

FDA to Address Proposed Rule to Subject Laboratory-Developed Tests to Agency Oversight in Public Webinar

FDA will hold a webinar regarding the proposed rule, which reiterates FDA's assertion of jurisdiction over laboratory developed tests and proposes a phaseout of its general enforcement discretion approach.

On October 31, 2023, the US Food and Drug Administration (FDA or the Agency) will host a webinar to provide information regarding a long-anticipated notice of proposed rulemaking published on October 3, 2023, which would amend the Agency's regulations to formalize FDA's long-standing position that laboratory-developed tests (LDTs) meet the statutory definition of medical devices and therefore are subject to FDA's medical device authorities.¹ Historically, FDA has not asserted its medical device authorities over LDTs that meet certain criteria. As a result, most LDTs have been marketed without FDA premarket review or oversight.

During the webinar, FDA will describe how the proposed rule, if finalized, would provide for a phaseout of FDA's general enforcement discretion approach to LDTs and would subject LDTs to FDA regulation as medical devices, including with respect to FDA registration and listing, current good manufacturing practice requirements set forth in the Quality System Regulation, and premarket review and authorization. FDA has also committed to answer questions from stakeholders received prior to the webinar.

Background

The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to, among other things, regulate the testing, development, manufacturing, and marketing of medical devices, including in vitro diagnostics (IVDs).² FDA regulations define IVDs broadly to include "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 disease or its sequelae ... [including] such products ... intended for use in the collection, preparation, or examination of specimens taken from the human."³

FDA has historically exercised enforcement discretion over a subcategory of IVDs known as LDTs. LDTs are IVDs that are designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity testing. Thus, absent limited exceptions, LDTs have generally not been subject to FDA oversight, including the potential requirement for premarket review and FDA authorization.⁴ As a result, manufacturers of LDTs generally have not obtained premarket authorization from FDA prior to commercialization of such tests. However, FDA has at times asserted its medical device authorities over LDTs, including when the LDTs are

intended to address a public health emergency, such as those intended to address the COVID-19 pandemic,⁵ or in the case of LDTs that are “direct-to-consumer” tests.

Both FDA’s assertion of jurisdiction over, and its policy of enforcement discretion for, LDTs have been subject to public discussion by Congress, FDA, and other stakeholders in recent years. In 2010, FDA announced its intention to “reconsider its policy of enforcement discretion over LDTs,” citing the potential for “LDTs that have not been properly validated for their intended use [to] put patients at risk,” and hosted a public workshop on the topic.⁶ Thereafter, Congress enacted Section 1143 of the Food and Drug Administration Safety and Innovation Act, which required FDA to provide a 60-day notification before issuing any draft or final guidance on the regulation of LDTs.⁷

On July 31, 2014, the Agency notified Congress of its intent to issue draft guidance concerning LDTs.⁸ Subsequently, in October 2014, FDA issued a draft guidance document that described a potential “risk-based framework” for regulatory oversight over LDTs⁹ and solicited comments from stakeholders. Following receipt of feedback from stakeholders, and the election of President Trump in November 2016, FDA announced in January 2017 that it would not finalize the draft guidance “to allow for further public discussion on an appropriate oversight approach and to give [Congress] the opportunity to develop a legislative” approach to LDT oversight.¹⁰ In connection with this announcement, FDA published a discussion paper suggesting a possible “phased” approach for subjecting LDTs to FDA oversight.¹¹ Until recently, however, FDA had not taken significant steps in the regulation of LDTs, as it awaited congressional action.

