Lawsuit Filed Challenging FDA Final Rule Regulating Laboratory Developed Tests

On May 29, 2024, a lawsuit was filed in the U.S. District Court for the Eastern District of Texas, challenging the U.S. Food and Drug Administration's **final rule** concerning the regulatory status of laboratory developed tests ("LDTs") under the Federal Food, Drug and Cosmetic Act ("FDCA"). As detailed in our prior analysis (**here**), the final rule amended the FDA's existing regulations to make explicit the agency's interpretation that LDTs are "devices" under the FDCA, and established a five-stage plan to phaseout the agency's current general policy of "enforcement discretion" with respect to LDTs.

With the final rule's July 5 effective date looming, two entities—a trade association and a laboratory—filed suit in federal court to overturn the final rule. In this Insight, we briefly summarize the legal theories advanced in the lawsuit and likely next steps.

Read the full alert **here**.

FDA Issues Final Rule on Regulation of Laboratory Developed Tests

On April 29, 2024, the U.S Food and Drug Administration (FDA) announced its **final rule** on Laboratory Developed Tests (LDTs). This final ruling amends the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs), including those manufactured by laboratories, are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Alongside the amendment, FDA issued its policy to phase in regulatory requirements for certain LDTs over the

course of four years.

The FDA will host a webinar to provide an overview of the final rule on May 14, 2024. A link to register can be found **here**. The final rule is expected to have profound effects on many LDT developers. Goodwin's **Life Sciences Regulatory & Compliance Team** are ready to work with clients to navigate the challenges that the final rule may pose. Our breakdown and analysis of the rule will be upcoming on **Goodwin's LDT Resource page**.

FDA's Laboratory Developed Test (LDT) Final Rule Under OIRA Review; Subcommittee on Health to Hold Hearing on Regulation of Diagnostic Tests

On March 1, 2024, the Office of Information and Regulatory Affairs ("OIRA"), Office of Management and Budget ("OMB"), Executive Office of the President **received** the final version of FDA's rule on regulation of laboratory developed tests ("LDTs") for administrative review. Having swiftly moved to OIRA review in under 5-months from the publication of the **proposed rule** and under 3-months from the end of its comment period, the rule has undoubtedly been a top priority for the FDA. Further, as of the date of this post, OIRA has **scheduled** four back-to-back meetings with interested stakeholders, all of which are to be held the week of March 18th. All of this signals that the final rule remains on track for potential issuance in April 2024, the target date for final action on the rule as we previously discussed **here**.

Further, on March 14, 2024, the House Energy and Commerce Committee Chair and Subcommittee on Health Chair announced a subcommittee hearing titled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." The hearing is scheduled for Thursday, March 21, 2024 at 10:00 AM ET. Additional information on attending or viewing the hearing is available **here**.

Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.

FDA Targets April 2024 for Laboratory Developed Test (LDT) Final Rule

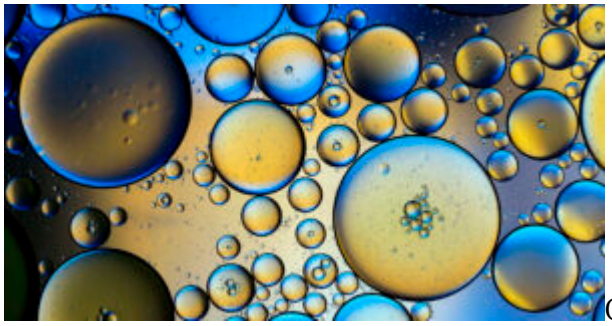
On December 6, 2023, the Office of Information and Regulatory Affairs ("OIRA") released the **Fall 2023 Unified Agenda of Regulatory and Deregulatory Actions** (the "Agenda"), a semiannual compilation of information regarding regulations under development by federal agencies. In its **preamble**, the Department of Health and Human Services ("HHS") notes that the regulatory actions forecasted for the Agenda reflect the priorities of HHS Secretary Xavier Becerra and the Biden-Harris Administration, HHS, and the U.S. Food and Drug Administration ("FDA").

As we analyzed in detail in recent articles (see **here**, **here** and **here**), the **proposed rule** for laboratory developed tests ("LDTs") was released in October 2023. Citing factors including "extensive background of public comment on this topic" and "the public health benefits of proceeding expeditiously," FDA **declined** to extend the 60-day comment period, which closed on December 4, 2023. FDA received over **6,000 comments** from individual citizens, laboratories, academic medical centers, and other industry stakeholders. As part of the Agenda, FDA has **updated** the target date for final action on the LDT proposed rule to **April 2024**.

