CAPITOL STREET

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New FDA Pathway Would Regulate Diagnostic Tests

Expect Lawsuits If Finalized & Congress May Step In

Relevant Companies

Today, the FDA released proposed guidance on how they plan to regulate laboratory developed tests (LDTs) here. The guidance asserts that device definition in the Federal Food, Drug, and Cosmetic (FD&C) Act does not differentiate between entities manufacturing the device and as a result LDTs will be regulated under FDA's medical device authorities. FDA intends to phase out general enforcement discretion approach so that LDTs will fall under the same enforcement approach as other IVDs.

Our Take & Next Up

The new pathway places LDTs under the FDA's medical device authorities and will likely invite lawsuits if finalized. A 60-day comment period will ensue. If finalized as proposed during 1H 2024, we believe that lawsuits will ensue. Congress could also step in to "fix" the regulatory pathway via a tweaked version of VALID Act. The FDA has asserted for years that LDTs are medical devices but simply did not require approval due to "enforcement discretion". The legal basis of categorizing LDTs as devices has several issues as LDTs may not satisfy the separate "commercial distribution requirement" of premarket review for medical devices as they are made and used in one location. Labs at public health centers and academic medical centers may not be required to register, undergo premarket review, or conduct adverse event reporting due to statutory definitions of who is subject to regulations.

Key Points

Lawsuits are likely as the industry asserts that the FDA is overstepping existing authorities. The industry is pushing back with the American Clinical Laboratory Association (represents clinical laboratories including DGX, LH), maintaining that LDTs are not medical devices. The FDA anticipated legal pushback with the guidance detailing their legal arguments for regulating diagnostics by labs as devices.

- The FDA claims to have regulatory authority over all IVDs under the Medical Device Amendments (MDA) of 1976 and Congress did not make an exception for devices manufactured by laboratories.
- The FDA also is relying upon court decisions (*United States v. Regenerative Sciences*) that determined that articles manufactured by medical professionals fall within FDA's jurisdiction to make their case. The agency also asserts that CLIA did not repeal FDA's authority over IVDs manufactured by laboratories.
- The agency also asserts that Congress supported regulating lab diagnostics as devices because they list 510(k) clearance or premarket approval as one of the bases for Medicare payment for an "advanced diagnostic laboratory test" in Protecting Access to Medicare Act of 2014 (PAMA).

The FDA will collect feedback on the proposed rule for 60 days, with no timing on a final guidance. The FDA seeks comment on how to handle tests by smaller laboratories that fall below a certain threshold (<$150 K a year). The FDA is also asking for feedback on how to define academic medical centers (AMCs) that use tests that are integrated into direct patient care, and if they should qualify for general enforcement discretion. The agency also seeks comments on how to address the labs within the New York State Department of Health Clinical Laboratory Evaluation Program (NYSDOH CLEP) or those within the Veterans Health Administration (VHA).

FDA will regulate Laboratory-Developed Tests (LDTs) as medical devices. The agency will also regulate low-risk tests (class I devices), tests currently on the market, and tests for rare diseases under the same framework, unlike the 2017 discussion paper which called for less oversight. 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.

This proposed rule is expected to impact the currently unknown number (hundreds of thousands is estimated) of LDTs. LDTs are defined as in vitro diagnostic products (IVDs) that the FDA has described as intended for clinical use and designed, manufactured, and used within a single laboratory**.** As a reminder, there are an estimated 160,000 genetic tests available, which is one type of LDTs.

The rule is economically "significant" with a $6 B cost to FDA/industry, FDA asserts the savings will outweigh the costs. The FDA estimates that the proposed rule will reduce healthcare costs more than $22.3 B per year and cost industry and the FDA $5.6 B per year. The agency's economic analysis contends that the benefits would outweigh the costs of the rule as phasing out the general enforcement discretion would lead to a reduction in healthcare costs associated with unsafe or ineffective tests, including harmful therapeutic decisions.

There will be a 4-year phase out period 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 after FDA publishes a final phaseout policy.
- **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 after FDA publishes a final phaseout policy.
- **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 (After October 2027)**: End the general enforcement discretion approach for premarket reviews for high-risk IVDs 3½ years after FDA publishes a final phaseout policy, but not before October 1, 2027.
- **Stage 5 (after April 2028)**: End the general enforcement discretion approach for premarket review requirements for moderate risk and low risk IVDs 4 years after FDA publishes a final phaseout policy, but not before April 1, 2028.

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.

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