

Ipsita Smolinski
Managing Director | Capitol Street
ipsita@capitol-street.com

202.250.3741 | www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET

Copyright 2024 Capitol Street.

This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments