GIBSON DUNN

May 8, 2024

FDA's Final Rule on Laboratory-Developed Tests: Four Key Takeaways

The U.S. Food and Drug Administration's highly anticipated final rule on laboratory-developed tests was officially published in the Federal Register on Monday, May 6, 2024.

On April 29, 2024, the U.S. Food and Drug Administration (FDA) released its highly anticipated final rule on laboratory-developed tests (LDTs) ("LDT Final Rule"), which was officially published in the *Federal Register* on Monday, May 6, 2024.[1] The LDT Final rule comes roughly six months after FDA published its proposal to assert jurisdiction over LDTs.[2] In the LDT Final Rule, FDA amended its regulations to make explicit that LDTs fall within the definition of "device" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), subjecting these tests to extensive premarket review and postmarket compliance requirements over a four-year phase-in period.

In this update, we summarize four key takeaways from the LDT Final Rule. First, the LDT Final Rule is largely identical in substance to the 2023 proposed rule. Second, there have been significant changes to FDA's targeted enforcement discretion policies, which are intended, in part, to allocate the agency's scarce enforcement resources on a risk-benefit basis. Third, the LDT Final Rule has spurred significant opposition from Congress, suggesting a potential revival of congressional efforts to clarify FDA's authority over LDTs. And fourth, litigation is coming, bringing some uncertainty as to how final, in fact, the Final LDT Rule is.

1. **The LDT Final Rule makes minimal changes to the FDA regulatory text, consistent with the 2023 proposed rule**

Last year, we reported on the small wording changes FDA proposed to make to its regulations. As we noted, FDA planned to make a surgical change to its definition of "in vitro diagnostic products" ("IVDs"), which are deemed to be "devices" under the FDCA in the agency's regulations. The codified amendment to the regulatory language in the LDT Final Rule is the same as in the proposed rule:

In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory.[3]

The sole change in the LDT Final Rule is to the authorities listed to 21 C.F.R. Part 809, which governs IVDs. In addition to adding various device authorities introduced in the 2023 proposed rule, FDA also added a reference to section 351 of the Public Health Service Act ("PHSA"), which addresses IVDs that are subject to licensure as biological products, rather than the approval or clearance pathways for most medical devices.[4]

2. **The LDT Final Rule expands the scope of FDA's enforcement discretion policies, which will help appease opponents of the rule**

As in the 2023 proposed rule, the preamble of the LDT Final Rule includes enforcement discretion policies in acknowledgement of the significant changes to industry's compliance obligations. While some of these policies were the same as originally proposed, there are some differences:

- *Four-year phase-in of medical device regulatory requirements:* In the LDT Final Rule, FDA established a slightly modified version of its proposed phase-in schedule for industry to comply with medical device requirements:
    - Stage 1 (1 year after the effective date of the LDT Final Rule, July 5, 2024): Compliance with respect to medical device reports ("MDR") and correction and removal reporting requirements, and complaint file requirements under the Quality System Regulation ("QSR"). Notably, FDA expects manufacturers to comply with these requirements for the LDTs subject to this phaseout policy before it expects compliance with clearance or approval requirements.
    - Stage 2 (2 years after the effective date): Compliance with medical device requirements other than MDR, correction and removal reporting, complaint files, and registration and listing.
    - Stage 3 (3 years after effective date): Compliance with respect to QSR requirements other than complaint files.
    - Stage 4 (3.5 years after effective date of the final rule): Compliance with respect to premarket review for high-risk LDTs. FDA indicates that it will use the existing device classification rubric for LDTs, with "low," "medium," and "high" risk corresponding to Class I, II, and III, respectively. FDA notes that it does not intend to take enforcement against high-risk devices with timely-submitted premarket submissions until the agency completes review of its application. The phase-in period for premarket review notably aligns with the timeframe for renewal of the Medical Device User Fee Amendments ("MDUFA") in 2027.
    - Stage 5 (4 years after effective date of the final rule): Compliance with respect to premarket review for moderate- and low-risk LDTs.[5]
- *Targeted enforcement discretion policies:* FDA has also adopted various enforcement discretion policies based on its assessments of the risks and benefits of certain classes of LDTs. These include a number of new policies in the LDT Final Rule in response to comments.
    - FDA plans to continue to exempt from all medical device requirements certain categories of tests that it believes are unlikely to pose significant risks, or are conducted in circumstances that will mitigate those risks, such as being subject to other regulatory oversight. These include LDTs of the type on the market at the time of the 1976 Medical Device Amendments to the FDCA; human leukocyte

antigen ("HLA") tests designed, manufactured, and used within a single laboratory appropriately certified under the Clinical Laboratory Improvement Amendments ("CLIA"); and, tests solely for forensic or law enforcement purposes. In the LDT Final Rule, FDA added to this list LDTs manufactured and performed within the U.S. Department of Defense ("DoD") or the Veterans Health Administration ("VHA").[6]