At various points during this period, Congress considered, but did not pass, legislation concerning jurisdiction over, and the regulatory framework applicable to, LDTs and other IVDs. Most recently, Congress considered but did not enact the Verifying Accurate Leading-edge IVCT Development Act (VALID Act),¹² which would have created a new FDA-regulated product category for “in vitro clinical tests (IVCTs).” This new product category would have been subject to a new regulatory framework separate from that applicable to medical devices, including a new premarket review scheme.¹³ A version of the VALID Act was most recently reintroduced in March 2023.¹⁴

After Congress did not enact the VALID Act, FDA officials publicly signaled that, while legislation remained the Agency’s “preferred approach” to LDT regulation, it would not “stand by” in the absence of congressional action concerning LDTs.¹⁵ Publication of the proposed rule reflects FDA’s decision to act in the absence of such legislation.

Proposed Rule

The proposed rule would lift FDA’s policy of enforcement discretion for LDTs using a phased approach, and FDA would begin to require LDTs to comply with existing medical device regulations.¹⁶ FDA asserted in the proposed rule that its current approach to LDTs “has led to an oversight scheme that does not best serve the public health.”¹⁷ Among other things, FDA cites its experience reviewing requests for emergency use authorization for COVID-19 diagnostic tests from laboratories and academic medical centers as supporting the need for increased FDA oversight to ensure adequate test design and validation.¹⁸

In order to affirm its position that LDTs are IVDs subject to the Agency’s jurisdiction, FDA proposes to amend the regulatory definition of “in vitro diagnostic products” to state that “[t]hese products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act . . . including when the manufacturer of these products is a laboratory.”¹⁹

FDA's phased approach to rescind its enforcement discretion policy for LDTs would result in stages of incremental increases in application of the Agency's medical device regulatory requirements to LDTs over a period of four years.²⁰ Interestingly, FDA has proposed to extend the scope of the phaseout policy to include IVDs that it acknowledges do not satisfy the criteria for enforcement discretion under its existing policy, but which are manufactured and offered as LDTs by laboratories that are certified under CLIA, "even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory."²¹ Specifically, the proposed "phaseout" of FDA's general enforcement discretion policy would be sequenced as follows:

- *Stage 1 (Medical Device Reporting (MDR) and Corrections and Removals Reporting)*: One year after publication of a final rule, FDA would "[e]nd [its] general enforcement approach with respect to MDR requirements and correction and removal reporting requirements."²² At that time, manufacturers of LDTs would become subject to MDR and correction and removal reporting requirements.
- *Stage 2 (Remaining Medical Device Requirements Other Than the Quality System Regulation (QSR) and Premarket Review)*: Two years after publication of a final rule, FDA would "[e]nd [its] general enforcement discretion approach with respect to requirements" for registration and listing, labeling, and investigational use.²³ At that time, LDTs would become subject to all medical device requirements other than compliance with the QSR and the potential requirement for marketing authorization.
- *Stage 3 (QSR)*: Three years after publication of a final rule, FDA would generally "[e]nd [its] general enforcement discretion approach with respect to [QSR] requirements."²⁴ However, in the proposed rule FDA states that "for IVDs for which all manufacturing activities occur within a single CLIA-certified laboratory that meets the regulatory requirements to perform high complexity testing and for which distribution of the IVD does not occur outside that single laboratory, FDA would expect compliance at the three-year mark with some, but not all, of the [QSR] requirements."²⁵ Specifically, FDA states that it would require such IVDs to comply only with "certain [QSR] requirements for which CLIA regulations do not provide assurances that FDA requirements would provide," such as requirements concerning design controls, purchasing controls, acceptance activities, corrective and preventative actions, and recordkeeping.²⁶ At that time, LDTs would become subject to all medical device requirements other than the potential requirement for marketing authorization, and in some cases, certain of the QSR requirements.
- *Stage 4 (Premarket Review of High-Risk LDTs)*: On the later of October 1, 2027, or three and a half years after publication of a final rule, FDA would "[e]nd [its] general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs."²⁷ FDA describes such high-risk LDTs as those "that may be eligible for classification into class III" under FDA's medical device risk classification framework.²⁸ Under that framework, FDA classifies medical devices into one of three classes — class I, class II, or class III — depending on the degree of risk associated with the medical device and the regulatory controls deemed necessary to provide reasonable assurance of safety and effectiveness.²⁹ Class III devices include devices deemed by FDA to pose the greatest risk.³⁰ Generally, class III devices require FDA review and approval of a premarket approval (PMA) application before such device can be commercialized. FDA states that it "generally would not enforce against LDTs after a PMA has been submitted (within the 3½-year timeframe) until FDA completes its review of the application."³¹ Thus, at this stage, LDTs that are deemed high-risk/class III devices would be subject to all of the requirements applicable to medical devices (other than, in some cases, certain of the QSR requirements).

