

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...

Want to keep reading or learn more?

Contact team@capitol-street.com

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

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

202.250.3741 | www.capitol-street.com

CAPITOL STREET