- In the final rule, FDA also adopted an enforcement discretion policy with respect to premarket review requirements for LDTs approved by the New York State Department of Health's Clinical Laboratory Evaluation Program ("NYS CLEP"). The agency acknowledged that NYS CLEP's review of high and moderate risk LDTs for analytical and clinical validity mitigated risks of inaccurate or unreliable LDTs.[7]

- Lastly, FDA stated that it would not enforce premarket requirements and most QSR requirements for certain classes of LDTs, based on the lower risk associated with those tests, a specific unmet need for those devices, or both factors.

    - These classes include validated LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system—a nod to concerns from academic medical centers.

    - Other classes of LDT subject to this enforcement discretion policy include currently marketed IVDs offered as LDTs prior to the issuance of the LDT Final Rule, provided they are not modified in ways that could affect their basic safety and effectiveness profile, and non-molecular antisera LDTs for rare red blood cell (RBC) antigens manufactured and performed by blood establishments, for which there is no alternative IVD available to meet a patient's need for a compatible blood transfusion.[8]

- FDA also indicated that it could adopt additional enforcement discretion policies in the future, similar to the agency's policies for COVID-19 and mpox tests during the respective public health emergencies.[9] Indeed, on the same day the agency announced the Final LDT Rule, it also released two draft guidance documents related to public health emergencies.[10] The first guidance document outlines an enforcement discretion policy for "immediate response" tests in the absence of an emergency declaration under FDCA section 564, provided certain validation, FDA notification, and transparency measures are taken.[11] The second guidance document describes FDA's considerations in adopting enforcement policies for unapproved and uncleared tests during a Section 564 public emergency.[12] Notices announcing both policies were published in the *Federal Register* on May 6, 2024.[13]

3. **Scrutiny of the LDT Final Rule from Capitol Hill is hot—and heating up—with possible legislative action on the horizon**

Republican leadership has swiftly rebuked FDA for issuing the LDT Final Rule, indicating a legislative response may be brewing. Echoing his prior comments on the proposed rule,[14] Sen. Bill Cassidy (R – La.), the ranking member of the Senate Health, Education, Labor and Pensions ("HELP") Committee, stated that "[t]he FDA does not have the authority to unilaterally increase its regulatory jurisdiction," that "Congress has made clear across multiple statutes that LDTs are not medical devices subject to FDA regulation," and that the LDT Final Rule "will undermine access to essential laboratory tests, increase health care costs, and ultimately harm patients."[15] Similarly, Rep. Cathy McMorris (R – Wash.), the chair of the House Energy and Commerce Committee, denounced the LDT Final Rule as "the latest example of executive branch overreach that will have devastating impacts on patients and families across the country."[16] Her comments followed a hearing of the House Health Subcommittee on the impact of FDA's proposed rule, in which leadership from laboratory entities and the medical device industry provided their disparate views.[17]

Indeed, the LDT Final Rule could reinvigorate congressional efforts to pass the Verifying Accurate Leading-Edge IVCT Development Act ("VALID Act"), which failed to become law at the end of 2022,[18] and was most recently introduced in the House of Representatives (but not yet the Senate) in 2023.[19] If passed, the VALID Act would provide FDA clear statutory authority to LDTs as a separate category of medical products (in vitro clinical tests, or "IVCTs") under a more tailored, risk-based approach—an approach favored by a number of comments to the proposed rule.[20] Nonetheless, the VALID Act faces challenging headwinds, particularly from laboratories and academic medical centers opposed to any FDA regulation of LDTs, and may require an external push in order to succeed. Litigation over the LDT Final Rule—and particularly any outcome that forecloses FDA jurisdiction without statutory changes—may very well be the tipping point for legislative efforts at LDT regulation, especially as negotiations begin on policy riders for the next FDA user fee reauthorization legislation in 2027.