- *Stage 5 (Premarket Review of Moderate- and Low-Risk IVDs)*: On the later of April 1, 2028, or four years after publication of a final rule, FDA would “[e]nd [its] general enforcement discretion approach with respect to premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions).”³² Low- and moderate-risk IVDs subject to the stage 5 phaseout would be those for which a 510(k) premarket notification or de novo classification request may be required. FDA states that it “generally would not intend to enforce against IVDs” during the pendency of its review of a 510(k) premarket notification or de novo classification request.³³ At this point in time, FDA would begin to enforce all medical device requirements to LDTs (other than, in some cases, certain of the QSR requirements).

Takeaways and Next Steps

The proposed rule reflects the Agency’s long-standing desire to subject LDTs (and IVDs offered as LDTs) to FDA oversight. If finalized, manufacturers of/laboratories offering such tests would become subject to FDA oversight through a staggered approach that would ultimately necessitate compliance with a range of FDA regulatory obligations, including with respect to registration and listing, product labeling, manufacturing, and premarket review.

The proposed rule, which would bring a sea change to the regulation of LDTs (and IVDs offered as LDTs), has generated some controversy. Some stakeholders strongly object to the proposed rule, while others are strongly supportive. In light of this, FDA recently announced it will hold an October 31, 2023 webinar to provide an overview of the proposed rule and potential phaseout of FDA’s general enforcement discretion approach and to address pre-submitted questions from interested parties. These questions were required to be submitted to FDA by October 23, 2023 to be considered for discussion during the webinar.

FDA has established a deadline of December 4, 2023, for interested parties to submit comments on the proposed rule. However, there have been multiple requests for extension of the comment period. Industry participants and other stakeholders should continue to monitor developments concerning the evolving regulatory framework for LDTs before FDA and Congress in the days, weeks, and months ahead.

If you have questions about this Client Alert, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

[Elizabeth M. Richards](#)

elizabeth.richards@lw.com
+1.202.637.2130
Washington, D.C.

[Nathan A. Beaton](#)

nathan.beaton@lw.com
+1.202.637.1062
Washington, D.C.

[Kiera A. Murphy](#)

kiera.murphy@lw.com
+1.858.509.8477
San Diego

[J. Seth Olson](#)

seth.olson@lw.com
+1.202.637.2119
Washington, D.C.

[Trevor Thompson](#)

trevor.thompson@lw.com
+1.202.350.5177
Washington, D.C.

You Might Also Be Interested In

[Recent FDA Guidance Signals Increased Willingness to Engage Industry Stakeholders](#)

[US State Regulatory Spotlight on Healthcare Transactions](#)

[Shooting for the Moon: The Evolution of Key AI/ML Regulations Governing Certain Health Care Products and Services](#)

[Resource: Healthcare & Life Sciences Market Update — July 2023](#)

Client Alert is published by Latham & Watkins as a news reporting service to clients and other friends. The information contained in this publication should not be construed as legal advice. Should further analysis or explanation of the subject matter be required, please contact the lawyer with whom you normally consult. The invitation to contact is not a solicitation for legal work under the laws of any jurisdiction in which Latham lawyers are not authorized to practice. A complete list of Latham's Client Alerts can be found at www.lw.com. If you wish to update your contact details or customize the information you receive from Latham, [visit our subscriber page](#).