FDA is under no obligation to publish the LDT rule according to the schedules reflected in the Unified Agenda. If the rule and related LDT policy are finalized as proposed by April 2024, **high-risk LDTs** may be called-in for premarket review as early as **October 1, 2027**. Subsequently, **low-to-moderate risk LDTs** may be called-in for premarket review as early as **April 1, 2028**.

To stay informed on the latest news and analysis affecting LDTs, be sure to bookmark our dedicated **LDT Resource Page**.

Newly Launched: Goodwin's Laboratory Developed Tests Resource Page



Our Life Sciences Regulatory & Compliance team has launched a new resource page, keeping you up-to-date on the latest regulatory developments affecting laboratory developed tests (LDTs). Our dedicated LDT page provides foundational materials, legislative and regulatory history, and updates and analyses regarding initiatives to increase oversight over LDTs, including FDA's LDT Proposed Rule (October 2020). Our Life Sciences Regulatory & Compliance team will continue to keep this page updated with the latest happenings.

Read the full announcement **here**.

Mark Your Calendars: This Halloween, Don’t Miss FDA’s LDT Webinar

The U.S. Food and Drug Administration (FDA) has announced an upcoming **webinar** on its **proposed rule** on the regulation of laboratory developed tests (LDTs).

The webinar is scheduled for **October 31, 2023 from 1:00 – 2:00 PM ET** and will include an overview of the proposed rule, a description of the proposed phaseout of FDA’s general enforcement discretion approach to LDTs, and a question and answer session. Stakeholders must submit questions by **October 23, 2023** to be considered for the discussion.

For our detailed analysis of the 83-page proposed rule, please see our two-part Insight series: **Part I: Underpinnings of FDA’s Proposed Rule** and **Part II: FDA’s Proposed Phaseout Policy – Key Considerations & Open Questions**.

If you have questions on the proposed rule or its potential impact, contact the authors or a member of the **Goodwin Life Sciences Regulatory & Compliance** team.

FDA’s Proposed Rule for Oversight of Laboratory Developed Tests: Part II: FDA’s Proposed Phaseout Policy – Key Considerations & Open Questions

After an over decade-long discourse amongst interested stakeholders, on October 3, 2023, FDA unveiled its **proposed rule and policy** to increase oversight

over LDTs.

If finalized as proposed, FDA would implement a new "phaseout policy" that would, across five stages and within four years, apply the same regulatory requirements applicable to in vitro diagnostics (IVDs) on the majority of clinical laboratories offering tests as LDTs. Once implemented, tests offered as LDTs that do not meet the applicable regulatory requirements, including premarket review and the quality system regulation, may be expected to come off the market.

In our **first post** in this Insight series, we recapped the underpinnings of the proposed rule and policy, including the significant discussions contained in the proposed rule on (1) the rationale for the agency's proposed phaseout policy and (2) FDA's legal authority for issuing the rule.

In this Insight, we provide our full analysis of FDA's proposed five-stage phaseout policy and the open questions that remain. Read the full Insight **here**.

FDA's Proposed Rule for Oversight of Laboratory Developed Tests: Part I: Underpinnings of FDA's Proposed Rule

On October 3, 2023, the U.S. Food and Drug Administration (FDA) published its widely anticipated **proposed rule** on the regulation of laboratory developed tests (LDTs). The proposed rule and policy are the latest in an over decade-long discourse amongst interested stakeholders – laboratories, IVD manufacturers, regulatory agencies, Congress, providers, and patients – as FDA has sought to enhance oversight over LDTs.

In this Insight, we recap the underpinnings of the proposed rule and policy, including the two lengthy discussions contained in the proposed rule on (1) the rationale for the agency's proposed phaseout policy and (2) FDA's legal authority for issuing the rule. Stay tuned next week for our additional analysis of the details of FDA's proposed five-stage "phaseout" policy and the open questions that remain.

Contact the authors or a member of the Goodwin **Life Sciences Regulatory & Compliance** team for any questions. Read the full Insight **here**.

FDA Proposes Phased Approach to Regulating Laboratory Developed Tests

On September 29, 2023, the U.S. Food and Drug Administration (FDA) posted and scheduled for publication its long-awaited **proposed rule** concerning FDA regulation of laboratory developed tests (LDTs). If enacted, the proposed rule would amend the Agency's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act; and this includes when the manufacturer of the IVD is a laboratory.

Upon finalization of the rule, FDA proposes to phase out its general "enforcement discretion" approach for LDTs so that tests manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

Comments to the proposed rule are due 60 days after the date of publication of the proposed rule in the Federal Register. We will provide our full analysis of the proposed rule in the coming days. Contact the authors or a member of the Goodwin **Life Sciences Regulatory & Compliance** team for any questions.