Most Favored Nation Drug Pricing Executive Order Resurrects Prior President Trump Policy

 On May 12, 2025, President Trump signed the most recent Executive Order on drug pricing, **Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients**. This latest Executive Order simultaneously pushes key stakeholders (i.e. foreign governments and drug manufacturers) to modify their current practices while threatening potential most-favored nation (MFN)-based price caps and other scrutiny. The Executive Order Fact Sheet is available **here**.

Read the full alert **here**.

Goodwin's 2025 Rare Disease Symposium: Momentum Builds for Addressing Critical Diagnosis and Treatment Gaps

Attendees at this year's **symposium** were optimistic about the potential for progress, citing momentum from new FDA initiatives, growing legislative support, and increased global innovation in research and development. These efforts, alongside increased patient advocacy and a presidential administration focused on speeding patient access, could lead to significant advances in rare disease treatments and cures in 2025.

Read the full insight **here**.

How the Trump Administration Could Reshape Regulation in the Life Sciences Sector

 Based on recent policy signals and statements from incoming administration officials, a picture of potential regulatory and policy changes that could affect biotech, pharmaceutical, and medical device companies in coming months and years is emerging.

Anticipated changes span multiple regulatory fronts: a revamped approach to antitrust review at the Federal Trade Commission (FTC), continued momentum on biosecurity measures, and a fundamental rethinking of agency regulation to streamline “red tape” and accelerate patient access to innovative treatments. The Trump administration’s stated focus on “making America healthy again” suggests a broader transformation in how healthcare is delivered and regulated, with emphasis on nutrition, prevention, longevity, enhanced physician autonomy, and a more holistic approach to health to reduce the burdens of chronic disease.

While some changes may create opportunities for innovation and growth, others could pose compliance and operational challenges. Understanding these emerging dynamics will be crucial for industry stakeholders as they position themselves for success under the new administration.

The following six sections are based on discussions from a regulatory panel held on January 15 at the **Goodwin + KPMG 6th Annual Symposium**, which was held during the 2025 JPM Healthcare Conference.

Read the full insight **here**.

New Momentum for a Time-Limited Conditional Approval Pathway for Rare Disease Drugs

 On October 4, 2024, a US House version of the revised Promising Pathway Act (PPA) 2.0 was introduced, sponsored by Rep. Bruce Westerman (R-AR). The bill (**H.R.9938**) mirrors a US Senate version that was introduced in May 2024 (**S.4426**) that would authorize the US Food and Drug Administration (FDA) to grant time-limited conditional approval to drugs for rapidly progressive, terminal diseases with substantial unmet need for treatments that are eligible for the Orphan Drug Act and result in a substantially shortened lifespan, substantial reduction in quality of life, or other substantial adverse health effects.

Read the full insight **here**.

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 Finalizes Rule and Sets Course to Phase In Oversight of Laboratory Developed Tests

 On May 6, 2024, following more than a decade of discourse with interested stakeholders on potential approaches to regulation of laboratory developed tests (LDTs), the U.S. Food and Drug Administration (FDA) published its **final rule** setting forth its framework for oversight of LDTs. The final rule and accompanying policy to phase out the agency's general policy of "enforcement discretion" for LDTs comes roughly six months after FDA published its **proposed rule** that outlined the agency's proposed approach to increasing oversight over LDTs. As detailed in our prior analyses of the proposed rule (see **here** and **here**), FDA proposed to implement a **phaseout policy** that would, across five stages and within four years, apply to clinical laboratories offering tests as LDTs the same regulatory requirements applicable to in vitro diagnostics (IVDs).

The proposed rule received more than **6,500 comments**, and while FDA did not change its amendments to the regulation or meaningfully modify the phaseout timeline, FDA has significantly modified its phaseout policy to extend full or partial enforcement discretion to additional categories of LDTs, creating a framework whereby the agency intends to take a more targeted enforcement approach, particularly in the near-term, to addressing LDTs.

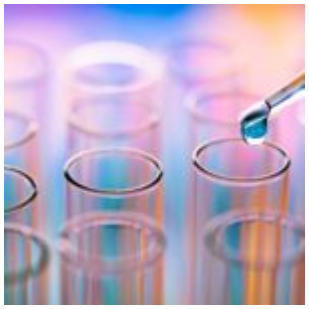
You can read our more in our **Insight**, where **Steven Tjoe**, **Matt Wetzel**, and **Sukrti Thonse** highlight the key features of the final rule and five-stage phaseout policy. Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.

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**.

A Practical Look at OIG's New Compliance Guidance

 On November 6, 2023, for the first time in 15 years, HHS OIG issued a new reference guide for the health care compliance community – **the General Compliance Program Guidance, or GCPG**. While the GCPG does not set new legal standards and largely reinforces existing guidance, it is a tremendous tool to help health care and life sciences companies advance their compliance efforts. Indeed, within its 91 pages, the GCPG provides the most comprehensive and user-friendly trove of health care compliance insights, tips, and guidance ever provided by the federal government.

Read the full alert **here**.