Endnotes

- ¹ 88 Fed. Reg. 68,006 (Oct. 3, 2023).
- ² See 21 U.S.C. § 321(h).
- ³ See 21 C.F.R. § 809.3(a).
- ⁴ See FDA, Laboratory Developed Tests, <https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests>; FDA, Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (Oct. 2014), at 5, <https://www.fda.gov/media/89841/download> [hereinafter “2014 LDT Framework Draft Guidance”]. FDA has stated that it will not exercise enforcement discretion for an LDT that is offered “direct-to-consumer” without the involvement of a health care provider involving collection of a specimen by the consumer to be mailed back for testing and analysis.
- ⁵ See 88 Fed. Reg. at 68,011.
- ⁶ 75 Fed. Reg. 34,463, 34,463-64 (June 17, 2010).
- ⁷ Pub. L. 112-144, 126 Stat. 993 (2012).
- ⁸ See FDA, Letter to Tom Harkin, Chairman of the Senate Committee on Health, Education, Labor and Pensions (July 31, 2014), <https://www.fda.gov/media/89316/download>. On that same day, the Agency denied a citizen petition request that FDA “cease and desist” in seeking to regulate LDTs as medical devices, with FDA asserting its longstanding position that LDTs are subject to FDA’s medical device authorities under the FDCA. See FDA, Citizen Petition Denial Response from FDA CDRH to Washington Legal Foundation, Docket No. FDA-2006-P-0149 (Jul. 31, 2014). Weeks prior, the Agency had denied two (2) other citizen petitions relating to the regulation of LDTs. See FDA, Citizen Petition Denial Response from FDA CDRH to American Clinical Laboratory Association, Docket No. FDA-2013-P-0667 (Jul. 14, 2013); FDA, Citizen Petition Denial Response from FDA CDRH to Genentech, Inc., Docket No. FDA-2008-P-0638 (Jul. 14, 2008).
- ⁹ 2014 LDT Framework Draft Guidance at 4.
- ¹⁰ FDA, Discussion Paper on Laboratory Developed Tests (LDTs) (Jan. 13, 2017), <https://www.fda.gov/media/102367/download>.
- ¹¹ See *id.* at 4-5.
- ¹² See H.R. 2369, 118th Cong. (2023).
- ¹³ A version of the VALID Act was most recently introduced during the 118th Congress in March 2023 but has not been enacted. See *id.* The VALID Act was also considered in connection with, but ultimately not included in, omnibus FDA reform legislation, the Food and Drug Omnibus Reform (FDORA), as part of the year-end 2022 omnibus appropriations bill.
- ¹⁴ See *id.*
- ¹⁵ E.g., Laura DiAngelo, FDA set to unveil new rule on Laboratory Developed Tests this August, AgencyIQ (Jun. 14, 2023), <https://www.agencyiq.com/blog/fda-set-to-unveil-new-rule-on-laboratory-developed-tests-this-august>.
- ¹⁶ 88 Fed. Reg. at 68,007.
- ¹⁷ *Id.* at 68,009.
- ¹⁸ See *id.* at 68,011.
- ¹⁹ *Id.* at 68,031 (proposed amendment to 21 C.F.R. § 809.3(a)) (emphasis added).
- ²⁰ *Id.* at 68,014.
- ²¹ *Id.* at 68,021.
- ²² *Id.* at 68,024.
- ²³ See *id.* at 68,025.
- ²⁴ *Id.* at 68,024.
- ²⁵ *Id.* at 68,025.
- ²⁶ *Id.*
- ²⁷ *Id.* at 68,024.
- ²⁸ *Id.* at 68,026.
- ²⁹ See 21 U.S.C. § 360c(a)(1)(A)-(C).
- ³⁰ See *id.* § 360(c)(a)(1)(C).
- ³¹ 88 Fed. Reg. at 68,026.
- ³² *Id.* at 68,024.
- ³³ *Id.* at 68,027.