4. **Litigation over the Final LDT Rule is coming**

Opponents to the LDT Final Rule have been eager to voice concerns about FDA's authority to regulate LDTs, with more than 25 groups meeting with the Office of Management and Budget during its review and almost 7,000 comments to the docket for the proposed rule.[21] As shown by the 160-page final rule, as published in the *Federal Register*, the agency can expect legal challenges on multiple fronts, including its statutory authority to regulate LDTs, First and Fifth Amendment constitutional concerns, and compliance with requirements under the Administrative Procedures Act ("APA") and the Unfunded Mandates Reform Act ("UMRA"). Thus, the future of FDA's oversight over LDTs remains far from clear, and the LDT Final Rule is likely to engender even more activity in the long-running saga of regulatory attention to the testing space.

---

[1] 89 Fed. Reg. 37286 (May 6, 2024).

[2] 88 Fed. Reg. 68006 (Oct. 3, 2023). FDA also published a press release accompanying the proposed rule. FDA News Release, "FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests" (Sept. 29, 2023).

[3] 89 Fed. Reg. at 37444-45 (amending 21 C.F.R. § 809.3(a)).

[4] As amended, the authorities for Part 809 now list the following: "21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, 381, and 42 U.S.C. 262." *Id*.

[5] *Id.* at 37294.

[6] *Id.* at 37297-28.

[7] *Id.* at 37299-301.

[8] *Id.* at 37301-07.

[9] *Id.* at 37925.

[10] FDA News Release, "FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests" (April 29, 2024).

[11] FDA, Draft Guidance for Laboratory Manufacturers and Food and Drug Administration Staff: Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564 (May 2024); *see* 21 U.S.C. § 360bbb-3.

[12] FDA, Draft Guidance for Industry and Food and Drug Administration Staff: Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency (May 2024).

[13] 89 Fed. Reg. 37158 (May 6, 2024); 89 Fed. Reg. 37232 (May 6, 2024).

[14] U.S. Senate Committee on Health, Education, Labor and Pensions. News Release, "Ranking Member Cassidy Releases Statement on FDA Proposed Laboratory Developed Tests Rule" (Sept. 29, 2023). Earlier this year, Sen. Cassidy also requested information from stakeholders on regulation of clinical tests, observing that "[s]ince 1976, there have been no significant reforms to the regulation of clinical tests, even as new, innovative tests are being used in health care settings." U.S. Senate Committee on Health, Education, Labor and Pensions News Release, "Ranking Member Cassidy Seeks Information from Stakeholders on Regulation of Clinical Tests" (March 13, 2024).

[15] U.S. Senate Committee on Health, Education, Labor and Pensions, News Release, "Ranking Member Cassidy Rebukes Biden Admin Attempt to Dramatically Increase FDA Authority over Laboratory Developed Tests" (Apr. 29, 2024).

[16] U.S. House Committee on Energy and Commerce Press Release, "Chair Rodgers Statement on FDA LDT Rule" (Apr. 29, 2024).

[17] U.S. House Committee on Energy and Commerce Press Release, "Health Subcommittee Hearing: 'Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule'" (Mar. 21, 2024).

[18] The VALID Act was approved by the Senate HELP Committee in 2022, but ultimately failed to become law. *See* U.S. Senate Committee on Health, Education, Labor and Pensions. News Release, "Murray Leads HELP Committee in Advancing Historic Bipartisan Bills to Lower Drug Costs, Strengthen Workers' Retirement Security, More" (June 14, 2022); "Healthcare groups urge Congress to pass diagnostic testing reform before year's end," *MedTech Dive* (Dec. 13, 2022).

[19] *See* H.R. 2369, 118th Cong. (2023).

[20] *See, e.g.*, 89 Fed. Reg. at 37352-55, 37366-67, 37379-81; *see also, e.g.*, "US lawmakers again propose diagnostics reform bill," *Regulatory Focus* (Mar. 30, 2023); "Stakeholders continue push for VALID Act in wake of FDA's proposed LDT rule," *Regulatory Focus* (Oct. 6, 2023).

[21] *See* Office of Information and Regulatory Affairs, "OIRA Conclusion of EO 12866 Regulatory Review; RIN 0910-AI85."

The following Gibson Dunn lawyers assisted in preparing this update: Katlin McKelvie and Carlo Felizardo.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's FDA and Health Care practice group:

Gustav W. Eyler – Washington, D.C. (+1 202.955.8610, geyler@gibsondunn.com)
Katlin McKelvie – Washington, D.C. (+1 202.955.8526, kmckelvie@gibsondunn.com)
John D. W. Partridge – Denver (+1 303.298.5931, jpartridge@gibsondunn.com)
Jonathan M. Phillips – Washington, D.C. (+1 202.887.3546, jphillips@gibsondunn.com)
Carlo Felizardo – Washington, D.C. (+1 202.955.8278, cfelizardo@gibsondunn.com)